TITLE PAGE

Protocol Number:	810P302
Title:	A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Molindone Hydrochloride Extended-Release Tablets for the Treatment of Impulsive Aggression in Pediatric Patients with Attention Deficit/Hyperactivity Disorder (ADHD) in Conjunction with Standard ADHD Treatment
Sponsor:	Supernus Pharmaceuticals, Inc. [redacted]
IND number:	106,515
Investigational Medicinal Product:	Molindone Hydrochloride Extended-Release Tablets (SPN-810)
Indication:	Treatment of Impulsive Aggression in patients with Attention Deficit/Hyperactivity Disorder (ADHD) in conjunction with standard ADHD treatment
Clinical CRO:	[redacted]
Medical Monitor	[redacted]
Phase:	3
Protocol Version:	7.0
Release Date:	29 March 2019
Good Clinical Practice (GCP) Statement:	This study is to be performed in full compliance with International Conference on Harmonization (ICH) GCP and all applicable local regulations. All required study documentation will be archived as required by regulatory authorities.

I, the undersigned, have read this protocol and agree to conduct this trial in accordance with all stipulations of the protocol and in accordance with ICH GCP and all applicable local guidelines, including the Declaration of Helsinki and all its accepted amendments to date.

Principal Investigator	**Signature**	**Date**

SIGNATURES

Authors:

[redacted]

Reviewers:

Approvers:

SUMMARY OF CHANGES

This summary table lists all clarifications, administrative changes or amendments to Supernus protocol 810P302. Additions are denoted by bold letters and deletions by strikethrough.

Section	Page	Description of Change	Rationale
Changes to 810P302 V3.0 Dated 21 Dec 2015			
Title Page	1	Protocol version and date was updated	Administrative
Signature page	3	The authorship was revised	For clarification
Synopsis	10	The following was added: [redacted]	To understand exposure of metabolites in children
Synopsis	11	The following was changed: Total subject duration on study: Approximately **13** ~~10-12~~ weeks • Pre-treatment phase: **Up to 45 days** ~~4-6 weeks~~ o Screening period: **Up to 30 days** 2- ~~4 weeks~~ o Baseline period: **At least 15 days** ~~2 weeks~~	To facilitate study conduct
Synopsis	13	The following was added: [redacted]	To understand exposure of metabolites in children
Synopsis	13	The following was added: [redacted]	To understand exposure of metabolites in children
List of Abbreviations	20	List of Abbreviations was updated to include Adverse Event of Special Interest (AESI)	For clarification
2.3	26	The following was changed: [redacted]	To understand exposure of metabolites in children
3.2	27	The following was changed: Following screening, eligible subjects will enter a ~~two-week~~ **flexible** baseline period, at which time the IA diary will be issued to the subject's primary caregiver. At the end of the ~~two-week~~ baseline period, eligible subjects whose primary caregiver has maintained at least 80% compliance with the IA diary will be randomized 1:1:1 to 18 mg/day SPN-810, 36 mg/day SPN-810, or placebo.	To give caregivers the opportunity to improve diary compliance
3.2.1.1	27	The following was changed:	To facilitate study conduct

		Screening will take place for up to ~~28~~ **45** days prior to randomization and may be carried out over more than one visit if necessary.	
3.2.1.1	27	The following was added: **Staff at study sites are encouraged to complete screening procedures as early as possible to provide more flexibility in the baseline period for the caregivers to achieve IA diary compliance (see Section 3.2.1.2).**	For clarification
3.2.1.2	28	The following was changed: Subjects who meet study entry requirements will proceed to the ~~two-week~~ **flexible 15-day** baseline period. At Visit 2 ~~primary and (if assigned) secondary caregivers will receive training on the use of the IA diary. A~~an IA diary device (LogPad) will be issued to the primary caregiver. **The primary and (if assigned) secondary caregivers will receive training on the use of the IA diary. Every effort will be made to provide adequate caregiver training on the use of the IA diary at Visit 2 and acknowledgement of training will be captured on the device.** ~~The caregiver will be instructed to maintain the diary for two weeks. At the end of this period, caregiver compliance with the IA diary will be assessed.~~ **Following at least 15 days of IA diary use, caregiver compliance with the IA diary will be assessed.** Compliance will be calculated as the percentage of days **over the past 15 days** during the baseline period for which an evening diary was completed. ~~Compliance of at least 80% must be demonstrated to continue into the titration period and to be eligible for randomization. Compliance will be measured by the percentage of evening diary entries completed during the baseline period.~~ **Subjects whose caregivers demonstrate at least 80% compliance will be eligible for randomization and continue into the titration period.** **Subjects whose caregivers do not reach 80% compliance during the first 15 days of the baseline period may be allowed to continue to use the diary for up to 15 additional days. For these subjects, caregivers will receive remedial training on the use of the IA diary. During this time, caregiver compliance with the IA diary will be monitored daily by study site personnel over the past 15-days as a "rolling window". When the caregivers' performance with the IA diary improves such that the caregivers are able to demonstrate at least 80% compliance over the past 15-day rolling window, the subject will be eligible for randomization and allowed to continue into the titration period.** **Although there are up to 30 days available for each of the screening and the baseline period, the total duration of screening and baseline periods may not exceed 45 days.** **<u>Rescreening</u>** **As a general rule, rescreening of subjects is not allowed. The only exception to this will be for subjects who had failed screening due to caregiver non-compliance with the IA diary under protocol version 3.0. These subjects may be rescreened**	To give caregivers the opportunity to improve diary compliance

		to participate in the study under protocol 4.0. These subjects will be assigned a new subject ID number and will complete all study screening procedures.	
3.2.4	29	The following was changed: Subjects will return to the study site for a final visit, after completing the 1-week Taper/Conversion Period. Those subjects who elect to continue in the OLE study will have procedures performed for that study as well. ~~All subjects who discontinue early will return to the study site for a final visit. Any s~~Subject who discontinue~~s~~ from the study during the maintenance period will be offered a Taper kit **and will return to the study site for a follow-up visit (EOS). Subjects who discontinue during the titration period will not receive a taper kit and will only complete the EOS procedures.**	For clarification
Figure 1 and 2	30, 31	These figures were updated with the new visit windows and screening period	Updated as per changes in the protocol
4.1.1	32	The following was added: **8. α 2- adrenergic agonists (e.g. clonidine and guanfacine) used for any other reason except for monotherapy treatment for ADHD (e.g. aggression or insomnia) must be discontinued at least two weeks prior to Visit 2.**	To facilitate study conduct
Table 1	34, 35	Table 1 was updated with the new visit windows, screening period, baseline period, and footnotes. Due to the addition of a new footnote, this section had to be renumbered	Updated as per changes in the protocol
Table 1	34, 35	The following new foot note "c" was added for Visit 3 window days: **Visit 3 will occur at least 15 days following Visit 2.** Footnote "g" was renumbered to "h" and changed as follows: ~~g~~**h** Total of 5 PK blood samples **will be obtained over one or two visits (Visit 4 and/or Visit 5)** ~~to be divided between Visit 4 and Visit 5.~~ Footnote "d" was renumbered to "e" and changed as follows: ~~d~~**e** Diary compliance must be at least 80% (minimum of 12 days out of ~~14~~**15**) to qualify for randomization.	Updated as per changes in the protocol
4.2.1	36	The following was changed: Subject screening procedures will be performed within ~~28~~ **45** days prior to Visit 3 and may be done on more than one day.	To facilitate study conduct
4.2.2	36	The following was changed: Visit 2 will occur at least ~~14~~ **15** days prior to Visit 3.	To facilitate study conduct
4.2.2	36	The following was added: **Please note that, per protocol and within the EDC, Visit 1 and Visit 2 may occur on the same day.**	For clarification
4.2.3	36	The following was changed: Visit 3 will occur at least ~~14~~**15** days following Visit 2 according to the Schedule of Visits and Procedures.	To facilitate study conduct
4.2.3	37	The following was changed: 10. Collect urine samples for urinalysis, **urine drug screen (all subjects)**, and pregnancy test (FOCP only)	For clarification
4.2.4	37	The following was changed:	To facilitate study conduct

		Visit 4 will occur 7 (±~~1~~**2**) days following Visit 3 according to the Schedule of Visits and Procedures.	
4.2.5	37	The following was changed: Visit 5 will occur 14 (±~~1~~**2**) days following Visit 3 according to the Schedule of Visits and Procedures.	To facilitate study conduct
4.2.6	38	The following was changed: Visit 6 will occur 21 (±~~1~~**3**) days following Visit 5 according to the Schedule of Visits and Procedures.	To facilitate study conduct
4.2.8	38, 39	The following was changed: T**hese will include pre and post-dose samples obtained over one visit (Visit 4 or Visit 5) or can be obtained over two visits (Visit 4 and Visit 5)** ~~Blood will be drawn for quantitative PK analysis at Visit 4 and Visit 5.~~ **If the subject decides to complete the PK sampling over one visit then he/she will arrive at the clinic in the morning prior to taking the morning dose.** **A PK sample will be drawn pre-dose; then the dose will be observed in the clinic. Post-dose PK samples will be taken at approximately 1 hour, 2 hours, 4 hours and 6 hours after the time of the observed dose. PK samples should be obtained within 15 minutes of the 1 hour and 2 hour timepoints and within 30 minutes of the 4 hour and 6 hour timepoint**. ~~At one of these visits, subjects will arrive at the clinic in the morning, prior to taking their morning dose. A PK sample will be drawn pre-dose; then the dose will be observed in the clinic. Post-dose PK samples will be taken at approximately 1 hour and 2 hours after the time of the observed dose. PK samples should be obtained within 15 minutes of the targeted timepoints.~~ **If the subject decides to come for the PK sampling over two visits, then on one visit the subject will arrive at the clinic in the morning, prior to taking their morning dose. A PK sample will be drawn pre-dose; then the dose will be observed in the clinic. Post-dose PK samples will be taken at approximately 1 hour and 2 hours after the time of the observed dose. PK samples should be obtained within 15 minutes of the targeted timepoints.**	To facilitate study conduct
4.4	42	The following was added: **4.4 Prohibited Medications:** **Subjects may not be on any prohibited medication while on study as indicated in the Inclusion/Exclusion Criteria. These medications include:** • **α 2- adrenergic agonists (e.g. clonidine and guanfacine) used for any other reason except for monotherapy treatment for ADHD** • **Anti-psychotics including aripiprazole, risperidone, quetiapine, and ziprasidone** • **Anticonvulsants including carbamazepine and valproic acid, antidepressants, mood stabilizers including lithium, benzodiazepines, cholinesterase inhibitors or any drug known to inhibit CYP2D6 activity** • **Herbal supplements**	For clarification

4.5	42	The following was deleted: ~~Subjects may not be on any prohibited medication as indicated in the Inclusion/Exclusion Criteria.~~	For clarification
5.2.1	44	The following was changed: • CGI-I, relative to the condition at ~~baseline~~ **Visit 3**, will be evaluated by the caregiver and by the Investigator at each post-baseline visit on a 7-point scale with 1=Very much improved, 2=Much improved, 3=Minimally improved, 4=No change, 5=Minimally worse, 6=Much worse, and 7=Very much worse.	For clarification
5.3	45	The following was added: [redacted]	To understand exposure of metabolites in children
5.3.2	45	The following was added: [redacted]	To understand exposure of metabolites in children
5.4.2.1	48	The following was changed: All SAEs must be reported to the Drug Safety Contact within 24 hours of first becoming aware of the SAE. The Investigator must complete an SAE **eCRF in EDC** ~~**Form**~~ and include a detailed description of the SAE, as well as other available information pertinent to the case (e.g., hospital records, autopsy reports and other relevant documents). **Should the site be unable to access EDC, a paper SAE form must be completed and sent to WCT Drug Safety by email or fax.** The investigator will keep a copy of this SAE Report form on file at the study site. **Once EDC becomes available, the site must complete the SAE eCRF in EDC.**	For Clarification
5.4.2.1	49	The E-mail address for drug safety contact was updated: [redacted]	Administrative
5.4.2.2.	49	The following was added: **The Investigator must complete a Pregnancy Outcome Form as a follow up.**	For Clarification
5.4.2.2	49	The following was changed: Treatment-emerging EPS (e.g. akathisia, dystonia, Parkinsonism, tardive dyskinesia) and neuroleptic malignant syndrome should be reported to the Drug Safety Contact person(s) by **completing the Adverse Event Special Interest (AESI) eCRF in EDC. Should the site be unable to access EDC, a paper AESI form must be completed and sent to** [redacted] **Drug Safety by email or fax** ~~faxing or scanning the appropriate source documentation~~ within 24 hours of first becoming aware of the event. **Once EDC becomes available the site must complete AESI eCRF in EDC.** EPS incidence will be summarized and shared with study Investigators throughout the trial.	For Clarification
5.4.4	50	The following was added: **A subject will be excluded if the Screening blood test results indicates > 2 times the upper limit of normal (ULN) of alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma glutamyl transpeptidase (GGT), and/or serum creatinine. Laboratory tests will not be repeated for these subjects.**	For Clarification

		Any repeat laboratory testing will be conducted under fasting condition.	
6.5	55	The following was added: Only one **(primary)** reason for study discontinuation will be recorded for each subject.	For Clarification
6.9.2	57	The following was changed: The secondary endpoints are: 1**.** Actual **Caregiver** CGI-I score at Visit 6 2. **Actual Investigator CGI-I score at Visit 6** ~~2.~~3. Change from Visit 3 to Visit 6 in Investigator CGI-S **score** ~~3.~~4. Change from Visit 3 to Visit 6 in CHQ-28 **score** **5.** Change from Visit 3 to Visit 6 in PSI-4-SF **scores in**: **a. Parental Distress** **b. Parent-Child Dysfunctional Interaction** **~~a~~.c. Difficult Child** ~~4. Change from Visit 3 to Visit 6 in Caregiver-completed CGI-I~~ **~~5.~~6.** Change from Visit 3 to Visit 6 in SNAP-IV ADHD scores in: a. Inattention ratings b. Hyperactivity/Impulsivity ratings c. Combined Scale ratings	For Clarification
6.12	59	The following was added: [redacted]	To understand exposure of metabolites in children
7.4.4	63	The following was added: [redacted]	To understand exposure of metabolites in children

Changes to 810P302 V4.0 Dated 16 Dec 2016

Section	Page	Description of Change	Rationale
Title page	1	Protocol version and date was updated	Administrative
Signature Page	3	The signature page was updated	Administrative
Signature Page	3	One of the reviewers was changed: [redacted]	Administrative
Synopsis	15	The following was added: **Based on the 810P301 study Interim Analysis result decision, the 18 mg dose arm was dropped partway through the study. As a result, subjects in the 18 mg dose arm will be re-**	Updated as per changes in the protocol due to interim analysis results in the 810P301 study.

		randomized in a ratio of 2:1 to receive 36 mg/day SPN-810 or placebo.	
Synopsis	15	The following was changed: Approximately 378 subjects aged 6-12 years (inclusive) will be screened to achieve 291 subjects randomized~~; 97 per treatment arm~~	Updated as per changes in the protocol due to interim analysis results in the 810P301 study
Synopsis	16	**Treatment, Dose and Mode of Administration** The following was added: **Based on the Interim Analysis results from the 810P301 study, Treatment 2 (18 mg) arm is discontinued.**	Updated as per changes in the protocol due to interim analysis results in the 810P301 study
Synopsis	17	**Sample size**: The following was changed: It is assumed that approximately 20% subjects will dropout before the completion of the study and hence, an adjusted total of 291 subjects will be randomized in a 1:1:1 ratio to obtain 231 subjects in the ITT population at the completion of the study. **Based on the 810P301 study Interim Analysis result decision, the 18 mg dose arm was dropped partway through the study. As a result, subjects in the 18 mg dose arm will be re-randomized in a ratio of 2:1 to receive 36 mg/day SPN-810 or placebo**. ~~The sample size was calculated using the nQuery Advisor Software, Version 7.~~ ~~The above sample size may be increased depending on the results of the interim analysis from study 810P301. If the results of the interim analysis warrant increased sample size for study 810P301, then the same increase will be applied to study 810P302, which will be described in a protocol amendments.~~	Updated as per changes in the protocol due to interim analysis results in the 810P301 study
Synopsis	17	**Hypotheses:** The following was changed: Let μ_1**-and-** μ_2~~, and μ_3~~ represent the median percent change in the frequency of IA behaviors per 7 days in the Maintenance period relative to the Baseline period in the ITT population for subjects treated with Placebo~~, 18 mg~~ and 36 mg doses of SPN-810, respectively. The null (H_0) and the alternative (H_a) hypotheses are as in the following. • H_{0}~~$_1$~~: $\mu_2 = \mu_1$, (there is no difference between the median of the ~~18~~ **36** mg dose SPN-810 and the median of placebo) vs. H_{a}~~$_1$~~: $\mu_2 \neq \mu_1$,(there is a difference between the median of the ~~18~~ **36**mg dose SPN-810 and the median of placebo) ~~H_{02}: $\mu_3 = \mu_1$, (there is no difference between the median of the 36 mg dose SPN-810 and the median of placebo) vs. H_{a2}: $\mu_3 \neq \mu_1$,(there is a difference between the median of the 36 mg dose SPN-810 and the median of placebo)~~	Updated as per changes in the protocol due to interim analysis results in the 810P301 study

Synopsis	18	**Statistical Methods**: The following was changed: The primary efficacy analysis will be performed using the Wilcoxon rank-sum test to compare the median~~s~~ of ~~each of the two doses of~~ SPN-810 ~~(18 and~~ 36 mg **and~~)~~** ~~with~~ the median of the Placebo. The least squares mean of each treatment group, the difference in the least squares mean (~~18mg dose minus placebo and~~ 36 mg dose minus placebo), and the 2-sided 95% CI for the difference will be obtained.	Updated as per changes in the protocol due to interim analysis results in the 810P301 study
List of Abbreviation	25	FOCP changed to FOC**B**P	To Clarify
3.2	32	The following was added: Following screening, eligible subjects will enter a flexible baseline period, at which time the IA diary will be issued to the subject's primary caregiver. At the end of the baseline period, **per the original plan,** eligible subjects whose primary caregiver has maintained at least 80% compliance with the IA diary will be randomized to 1:1:1 to 18 mg/day SPN-810, 36 mg/day SPN-810, or placebo. **However, based on the 810P301 study Interim Analysis result decision, the 18 mg arm was dropped partway through the study. As a result, subjects planned to be randomized to the 18 mg arm will be re-allocated to the 36 mg or placebo arm in a ratio of 2:1.**	Updated as per changes in the protocol due to interim analysis results in the 810P301 study
3.2.1.2	33	The following was changed: These subjects may be rescreened to participate in the study under **current** protocol ~~4.0~~	To clarify
3.2.2.1	34	The following change was made: **Per the original randomization**, ~~E~~eligible subjects who complete the baseline period and meet the requirements for the double blind study will be randomized at Visit 3 (Day 1) in a 1:1:1 ratio to receive 18 mg/day, 36 mg/day SPN-810, or placebo and proceed to the titration period, which will be two weeks. **However, based on the 810P301 study Interim Analysis result decision, the 18 mg arm was dropped partway through the study. As a result, subjects planned to be randomized to the 18 mg arm will be re-allocated to the 36 mg or placebo arm in a ratio of 2:1.**	Updated as per changes in the protocol due to interim analysis results in the 810P301 study
3.2.3	34	The following was added: **The 18 mg line in the 2 figures below will not be applicable to subjects re-randomized following the 810P301 interim analysis decision to drop the 18 mg dose.**	Updated as per changes in the protocol due to interim analysis results in the 810P301 study
Table 1	40	f To be performed for female subjects of childbearing potential **prior to administration of first dose of SM and will have to be tested as negative for the subject to continue in the study**.	Procedural

4.2.1. 4.2.3 and 4.2.7	41.42, 43	FOCP changed to FOC**B**P	To Clarify
4.3.1	44	**Treatments Administered** The following was added: **Based on the 810P301 study Interim Analysis result decision, the 18 mg dose arm is dropped partway through the study.**	Updated as per changes in the protocol due to interim analysis results in the 810P301 study
4.3.4	45,46	The following change was made: The **original** randomization scheme assigns treatments to each randomization number in a 1:1:1. **However, based on the 810P301 study Interim Analysis result decision, the 18 mg arm was dropped partway through the study. As a result, subjects planned to be randomized to the 18 mg arm will be re-allocated to the 36 mg or placebo arm in a ratio of 2:1.**	Updated as per changes in the protocol due to interim analysis results in the 810P301 study
4.3.6	46	The following was added: **The 18 mg dose (Treatment 2) arm was dropped partway through the study as described in section 4.3.4.**	Updated as per changes in the protocol due to interim analysis results in the 810P301 study
Table 3	56	FOCP changed to FOC**B**P	To clarify
6.7	61	The following change was made: Percent of study drug compliance is defined as {(number of tablets dispensed – number of tablets returned) / ~~24~~*(date of last dose – date of first dose + 1)}* 100%. **Each subject is expected to take 4 tablets per day**. For each treatment, SM compliance will be summarized by compliance category (<80%, 80-120%, and >120%) and number of subjects in each compliance category.	To clarify
6.9.1	61,62	The following was changed: Let μ_1, **and** μ_2~~, and μ_3~~ represent the median percent change in the frequency of IA behaviors per 7 days in the Maintenance**)** period relative to the Baseline period in the ITT population for subjects treated with Placebo~~, 18 mg~~ and 36 mg dose~~s~~ of SPN-810, respectively. The null (H_0) and the alternative (H_a) hypotheses are as in the following. • H_{0}~~$_1$~~: $\mu_2 = \mu_1$, (there is no difference between the median of ~~the 18~~ **36** mg dose SPN-810 and the median of placebo) vs. H_{a}~~$_1$~~: $\mu_2 \neq \mu_1$,(there is a difference between the median of the **36**~~18~~ mg dose SPN-810 and the median of placebo) ~~• H_{02}: $\mu_3 = \mu_1$, (there is no difference between the median of the 36 mg dose SPN-810 and the median of placebo) vs. H_{a2}: $\mu_3 \neq \mu_1$,(there is a difference between the median of the 36 mg dose SPN-810 and the median of placebo)~~ The primary efficacy analysis will be performed using the Wilcoxon rank-sum test to compare the median~~s of each of the two doses of~~ SPN-810 36 mg dose with the median of the Placebo.	Updated as per changes in the protocol due to interim analysis results in the 810P301 study

		~~To preserve the overall Type I error rate at 0.050 for the primary efficacy endpoint, a step-up Hochberg procedure (Hochberg 1988) will be used to compare SPN-810 36 mg dose group with Placebo. If the observed p-value from the comparison is < 0.050 in favor of the SPN-810 dose group, then 36mg dose group will be declared statistically significantly better than placebo.~~ **The superiority of 36 mg dose to placebo will be claimed if the p-value from this analysis < 0.05 at alpha of 5% significance level. There is no multiplicity adjustment with respect to the primary endpoint since only 2 treatments are compared.**	
6.9.2	62	The following was changed: The least squares mean of each treatment group, the difference in the least squares mean (~~18~~ 36mg dose minus placebo ~~and 36 mg dose minus placebo~~), and the 2-sided 95% CI for the difference will be obtained. ~~To preserve the overall type I error rate at 0.05 for the secondary endpoints, a sequential testing procedure will be used with the following features. First only dose or doses that are significantly different from placebo for the primary endpoint will be tested for secondary endpoints. The first of the secondary endpoints will be compared to placebo using the Hochberg step up procedure but only using those doses retained as a result of testing the primary endpoint. The second secondary endpoint will be tested in the same manner but only using those doses that were retained from the primary and the first secondary endpoint and so forth. As the endpoints are gone through in the pre-defined order doses will only be retained if significant for all endpoints tested so far and at the given stage the Hochberg step-up procedure will be applied.~~ ~~The ordering of the 6 secondary endpoints from first to be tested to sixth is: Investigator Clinical Global Impression – Improvement Scale (CGI-I)(Endpoint 1), Clinical Global Impression – Severity Scale (CGI-S)(Endpoint 2), Child Health Questionnaire (CHQ-28) (Endpoint 3), Parenting Stress Index (PSI-4-SF) (Endpoint 4), Caregiver-completed CGI-I (Endpoint 5)and SNAP-IV Rating Scale (Endpoint 6).~~ **The superiority of 36 mg dose to placebo will be claimed if the p-value from this analysis < 0.05 at alpha of 5% significance level. There is no multiplicity adjustment with respect to the primary endpoint since only 2 treatment groups are compared. The Type I error rate of the tests involving the secondary efficacy endpoints will be controlled by the Hochberg's method at the 0.05 two-sided level.**	Updated as per changes in the protocol due to interim analysis results in the 810P301 study
6.10	64	The following changes were made: A sample size of 77 subjects per arm (231 subjects for 3 arms **per the original plan)**.	Updated as per changes in the protocol due to interim analysis results in the 810P301 study

		~~The above-sample size may be increased depending on the results of the interim analysis from study 810P301. If the results of the interim analysis warrant increased sample size for 810P301, then the same increase will be applied to study 810P302, which will be described in a protocol amendment~~. It is assumed that approximately 20% subjects will dropout before the completion of the study and hence, an adjusted total of 291 subjects will be randomized in a 1:1:1 ratio to obtain 231 subjects in the ITT population at the completion of the study. **However, based on the 810P301 study Interim Analysis result decision, the 18 mg arm was dropped partway through the study. As a result, subjects planned to be randomized to the 18 mg arm will be re-allocated to the 36 mg or placebo arm in a ratio of 2:1.**	
		Changes to Version 6.0 dated 13 Oct 2017	
Section	**Page**	**Description of Change**	**Rationale**
Title page	1	Protocol version and date was updated	Administrative
Signatures	3	Reviewers: [redacted]	Administrative
Synopsis	23	Objectives, Secondary The **key secondary objective of the study is to assess the effect of SPN-810 on the Clinical Global Impression – Severity Scale (CGI-S).** **Additional** secondary objectives ~~of the study~~ are to assess the following: (Deleted) • ~~the effect of SPN-810 on the Clinical Global Impression – Severity Scale (CGI-S)~~ (Added) • **the effect of SPN-810 on the responder rate (defined as ≥ 50% in the reduction of the frequency of IA behaviors)** • **the effect of SPN-810 on the responder rate (defined as ≥ 30% in the reduction of the frequency of IA behaviors)**	Clarification
Synopsis	24	Number of Subjects: Approximately ~~378~~ **398** subjects aged 6-12 years (inclusive) will be screened to achieve ~~291~~ **306** subjects randomized.	Revised following re-estimation of sample size

Synopsis	24	Endpoints, Primary Efficacy Endpoint: The primary efficacy endpoint is the percent change (~~PCH_M~~ **PCH_T**) in the frequency (unweighted score) of IA behaviors per 7 days in the ~~Maintenance~~ **Treatment (Titration and Maintenance)** period relative to the Baseline period calculated over the number of days with non-missing IA diary data. The primary efficacy endpoint ~~PCH_M~~ **PCH_T** will be calculated by ~~PCH_M~~ **PCH_T** = 100*(~~M~~ **T** – B)/B, where ~~M~~ **T** and B are IA behavior frequencies per 7 days during the ~~maintenance~~ **treatment** period and baseline period, respectively.	Clarification
Synopsis	24-25	Endpoints, (Added) **Key Secondary Efficacy Endpoint** **Change from Visit 3 to Visit 6 in Investigator CGI-S score** **Additional** Secondary Efficacy Endpoints 1. Investigator~~-rated~~ CGI-I **score at Visit 6** ~~2. CGI-S~~ ~~3.~~ **2.** CHQ-PF28 **score at Visit 6** ~~4.~~ **3.** PSI-4-SF **scores at Visit 6 in:** ~~5. Caregiver-rated CGI-I~~ **a**. **Parental Distress** **b. Parent-Child Dysfunctional Interaction** **c. Difficult Child** **4. Caregiver CGI-I score at Visit 6** 5. SNAP-IV ~~Rating~~ **ADHD scores at Visit 6 in:** **a. Inattention ratings** **b. Hyperactivity/Impulsivity ratings** **c. Oppositional Defiant Disorder** ~~a.~~ **d. Combined** Scale **ratings** **6. Percent of responders with ≥50% reduction in the frequency of IA behaviors from baseline** **7. Percent of responders with ≥30% reduction in the frequency of IA behaviors from baseline**	Clarification
Synopsis	25	Sample size: Based on results from the Phase 2 study, ~~it is assumed that the~~ **a 15-point** average **difference in favor of the SPN-810** treatment ~~difference between SPN-810 dose groups and~~ **arms compared with** placebo is ~~15 with~~ **assumed; the change from baseline to endpoint in total R-MOAS rating was used to evaluate the difference. The R-MOAS was used because there have been no prior studies with the IA diary.** A common standard deviation of ~~27.3. A~~ **34.83 was obtained from a blinded analysis of SPN-810P301 data. Based on these parameter assumptions,** a sample size of ~~77~~ **122** subjects per arm ~~(231 subjects for 3 arms)~~ will yield 90% power to detect a non-zero difference between the median of ~~18 mg or 36 mg dose group~~ **SPN-810 treatment** and the placebo **groups** using the Wilcoxon rank-sum test with a 2-sided significance level ~~alpha~~ **α**=0.05. ~~It is assumed that approximately 20% subjects will dropout before the completion of the study and hence, an adjusted total~~ **The original sample size** of 291 ~~subjects will be randomized in a~~	Revised sample size estimate based on updated parameter assumptions

		~~1:1:1 ratio to obtain 231 subjects in the ITT population at~~ **was based on having 3 treatment groups (97 subjects per arm) and specific assumptions on** the ~~completion of the study. Based on~~ **drug placebo difference, standard deviation and discontinuation rate.** **After** the 810P301 study Interim Analysis result ~~decision, the 18 mg dose arm was dropped partway through the study. As a result, subjects in~~ **was completed**, the 18 mg dose arm ~~will~~ **was discontinued and subjects planned to be randomized to the 18 mg arm would** be re-~~randomized~~ **allocated to the 36 mg or placebo arm** in a ratio of 2:1 ~~to receive 36 mg/day SPN-810 or placebo~~. **As such there will be an unequal randomization between the 36 mg dose group and placebo. With this post-interim analysis un-equal randomization, the placebo arm is expected to approach approximately 121 subjects of the total of 306 subjects randomized.** **The sample size was calculated using the nQuery Advisor Software, Version 7.**	
Synopsis	26	~~Hypotheses~~ **Hypothesis**: **Per the adaptive design feature of protocol 810P301 that led to discontinuation of the 18 mg dose group, SPN-810 36 mg vs. placebo will be tested.** ~~Let μ1, and μ2 represent the median percent change in the frequency of IA behaviors per 7 days in the Maintenance period relative to the Baseline period in the ITT population for subjects treated with Placebo and 36 mg dose of SPN-810, respectively.~~ The null (H_0) and the alternative (H_a) hypotheses are as in the following. • H_{01}: ~~$\mu_2 = \mu_1$, (t~~**T**here is no difference between the median of the 36 mg dose SPN-810 and the median of placebo~~)~~ vs. H_{a1}: ~~$\mu_2 \neq \mu_1$, (t~~**T**here is a difference between the median of the 36 mg dose SPN-810 and the median of placebo.~~)~~	Testing the 18 mg dose is no longer applicable after discontinuation of this arm
Synopsis	26	Handling Missing Data: For the primary efficacy endpoint, the frequency of IA behaviors during the ~~maintenance~~ **Treatment** period will be calculated over the number of days with non-missing IA diary data in the ~~maintenance~~ **Treatment** period.	Clarification
Synopsis	27	Statistical Methods: The primary efficacy endpoint is the percent change in the frequency (unweighted score) of IA behaviors per 7 days in the ~~Maintenance~~ **Treatment (Titration and Maintenance)** period relative to the Baseline period in the ITT population calculated over the number of days with non-missing IA diary data. (Deleted) ~~The robustness of the primary analyses will be checked by performing at least two sensitivity analyses.~~ ~~Each one of the six~~ **The key secondary endpoint will be analized using Mixed-Effect Model for Repeated Measure (MMRM). The model includes treatment, visit, and interaction between**	Clarification

		treatment and visit as fixed factors, and baseline as covariate. The between-group comparison will be performed using the simple contrast at the respective visits. The least squares means for 36 mg dose and placebo, the difference in the least squares mean (36 mg dose minus placebo), and the 2-sided 95% CI for the difference will be calculated at Visit 6 using the simple contrast. **The other** secondary endpoints will be analyzed **as follows:** • **Actual scores of CGI-I (investigator and caregiver) will be analyzed using a Mixed-Effect Model for Repeated Measure (MMRM) similar to the key secondary outcome.** • **Actual Scores for CHQ-PF28, PSI-4-SF, and SNAP-IV will be analyzed** using the analysis of covariance method based on the ITT population ~~with missing data imputed using the Last Observation Carried Forward (LOCF) method~~**.** The model includes treatment and baseline as fixed independent covariates and ~~change from baseline to final maintenance visit~~ **Visit 6 value** as a response variable. The least squares mean of each treatment group, the difference in the least squares mean (36 mg dose minus placebo), and the 2-sided 95% CI for the difference will be obtained. • **The percentage of responders with at least 30% reduction and with at least 50% reduction in the frequency of IA behaviors per 7 days in the Treatment (Titration and Maintenance) period relative to the Baseline period will be derived analyzed using the logistic regression model with treatment as explanatory variables and baseline as covariate. Odds ratio (36 mg dose/placebo), and 95% CI for the odds ratio and p-value will be presented. In addition, the number and percentage of responders will also be tabulated.**	
1.1	35, 36	IA is ~~a~~ common**ly associated with** ~~comorbidity in~~ attention-deficit/hyperactivity disorder (ADHD) and is often refractory to primary ADHD therapy. Risperidone and other “atypical” antipsychotics have historically been at the forefront of treatment recommendations regarding combination therapy for managing ~~comorbid~~ aggression ~~in children~~ **associated** with ADHD **in children** (Pappadopulos et al. 2003; Pliszka et al. 2006; Pliszka et al. 2007). Results of randomized controlled trials such as TEOSS stimulated interest in the potential usefulness of molindone as a weight- and metabolically-neutral D2-receptor antagonist in children with ADHD and ~~comorbid~~ **associated with** IA.	Clarification
1.3	37	One (1) **subject** ~~patient~~ in the low dose arm and 2 **subjects** ~~patients~~ in the medium dose arm had severe AEs that were considered either possibly or definitely related to the drug. Six (6) **subjects** ~~patients~~ in total discontinued the study because of AEs in the active treatment arms: 1 in low dose; 2 in medium dose; and 3 in high dose.	Clarification

2.2	39	The **key secondary ~~objectives~~ objective of the study is to assess the effect of SPN-810 on the Clinical Global Impression – Severity Scale (CGI-S).** **Additional** secondary objectives ~~of the study~~ are to assess the following: (Deleted) • ~~the effect of SPN-810 on the Clinical Global Impression – Severity Scale (CGI-S)~~ (Added) • **the effect of SPN-810 on the responder rate (defined as ≥ 50% in the reduction of the frequency of IA behaviors)** • **the effect of SPN-810 on the responder rate (defined as ≥ 30% in the reduction of the frequency of IA behaviors)**	Clarification
3.1	39	The present study is designed to evaluate the efficacy, safety, and tolerability of SPN-810 in patients aged 6 to 12 years with ADHD ~~and comorbid~~ **associated with** IA, when taken in conjunction with a standard ADHD treatment.	Clarification
3.2.3	42	All subjects who complete the randomized, double blind portion of study ~~810P301~~ **810P302** will have the option to participate in an OLE study (study protocol 810P304) in which all subjects will receive active SM treatment.	Correction
Figure 1	43	(Added) **NOTE: Based on the 810P301 study Interim Analysis result decision, the 18 mg dose arm was dropped partway through the study.**	Clarification
Figure 2	44	(Added) **NOTE: Based on the 810P301 study Interim Analysis result decision, the 18 mg dose arm was dropped partway through the study.**	Clarification
4.1	45	Approximately ~~291~~ **306** subjects will be randomized in this clinical investigation.	Revised sample size estimate based on updated parameter assumptions
Table 1	48	Footnote e: Diary compliance must be at least 80% (minimum of 12 days out of ~~1415~~ **15**) to qualify for randomization	Correction
5.2.1	57	Investigators should consider their total clinical experience with children who have IA ~~comorbid~~ **associated** with ADHD and rate how severe the subject's condition is at the time.	Clarification
5.2.1	57	• CGI-I, relative to the condition at **Baseline (**Visit **1)** ~~3~~, will be evaluated by the caregiver and by the Investigator at each post-baseline visit on a 7-point scale with 1=Very much improved, 2=Much improved, 3=Minimally improved, 4=No change, 5=Minimally worse, 6=Much worse, and 7=Very much worse.	Correction
6.2	67	For the primary efficacy endpoint, the frequency of IA behaviors during the ~~maintenance~~ **Treatment** period will be calculated over the number of days with non-missing IA diary data in the ~~maintenance~~ **Treatment** period.	Clarification
6.9.1	69-70	The primary efficacy endpoint is the percent change (~~PCH_M~~ **PCH_T**) in the frequency (unweighted score) of IA behaviors per 7 days	Clarification

		in the ~~Maintenance~~ **Treatment (Titration and Maintenance)** period relative to the Baseline period calculated over the number of days with non-missing IA diary data. The primary efficacy endpoint ~~PCH_M~~ **PCH_T** will be calculated by ~~PCH_M~~ **PCH_T** = 100*(**T** ~~M~~ – B)/B, where ~~M~~ **T** and B are IA behavior frequencies per 7 days during the ~~maintenance~~ **treatment** period and baseline period, respectively. (Deleted) ~~Let μ1 and μ2 represent the median percent change in the frequency of IA behaviors per 7 days in the treatment Maintenance period relative to the Baseline period in the ITT population for subjects treated with Placebo and 36 mg doses of SPN-810, respectively.~~ **(Added)** **Per the adaptive design feature of protocol 810P301 that led to discontinuation of the 18 mg dose group, SPN-810 36 mg vs. placebo will be tested.** • ~~H_0: $\mu_2 = \mu_1$, (~~**H_{01}:** There is no difference between the median of the 36 mg dose SPN-810 and the median of placebo) vs. ~~H_a: $\mu_2 \neq \mu_1$, (~~ • **H_{a1}:** There is a difference between the median of the 36 mg dose SPN-810 and the median of placebo~~)~~**.**	
6.9.2	70	6.9.2 **Key** Secondary Efficacy Analyses The **key** secondary ~~endpoints are:~~ ~~1. Actual Caregiver CGI-I score at Visit 6~~ ~~2. Actual Investigator CGI-I score at Visit 6~~ **efficacy analysis is the** change from Visit 3 to Visit 6 in Investigator CGI-S score**.** ~~Change from Visit 3 to Visit 6 in~~ **The Key Secondary endpoint will be analyzed using Mixed-Effect Model for Repeated Measure (MMRM) for the ITT population. The model includes treatment, visit, and interaction between treatment and visit as fixed factors, and baseline as covariate. The model parameters will be estimated using restricted maximum likelihood method with unstructured variance-covariance matrix and Kenward-Roger approximation to estimate denominator degrees of freedom. The between-group comparison will be performed using the simple contrast at the respective visits. The least squares mean of 36 mg dose and placebo, the difference in the least squares mean (36 mg dose minus placebo), and the 2-sided 95% CI for the difference will be calculated.**	Clarification
6.9.3	70	**6.9.3 Additional Secondary Efficacy Analyses** **1. Investigator CGI-I score at Visit 6** ~~3.~~ **2.** CHQ-28 score **at Visit 6** ~~4.~~ **3.** ~~Change from Visit 3 to Visit 6 in~~ PSI-4-SF scores **at Visit 6** in: **4.** ~~Change from Visit 3 to Visit 6 in~~ **Caregiver CGI-I score at Visit 6**	Clarification

		5. SNAP-IV ADHD scores **at Visit 6** in: a. Inattention ratings b. Hyperactivity/Impulsivity ratings **c. Oppositional Defiant Disorder** ~~c.~~ **d.** Combined Scale ratings **6.** ~~Each one of the six~~ **Percentage of responders with ≥50% reduction in the frequency of IA behaviors from baseline** **7. Percentage of responders with ≥30% reduction in the frequency of IA behaviors from baseline** **The other** secondary endpoints will be analyzed using the **ITT Population as follows:** **Scores of CGI-I (investigator and caregiver) will be analyzed using a Mixed-Effect Model for Repeated Measure (MMRM) similar to the key secondary outcome.** **Scores for CHQ-PF28, PSI-4-SF, and SNAP-IV will be analyzed using the** analysis of covariance method based on the ITT population ~~with missing data imputed using the Last Observation Carried Forward (LOCF) method~~. The model includes treatment and baseline as fixed independent covariates and ~~change from baseline to final maintenance visit~~ **Visit 6 value** as a response variable. ~~The superiority of 36 mg dose to placebo will be claimed if the p-value < 0.05 at alpha 5% significance level. There is no multiplicity adjustment with respect to the primary endpoint since only 2 treatments groups are compared.~~ ~~The Type I error rate of the tests involving the secondary efficacy endpoints will be controlled by the Hochberg's method at the 0.05 two-sided level.~~ **The percentage of responders with at least 30% reduction and with at least 50% reduction in the frequency of IA behaviors per 7 days in the Treatment (Titration and Maintenance) period relative to the Baseline period will be derived analyzed using the logistic regression model with treatment as explanatory variables and baseline as covariate. Odds ratio (36 mg dose/placebo), and 95% CI for the odds ratio and p-value will be presented. In addition, the number and percentage of responders will also be tabulated.** **If the null hypothesis for the primary analysis is not rejected, then no multiplicity adjustment will be done for the key secondary endpoint. If the key secondary endpoint hypothesis is rejected then, a sequential testing procedure to preserve the type I error rate at 0.05 will be conducted for the additional secondary endpoints as described below:**	

		First, the first of the additional secondary endpoints (Investigator CGI-I score at Visit 6) will be used to test H_{01}: no difference between SPN-810 36 mg and Placebo in the treatment of IA in subjects with ADHD in conjunction with standard ADHD treatment. If this test is rejected, then the 2nd test using the same hypothesis will be repeated using the 2nd additional secondary endpoint (CHQ-28 score at Visit 6). If the first hypothesis is not rejected then no other additional secondary endpoint test will be performed. If the 2nd test is rejected then the 3rd test will be conducted for the 3rd additional secondary endpoint (PSI-4-SF scores) and so on until the last additional secondary endpoint is used for testing in the above pre-specified order above.	
6.9.4	71	To this end, ~~the three~~ **two** sensitivity analyses will be performed: 1. Multiple imputation under MAR using available data on the primary endpoint 2. Placebo- based imputation under MNAR ~~3. Per Protocol Analysis~~	Correction
6.9.4	de-leted	(Deleted) ~~6.9.4 Per Protocol Analysis~~ ~~This analysis will be conducted by repeating the primary analysis on the per protocol population.~~	Correction
6.9.5	72	(Added) **6.9.5 Supplementary Analysis** **A supplementary analysis based on the per-protocol population will be performed.**	Clarification
6.10	72-73	Based on results from the Phase 2 study, ~~it is assumed that the~~ **a 15-point** average ~~treatment~~ difference ~~between~~ **in favor of the** SPN-810 ~~dose groups and~~ **treatment arms compared with** placebo ~~=15 with~~ **is assumed; the change from baseline to endpoint in total R-MOAS rating was used to evaluate the difference. The R-MOAS was used because there have been no prior studies with the IA diary.** A common standard deviation of ~~27.3. A~~ **34.83 was obtained from a blinded analysis of SPN-810P301 data.** **Based on these parameter assumptions,** a sample size of ~~77 subjects per arm (231 subjects for 3 arms per the original plan)~~ **approximately 122 per arm** will yield 90% power to detect a non-zero difference between the median of ~~18 mg or 36 mg dose group~~ **SPN-810 treatment** and the placebo **groups** using the Wilcoxon rank-sum test with a 2-sided significance level ~~alpha~~ **α**=0.05. ~~It is assumed that approximately 20% subjects will dropout before the completion of the study and hence, an adjusted total~~ **The original sample size of** 291 ~~subjects will be randomized in a 1:1:1 ratio to obtain 231 subjects in the ITT population at the completion of the study. However,~~ **was** based on **having 3 treatment groups (97 subjects per arm) and specific**	Revised sample size based on updated parameter assumptions

		assumptions on the drug placebo difference, standard deviation and discontinuation rate. **After** the 810P301 study Interim Analysis result ~~decision~~ **was completed**, the 18 mg **dose** arm was ~~dropped partway through the study. As a result,~~ **discontinured and** subjects planned ~~to be randomized~~ to **be randomized to** the 18 mg arm ~~will~~ **would** be re-allocated to the 36 mg or placebo arm in a ratio of 2:1. **As such there will be an unequal randomization between the 36 mg dose group and placebo. With this post-interim analysis un-equal randomization, the placebo arm is expected to approach approximately 121 subjects of the total of 306 subjects randomized.**	

CLINICAL PROTOCOL SYNOPSIS

Name of Company: Supernus Pharmaceuticals, Inc.	**IND Number:** 106,515
Name of Product: Molindone Hydrochloride Extended-Release Tablets (SPN-810)	**Name of Active Ingredient:** Molindone Hydrochloride
Protocol Number: 810P302	**Phase of Development:** 3
Full Title of Study: A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Molindone Hydrochloride Extended-Release Tablets for the Treatment of Impulsive Aggression in Pediatric Patients with Attention Deficit/Hyperactivity Disorder (ADHD) in Conjunction with Standard ADHD Treatment	
Investigator(s) / Center(s): Approximately 25 US centers	

Objectives:

Primary

The primary objective is to assess the efficacy and safety of SPN-810 in reducing the frequency of impulsive aggression (IA) behaviors in pediatric patients with ADHD when taken in conjunction with standard ADHD treatment

Secondary

The key secondary objective of the study is to assess the effect of SPN-810 on the Clinical Global Impression – Severity Scale (CGI-S).

Additional secondary objectives are to assess the following:

- the effect of SPN-810 on the Investigator-rated Clinical Global Impression – Improvement Scale (CGI-I)
- the effect of SPN-810 on the child's overall health as measured by the Child Health Questionnaire Parent Form 28-item (CHQ-PF28)
- the effect of treating the child with SPN-810 on the parent-child relationship as measured by the Parenting Stress Index – Short Form (PSI-4-SF)
- the effect of SPN-810 on the Caregiver-rated CGI-I
- the effect of SPN-810 on inattention and hyperactivity-impulsivity measured by the SNAP-IV Rating Scale
- the effect of SPN-810 on the responder rate (defined as ≥ 50% in the reduction of the frequency of IA behaviors)
- the effect of SPN-810 on the responder rate (defined as ≥ 30% in the reduction of the frequency of IA behaviors)

Tertiary

[redacted]

Study Design: Double-blind, placebo-controlled, 3-arm, randomized (1:1:1), parallel group study. Based on the 810P301 study Interim Analysis result decision, the 18 mg dose arm was dropped partway through the study. As a result, subjects in the 18 mg dose arm will be re-randomized in a ratio of 2:1 to receive SPN-810 36 mg/day or placebo.

Number of Subjects: Approximately 398 subjects aged 6-12 years (inclusive) will be screened to achieve 306 subjects randomized.

Criteria for Inclusion:
Otherwise healthy male or female subjects, age 6 to 12 years at the time of screening with a primary diagnosis of ADHD and currently receiving monotherapy treatment with an optimized FDA-approved ADHD medication. IA will be confirmed at screening using R-MOAS and Vitiello Aggression Scale.

Criteria for Exclusion:
Current or lifetime diagnosis of epilepsy, major depressive disorder, bipolar disorder, schizophrenia or related disorder, personality disorder, Tourette's disorder, or psychosis not otherwise specified. Currently meeting DSM criteria for autism spectrum disorder, pervasive developmental disorder, obsessive compulsive disorder, post-traumatic stress disorder, or any other anxiety disorder as primary diagnosis. Known or suspected intelligence quotient (IQ) < 70, suicidality, pregnancy, or substance or alcohol abuse.

Treatment, Dose, and Mode of Administration:
Molindone hydrochloride extended-release tablet dosage forms of 3mg and 9mg with matching placebo tablets. Treatment to be administered orally twice daily with food. Subjects will be force-titrated over a period of 2 weeks to their final randomized dose.

- Treatment 1: placebo
- Treatment 2: 18mg
- Treatment 3: 36mg

Based on the Interim Analysis results from the 810P301 study, Treatment 2 (18 mg) arm was discontinued.

Duration of Treatment and Study Duration:
Total subject duration on study: Approximately 13 weeks

- Pre-treatment phase: Up to 45 days
  - Screening period: Up to 30 days
  - Baseline period: At least 15 days
- Treatment phase: 5 weeks
  - Titration period: 2 weeks
  - Maintenance period: 3 weeks
- Conversion/taper phase: 1 week

Endpoints:
Primary Efficacy Endpoint
The primary efficacy endpoint is the percent change (PCH_T) in the frequency (unweighted score) of IA behaviors per 7 days in the Treatment (Titration and Maintenance) period relative to the Baseline period calculated over the number of days with non-missing IA diary data.

The primary efficacy endpoint PCH_T will be calculated by $PCH_T = 100*(T - B)/B$, where T and B are IA behavior frequencies per 7 days during the treatment period and baseline period, respectively. The IA behavior frequency per 7 days is defined as (SUM/DAY) x 7, where SUM is the total of the IA behaviors reported in the subject IA diary, and DAY is the number of days with non-missing IA score in the subject IA diary during the specified study period.

Key Secondary Efficacy Endpoint
Change from Visit 3 to Visit 6 in Investigator CGI-S score

Additional Secondary Efficacy Endpoints

1. Investigator CGI-I score at Visit 6
2. CHQ-PF28 score at Visit 6
3. PSI-4-SF scores at Visit 6 in:
    a. Parental Distress
    b. Parent-Child Dysfunctional Interaction
    c. Difficult Child
4. Caregiver CGI-I score at Visit 6
5. SNAP-IV ADHD scores at Visit 6 in:
    a. Inattention ratings
    b. Hyperactivity/Impulsivity ratings
    c. Oppositional Defiant Disorder
    d. Combined Scale ratings
6. Percent of responders with ≥50% reduction in the frequency of IA behaviors from baseline
7. Percent of responders with ≥30% reduction in the frequency of IA behaviors from baseline

Safety and Tolerability Endpoints

1. Adverse events (AE)
2. Extrapyramidal symptoms (EPS) scales (Simpson-Angus Scale, Barnes Akathisia Scale, Abnormal Involuntary Movement Scale)
3. Clinical laboratory tests (Hematology, Chemistry and Urinalysis)
4. ECGs
5. Vital signs
6. Columbia Suicide Severity Rating Scale (C-SSRS)
7. Infrequent Behaviors Checklist

Sample size:

Based on results from the Phase 2 study, a 15-point average difference in favor of the SPN-810 treatment arms compared with placebo is assumed; the change from baseline to endpoint in total R-MOAS rating was used to evaluate the difference. The R-MOAS was used because there have been no prior studies with the IA diary. A common standard deviation of 34.83 was obtained from a blinded analysis of SPN-810P301 data. Based on these parameter assumptions, a sample size of 122 subjects per arm will yield 90% power to detect a non-zero difference between the median of SPN-810 treatment and the placebo groups using the Wilcoxon rank-sum test with a 2-sided significance level α=0.05.

The original sample size of 291 was based on having 3 treatment groups (97 subjects per arm) and specific assumptions on the drug placebo difference, standard deviation and discontinuation rate.

After the 810P301 study Interim Analysis result was completed, the 18 mg dose arm was discontinued and subjects planned to be randomized to the 18 mg arm would be re-allocated to the 36 mg or placebo arm in a ratio of 2:1. As such there will be an unequal randomization between the 36 mg dose group and placebo. With this post-interim analysis un-equal randomization, the placebo arm is expected to approach approximately 121 subjects of the total of 306 subjects randomized.

The sample size was calculated using the nQuery Advisor Software, Version 7.

Analysis Populations:
Safety Population: will include all randomized subjects who received at least 1 dose of study drug.
Intent-to-Treat (ITT) Population: will include all subjects who received at least 1 dose of study drug and have a baseline and at least 1 valid post-randomization assessment of frequency of IA behaviors based on IA diary entry.
Per-Protocol (PP) Population: will include all of the subjects in the ITT population who completed the treatment period with 80% diary completion compliance and who did not have major protocol deviations.
PK population: will include all subjects in the safety population who had at least one PK sample drawn which had a quantitatable concentration for at least one analyte of interest.

Hypothesis:
Per the adaptive design feature of protocol 810P301 that led to discontinuation of the 18 mg dose group, SPN-810 36 mg vs. placebo will be tested.
The null (H_0) and the alternative (H_a) hypotheses are as in the following.

- H_{01}: There is no difference between the median of the 36 mg dose SPN-810 and the median of placebo vs. H_{a1}: There is a difference between the median of the 36 mg dose SPN-810 and the median of placebo.

Handling Missing Data:
For the primary efficacy endpoint, the frequency of IA behaviors during the Treatment period will be calculated over the number of days with non-missing IA diary data in the Treatment period. No explicit imputation of missing data will be used, but this approach is implicitly equivalent to using the frequency of IA behaviors during the days with non-missing IA diary data to impute the frequency for days after study discontinuation and days with missing IA diary data.

Pharmacokinetic Methods:
Sampling:
5 blood samples divided between 2 visits.

Bioanalytical Analysis:
[redacted]

Pharmacokinetic Analysis:
[redacted]

Statistical Methods:
Summaries for continuous variables will include the sample size, mean, and standard deviation, median, minimum, and maximum. Summaries for discrete variables will include the tabulation of frequencies and percentages.

The primary efficacy analysis will be based on the ITT population. The primary efficacy endpoint is the percent change in the frequency (unweighted score) of IA behaviors per 7 days in the Treatment (Titration and Maintenance) period relative to the Baseline period in the ITT population calculated over the number of days with non-missing IA diary data.

The primary efficacy analysis will be performed using the Wilcoxon rank-sum test to compare the median of SPN-810 36 mg and the median of the Placebo. The Hodges-Lehmann estimate and the associated 95% confidence interval (CI) will be calculated.

The key secondary endpoint will be analized using Mixed-Effect Model for Repeated Measure (MMRM). The model includes treatment, visit, and interaction between treatment and visit as fixed factors, and baseline as covariate. The between-group comparison will be performed using the simple contrast at the respective visits. The least squares means for 36 mg dose and placebo, the difference in the least squares mean (36 mg dose minus placebo), and the 2-sided 95% CI for the difference will be calculated at Visit 6 using the simple contrast.

The other secondary endpoints will be analyzed as follows:

- Actual scores of CGI-I (investigator and caregiver) will be analyzed using a Mixed-Effect Model for Repeated Measure (MMRM) similar to the key secondary outcome.
- Actual Scores for CHQ-PF28, PSI-4-SF, and SNAP-IV will be analyzed using the analysis of covariance method based on the ITT population. The model includes treatment and baseline as fixed independent covariates and Visit 6 value as a response variable. The least squares mean of each treatment group, the difference in the least squares mean (36 mg dose minus placebo), and the 2-sided 95% CI for the difference will be obtained.
- The percentage of responders with at least 30% reduction and with at least 50% reduction in the frequency of IA behaviors per 7 days in the Treatment (Titration and Maintenance) period relative to the Baseline period will be derived analyzed using the logistic regression model with treatment as explanatory variables and baseline as covariate. Odds ratio (36 mg dose/placebo), and 95% CI for the odds ratio and p-value will be presented. In addition, the number and percentage of responders will also be tabulated.

Interim analysis:
There will be no planned interim analysis.

Safety analysis:
Safety analyses will be based on the safety population. All AEs will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) and will be summarized using discrete summaries at the subject and event level by system organ class and preferred term for each treatment group. Similarly, treatment-emergent AEs will be summarized by severity and relationship separately. Vital signs will be summarized using descriptive statistics by treatment groups. The summary includes sample size, mean, and standard deviation, median, minimum, and maximum. Continuous laboratory parameters will be summarized similarly. If applicable, categorical laboratory tests will be summarized using number and percent of subjects by treatment groups. Data on infrequent behaviors will be listed.

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LIST OF ABBREVIATIONS

ADHD	Attention-Deficit Hyperactivity Disorder
AE	Adverse Event
AESI	Adverse Event of Special Interest
AIMS	Abnormal Involuntary Movement Scale
ASD	Autism Spectrum Disorder
BID	Twice a Day
CFR	Code of Federal Regulations
CGI-S	Clinical Global Impression – Severity of Illness
CGI-I	Clinical Global Impression – Global Improvement
CHQ-PF 28	Child Health Questionnaire Parent Form 28-item
CL/F	Apparent Clearance
CRA	Clinical Research Associate
CRO	Contract Research Organization
C-SSRS	Columbia Suicide Severity Rating Scale
eCRF	Electronic Case Report Form
EPS	Extrapyramidal Symptoms
FOCBP	Females of Childbearing Potential
IA	Impulsive Aggression
IAF	Informed Assent Form
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IEC	Independent Ethics Committee
IRB	Institutional Review Board
ITT	Intent to Treat
KBIT-2	Kaufman Brief Intelligence Test, Second Edition
K-SADS-PL 2013	Schedule for Affective Disorders and Schizophrenia for School-aged Children – Present and Lifetime Versions 2013
LSM	Least-square Means
MAR	Missing at Random
MedDRA	Medical Dictionary for Regulatory Activities
MI	Multiple Imputation
MNAR	Missing Not at Random
ODD	Oppositional Defiant Disorder
PK	Pharmacokinetic(s)
PSI-4-SF	Parenting Stress Index – Short Form
QD	Once a Day
R-MOAS	Retrospective Modified Overt Aggression Scale
SAE	Serious Adverse Event

SAP	Statistical Analysis Plan
SM	Study Medication
SNAP-IV	Swanson, Nolan and Pelham Rating Scale - Revised
TDD	Total Daily Dose
ULN	Upper Limit of Normal
V/F	Apparent Volume of Distribution

1 INTRODUCTION

1.1 Background

Behavior with the immediate intent to cause harm – whether to self, others, objects, or property – constitutes aggression. Aggressive behavior becomes maladaptive when it persists, occurs outside an acceptable social context, and is of an intensity, frequency, severity and/or duration detrimental to the child's interests (Connor 2006; Jensen 2007). Maladaptive aggression is an expression of central nervous system dysfunction and may therefore be amenable to treatments targeting its neurobiologic substrate.

Aggression can be categorized into two broad subtypes based on the aggressor's motivation – 1) reactive or impulsive and 2) proactive or instrumental (Vitiello 1997). Impulsive aggression (IA) is angry, retaliatory aggression arising out of frustration, annoyance, or hostility to real or perceived provocations – stressors that youth of the same age typically experience with equanimity. IA is therefore an unplanned and immediate response reflecting out-of-control emotionality that satisfies immediate emotional pressures, albeit with negative consequences to the aggressor. In contrast, instrumental aggression is consciously planned, goal-oriented behavior with the specific intent of benefiting the aggressor (Jensen 2007).

IA is commonly associated with attention-deficit/hyperactivity disorder (ADHD) and is often refractory to primary ADHD therapy. In the Multimodal Treatment of Children with ADHD (MTA) study (MTA 1999), 54% of preadolescent study participants with ADHD Combined subtype displayed clinically significant aggression at baseline. Of these, 44% remained significantly symptomatic in terms of aggressive behavior after 14 months of optimal medication (stimulants) with/without behavioral therapy (Jensen 2007).

IA amplifies the psychological, academic, emotional, and social problems associated with ADHD (Shelton 1998), markedly increasing the risk of persistent behavioral problems, conduct disorder, encounters with the justice system, deficits in academic achievement, behavioral and disciplinary problems at school, and substance experimentation/abuse. Early-onset, pervasive and unremitting IA in the context of impulsive thoughts, emotional lability, and impulsive behavior is thought to represent a high-risk profile for progression from childhood ADHD to adult antisocial disorders (McKay 2001). In the context of ADHD it represents a serious clinical and public health concern and warrants effective and timely intervention.

Since primary ADHD therapy has limited effect on IA, a stepped-care approach has been recommended, with aggression-targeted therapy such as an antipsychotic added to ADHD therapy to manage residual aggressive behaviors (Scotto Rosato 2012). Risperidone and other "atypical" antipsychotics have historically been at the forefront of treatment recommendations regarding combination therapy for managing aggression associated with ADHD in children (Pappadopulos et al. 2003; Pliszka et al. 2006; Pliszka et al. 2007). However, only two double-blind randomized placebo-controlled trials of risperidone as adjunctive therapy in children with ADHD and aggression refractory to stimulants have been published – 1) a pilot study in 25 children that was likely underpowered and did not detect a significant treatment effect (Armenteros 2007; Aman 2014) and 2) the recently completed TOSCA (Treatment of

Severe Childhood Aggression) study (Farmer et al. 2011; Aman 2014; Gadow 2014). The effect size for risperidone's effect on IA was small (0.29), even though the dosage could be adjusted to optimal effect. The TOSCA study provides initial empirical evidence supporting a stepped-care approach in which ADHD children with severe aggression are initially treated with primary ADHD therapy followed by adjunctive antipsychotic therapy targeted to IA. However, the long-term effects of risperidone and similar antipsychotics in terms of metabolic derangements predictive of diabetes and cardiovascular disease, have become cause for considerable concern, especially in the face of very limited evidence of efficacy as aggression-targeted therapy in ADHD. The TOSCA study confirmed that stimulant co-therapy does not attenuate the adverse effects of risperidone or similar agents on body composition, metabolic parameters, prolactin, or sedation (Calarge 2009; Penzner 2009).

Molindone hydrochloride (molindone) is a medium potency antipsychotic, and is currently under development by the Sponsor as an extended-release formulation (SPN-810), for its potential utility in treating IA in children with ADHD.

In an open-label study, molindone improved aggressive behavior in children (N=6, 6-11 years of age) with undersocialized conduct disorder, aggressive type (Greenhill 1981). The optimum dose was 0.5 mg/kg/day. Molindone was also shown to be effective in treating aggressive behavior in a double-blind, 8-week, inpatient study of 31 children, ages 6 to 11, with undersocialized conduct disorder, aggressive type (Greenhill 1985).

Prior to its withdrawal from the US market for commercial reasons, Immediate-Release Molindone (Moban®) was approved for the treatment of schizophrenia in adults and adolescents. Its use was also evaluated in a pediatric population with early-onset schizophrenia and schizoaffective disorder when it was selected as the first-generation antipsychotic on the basis of its more favorable safety profile for comparison with second-generation agents (risperidone, olanzapine) in an NIH-sponsored study (TEOSS, Treatment of Early-Onset Schizophrenia Spectrum Disorders Study) (McClellan 2007). At an average dose of 60 mg/day (range, 10-140 mg/day), molindone was shown to be safe and well-tolerated (Sikich 2008). Molindone (10-140 mg/day) was not associated with significant increases in weight/BMI (in contrast to olanzapine). Molindone was also not associated with more dystonic or parkinsonian symptoms when given with benztropine, although akathisia was reported by more molindone-treated subjects. Results of randomized controlled trials such as TEOSS stimulated interest in the potential usefulness of molindone as a weight- and metabolically-neutral D2-receptor antagonist in children with ADHD and associated with IA.

1.2 **Sponsor's Phase 2a Study**

Study 810P201, was a proof-of-concept, multicenter, open-label, parallel-group, randomized, dose-ranging, safety, and tolerability study of molindone administered as experimental Molindone Immediate Release (IR) capsules in children with ADHD and persistent serious conduct problems (Stocks 2012). Target subjects were healthy male or female children aged 6 to 12 years, inclusive, with a diagnosis of ADHD accompanied by persistent serious conduct problems. A total of 78 subjects (19-20 per treatment group) in ten U.S sites were randomized. The primary objective was to evaluate the safety and tolerability of four weight-based dosages of Molindone IR dosed three times daily in children with ADHD

and persistent serious conduct problems (<30 kg: [redacted] day; ≥30 kg [redacted] mg/day). The secondary objectives were to 1) explore the relationship between molindone plasma concentration exposure and safety/tolerability endpoints and 2) assess the effect of Molindone IR after 6 weeks of maintenance treatment in reducing persistent serious conduct problems as measured by the Conduct Problem Subscale of the Nisonger Child Behavior Rating Form-Typical Intelligence Quotient (NCBRF-TIQ).

[redacted]

1.3 **Sponsor's Phase 2b Study**

Sponsor completed a Phase 2b multicenter, randomized, double-blind, placebo-controlled trial in the United States in pediatric subjects 6 to 12 years of age diagnosed with ADHD and IA that was not controlled by optimal stimulant and behavioral therapy (Sponsor Study 810P202). The primary objective of the study was to assess the effect of an extended-release tablet formulation of molindone hydrochloride (SPN-810) (12 to 54 mg/day) in reducing IA as measured by the Retrospective-Modified Overt Aggression Scale (R-MOAS) after at least three weeks of assigned treatment. Secondary endpoints included the rate of remission of IA and measurement of the effectiveness of SPN-810 on Clinical Global Impression (CGI) and ADHD scales as well as evaluation of the safety and tolerability of the drug. Patients who completed the study were offered the opportunity to continue into an open-label phase of six months duration.

SPN-810 dose within treatment groups was stratified by weight (below/above 20 kg). Both the medium (24/36 mg) and low (12/18 mg) dose groups showed statistically significant difference from the placebo group in the change from baseline to Visit 10 in R-MOAS but the high (36/54 mg) dose group was not significantly different from the placebo group. Furthermore, both the low dose and medium dose groups were significantly different from the high dose based on pair-wise comparison among the dose groups.

[redacted]

[redacted]

[redacted]

1.4 **Impulsive Aggression Diary (IA Diary)**

Sponsor has developed and validated a new measurement tool to assess behaviors associated with IA. The impulsive aggression diary (IA diary) is an electronic observer-reported outcome (eObsRO) instrument that comprises an episodic diary (to be reported as soon as possible after the parent or other guardian or observer witnesses the child's IA behavior) and an evening diary (to enable at a minimum, completion of the diary once each day). The IA diary monitors the frequency of occurrence of 15 IA behaviors: Yelling, Screaming, Threatening, Scratching, Throwing, Slamming, Hitting Self, Arguing, Cursing, Name Calling, Shoving, Hair Pulling, Fighting, Hitting Others, Kicking Others. The development process followed FDA's "Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims." Through this process, the IA diary was demonstrated to be a psychometrically valid and reliable tool to assess IA in children (Sponsor Study 810P501).

1.5 **Study Rationale**

The results of the Phase 2b study indicated that doses ranging from [redacted] were safe, effective and well tolerated. This Phase 3 study seeks to demonstrate the efficacy, safety, and tolerability of SPN-810 in the treatment of IA in patients with ADHD in conjunction with standard ADHD treatment. Study medication (SM) will be given as a divided dose twice daily (BID) with food. A randomized, placebo-controlled, double blind, multicenter, parallel group, fixed dose study design will be used. Frequency of IA behaviors will serve as a proxy for IA severity. The IA diary will be used to assess the frequency of IA behaviors. The IA diary was developed and validated for use as a contemporaneous, event-driven, observer-reported outcome measure. It monitors behaviors that have been specifically linked to IA. It does not rely on long periods of recall or subjective weighting of behaviors. For these reasons, the IA diary is uniquely suited to detect changes in the frequency IA behaviors, which in turn is indicative of the severity of IA.

Additionally, IA severity and improvement will be assessed using Clinical Global Impression (CGI) scales completed by both investigator and caregiver. Subject and caregiver quality of life will also be evaluated.

The effect of molindone on body composition, metabolic parameters, and prolactin will be evaluated. Emergence of extrapyramidal symptoms will be monitored.

2 STUDY OBJECTIVES

2.1 **Primary Objective**

The primary objective is to assess the efficacy and safety of SPN-810 in reducing the frequency of IA behaviors in pediatric patients with ADHD when taken in conjunction with standard ADHD treatment.

2.2 Secondary Objectives

The key secondary objective of the study is to assess the effect of SPN-810 on the Clinical Global Impression – Severity Scale (CGI-S).

Additional secondary objectives are to assess the following:

- the effect of SPN-810 on the Clinical Global Impression – Improvement Scale (CGI-I)
- the effect of SPN-810 on the child's overall health as measured by the Child Health Questionnaire Parent Form 28-item (CHQ-PF28)
- the effect of treating the child with SPN-810 on the parent-child relationship as measured by the Parenting Stress Index – Short Form version 4 (PSI-4-SF)
- the effect of SPN-810 on the caregiver-completed CGI-I
- the effect of SPN-810 on inattention and hyperactivity-impulsivity measured by the SNAP-IV Rating Scale
- the effect of SPN-810 on the responder rate (defined as ≥ 50% in the reduction of the frequency of IA behaviors)
- the effect of SPN-810 on the responder rate (defined as ≥ 30 %in the reduction of the frequency of IA behaviors)

2.3 Tertiary Objective

[redacted]

3 INVESTIGATIONAL PLAN

3.1 Rationale for Study Design, Including Choice of Treatment Groups, Appropriateness of Measurements

The present study is designed to evaluate the efficacy, safety, and tolerability of SPN-810 in patients aged 6 to 12 years with ADHD associated with IA, when taken in conjunction with a standard ADHD treatment. In this patient population, IA behaviors persist, despite monotherapy treatment with an FDA-approved ADHD medication, stimulant or non-stimulant, at an FDA-approved optimized dose.

A titration schedule will be followed to ensure a safe escalation to each dose level. The titration rate and dose range under investigation in the present study were demonstrated to be safe, efficacious, and well tolerated in a similar patient population in the previous Phase 2b study. Administration of study medication will be recorded using an electronic dosing diary.

The IA diary will serve as the primary assessment tool for efficacy. The IA diary is a new electronic observer-reported outcome (eObsRO) instrument developed by the Sponsor to record behaviors associated with IA. Secondary measures of efficacy will include the effect of SPN-810 on the Clinical Global Impression – Improvement Scale (CGI-I), the effect of SPN-810 on the Clinical Global Impression –

Severity Scale (CGI-S), the effect of SPN-810 on the child's overall health as measured by the Child Health Questionnaire Parent Form 28-item (CHQ-PF28), and the effect of treating the child with SPN-810 on the parent-child relationship as measured by the Parenting Stress Index – Short Form (PSI-4-SF). The child's ADHD symptoms will be measured using the Swanson, Nolan and Pelham Rating Scale - Revised (SNAP-IV).

Safety will be assessed by the monitoring of AEs, concomitant medications, vital signs, clinical laboratory tests, physical examinations, and ECGs, as well as by the Simpson-Angus Scale, the Barnes Akathisia Scale, and the Abnormal Involuntary Movement Scale (AIMS). The scales were chosen to specifically monitor EPS, since youth treated with antipsychotics are at greater risk for EPS side effects than adults (Findling 2005). These scales were utilized in Phase 2 studies and have been used in other clinical studies of atypical antipsychotics in children.

3.2 Overall Study Design and Plan

Protocol 810P301 is a randomized, placebo-controlled, double blind, multicenter, parallel group, fixed dose study to demonstrate the efficacy, safety, and tolerability of SPN-810 in the treatment of IA in patients aged 6-12 years with ADHD in conjunction with standard ADHD treatment. The study is presented schematically in Figure 1 and Figure 2. The study is divided into three phases: Pre-Treatment, Treatment, and Conversion/Taper.

Following screening, eligible subjects will enter a flexible baseline period, at which time the IA diary will be issued to the subject's primary caregiver. At the end of the baseline period, per the original plan, eligible subjects whose primary caregiver has maintained at least 80% compliance with the IA diary will be randomized to 1:1:1 to 18 mg/day SPN-810, 36 mg/day SPN-810, or placebo. However, based on the 810P301 study Interim Analysis result decision, the 18 mg arm was dropped partway through the study. As a result, subjects planned to be randomized to the 18 mg arm will be re-allocated to the 36 mg or placebo arm in a ratio of 2:1. A dose titration schedule will be followed, with dosing in the active treatment groups initiated at 3 mg/day and increased approximately every 3 days until the target dose is reached. After completing the two-week titration period and the three-week maintenance period, subjects will enter the conversion or tapering phase prior to discontinuing SM, at which time subjects will have the option to enter an open label extension (OLE) study. A subject who discontinues during the maintenance period prior to Visit 6 may be allowed to participate in the OLE on a case-by-case basis only after consultation between the Investigator, the Medical Monitor and the Sponsor. The OLE study will be conducted under a separate protocol. Subjects who choose to participate in the OLE will enter that study at a dose of 18 mg/day SPN-810.

3.2.1 Pre-Treatment Phase

3.2.1.1 Screening Period

Screening will take place for up to 45 days prior to randomization and may be carried out over more than one visit if necessary. Prior to conducting any screening procedures, written informed consent/assent must be obtained from the parent or legal representative, and subject (when required). Each screened subject will be assigned a subject number starting from 2001 to 2999 in a sequential

manner. Staff at study sites are encouraged to complete screening procedures as early as possible to provide more flexibility in the baseline period for the caregivers to achieve IA diary compliance (see Section 3.2.1.2).

The R-MOAS and CGI-S will be administered to determine entry to the baseline period of the study and also to determine eligibility for randomization to treatment. The Vitiello Aggression Scale will be used to evaluate subtype of aggression (planned vs. impulsive); only those children who score as predominantly impulsive will be included. The diagnosis of ADHD will be confirmed with the Schedule for Affective Disorders and Schizophrenia for School-aged Children—Present and Lifetime Versions 2013 (K-SADS-PL 2013). The K-SADS-PL 2013 is a semi-structured diagnostic interview designed to diagnose current and past episodes of psychopathology in children and adolescents according to DSM-5 criteria. The Introductory and Screen Interviews will be completed. The Screen Interview will assess the different diagnoses and determine which supplements should be completed. Supplement 4 (Neurodevelopment, Disruptive and Conduct Disorders) must be completed to assess ADHD, ODD, CD, Tic and ASD (Autism Spectrum Disorder). If an exclusionary diagnosis is confirmed, the remainder of the diagnostic will not be completed and the subject will be deemed a screen failure.

3.2.1.2 Baseline Period

Subjects who meet study entry requirements will proceed to the flexible 15-day baseline period. At Visit 2, an IA diary device (LogPad) will be issued to the primary caregiver. The primary and (if assigned) secondary caregivers will receive training on the use of the IA diary. Every effort will be made to provide adequate caregiver training on the use of the IA diary at Visit 2 and acknowledgement of training will be captured on the device.

Following at least 15 days of IA diary use, caregiver compliance with the IA diary will be assessed. Compliance will be calculated as the percentage of days over the past 15 days during the baseline period for which an evening diary was completed. Subjects whose caregivers demonstrate at least 80% compliance will be eligible for randomization and continue into the titration period.

Subjects whose caregivers do not reach 80% compliance during the first 15 days of the baseline period may be allowed to continue to use the diary for up to 15 additional days. For these subjects, caregivers will receive remedial training on the use of the IA diary. During this time, caregiver compliance with the IA diary will be monitored daily by study site personnel over the past 15-days as a "rolling window". When the caregivers' performance with the IA diary improves such that the caregivers are able to demonstrate at least 80% compliance over the past 15-day rolling window, the subject will be eligible for randomization and allowed to continue into the titration period.

Although there are up to 30 days available for each of the screening and the baseline period, the total duration of screening and baseline periods may not exceed 45 days.

<u>Rescreening</u>

As a general rule, rescreening of subjects is not allowed. The only exception to this will be for subjects who failed screening due to caregiver non-compliance with the IA diary under protocol version 3.0.

These subjects may be rescreened to participate in the study under current protocol. These subjects will be assigned a new subject ID number and will complete all study screening procedures.

3.2.2 Treatment Phase

3.2.2.1 Randomization

Inclusion/exclusion criteria will be re-assessed to verify eligibility prior to study randomization at the end of Visit 3 (Randomization). Eligible subjects whose primary caregiver has maintained at least 80% compliance with the IA diary will be randomized. Per the original randomization eligible subjects who complete the baseline period and meet the requirements for the double blind study will be randomized at Visit 3 (Day 1) in a 1:1:1 ratio to receive 18 mg/day, 36 mg/day SPN-810 or placebo and proceed to the titration period, which will be two weeks. However, based on the 810P301 study Interim Analysis result decision, the 18 mg arm was dropped partway through the study. As a result, subjects planned to be randomized to the 18 mg arm will be re-allocated to the 36 mg or placebo arm in a ratio of 2:1.

3.2.2.2 Titration Period

Subjects will be titrated to maintenance dose over a period of 2 weeks.

3.2.2.3 Maintenance Period

Following dose titration, subjects on active treatment will be maintained at their designated dose level for 3 weeks.

3.2.3 Conversion/Taper Phase

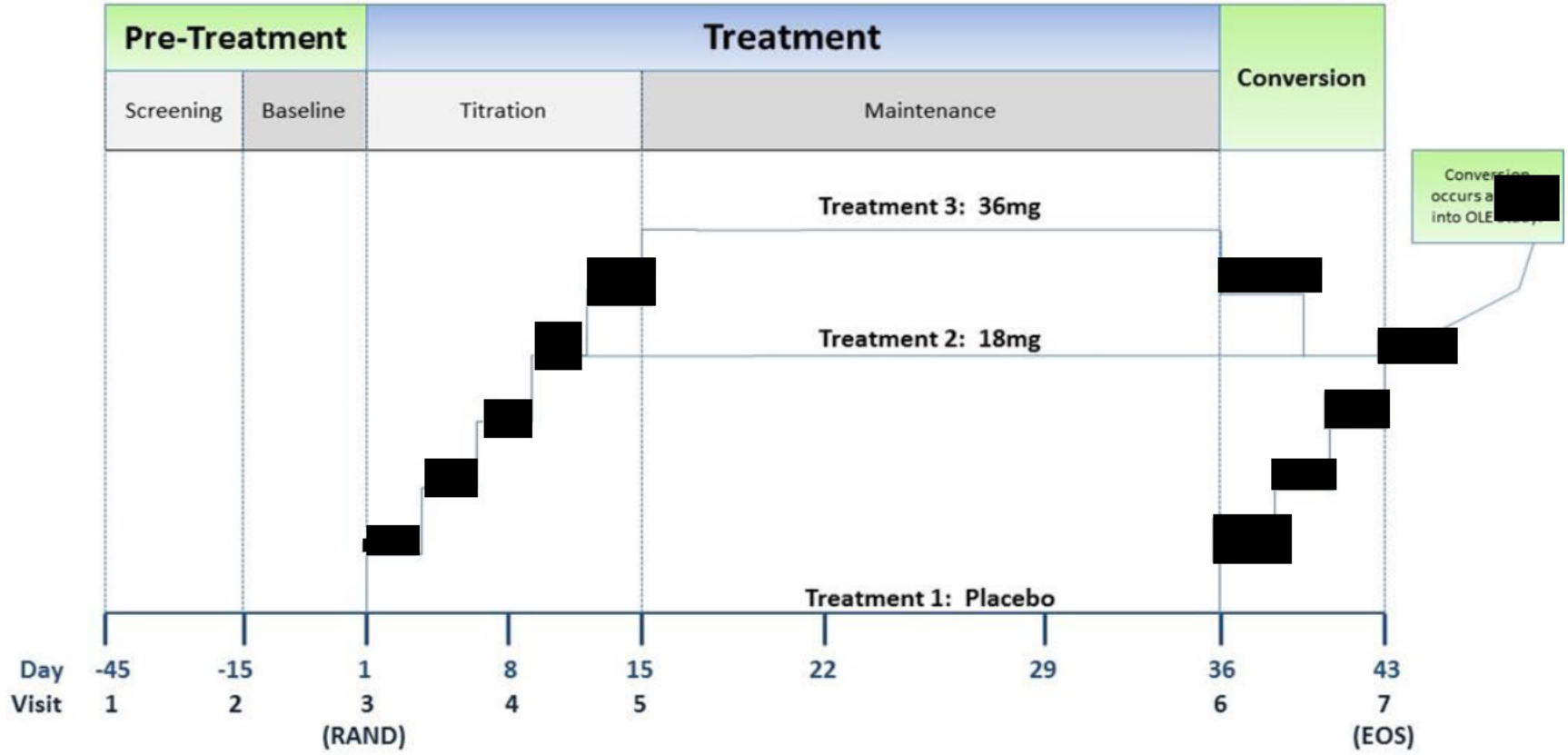
All subjects who complete the randomized, double blind portion of study 810P302 will have the option to participate in an OLE study (study protocol 810P304) in which all subjects will receive active SM treatment. Subjects choosing to participate will receive blinded conversion medication kits, and their total daily dose for the open label extension will be converted to 18 mg/day (Figure 1). Those subjects who do not elect to participate in this extension will be tapered off SM (Figure 2).

The 18 mg line in the 2 figures below will not be applicable to subjects re-randomized following the 810P301 interim analysis decision to drop the 18 mg dose.

3.2.4 End of Study / Early Termination

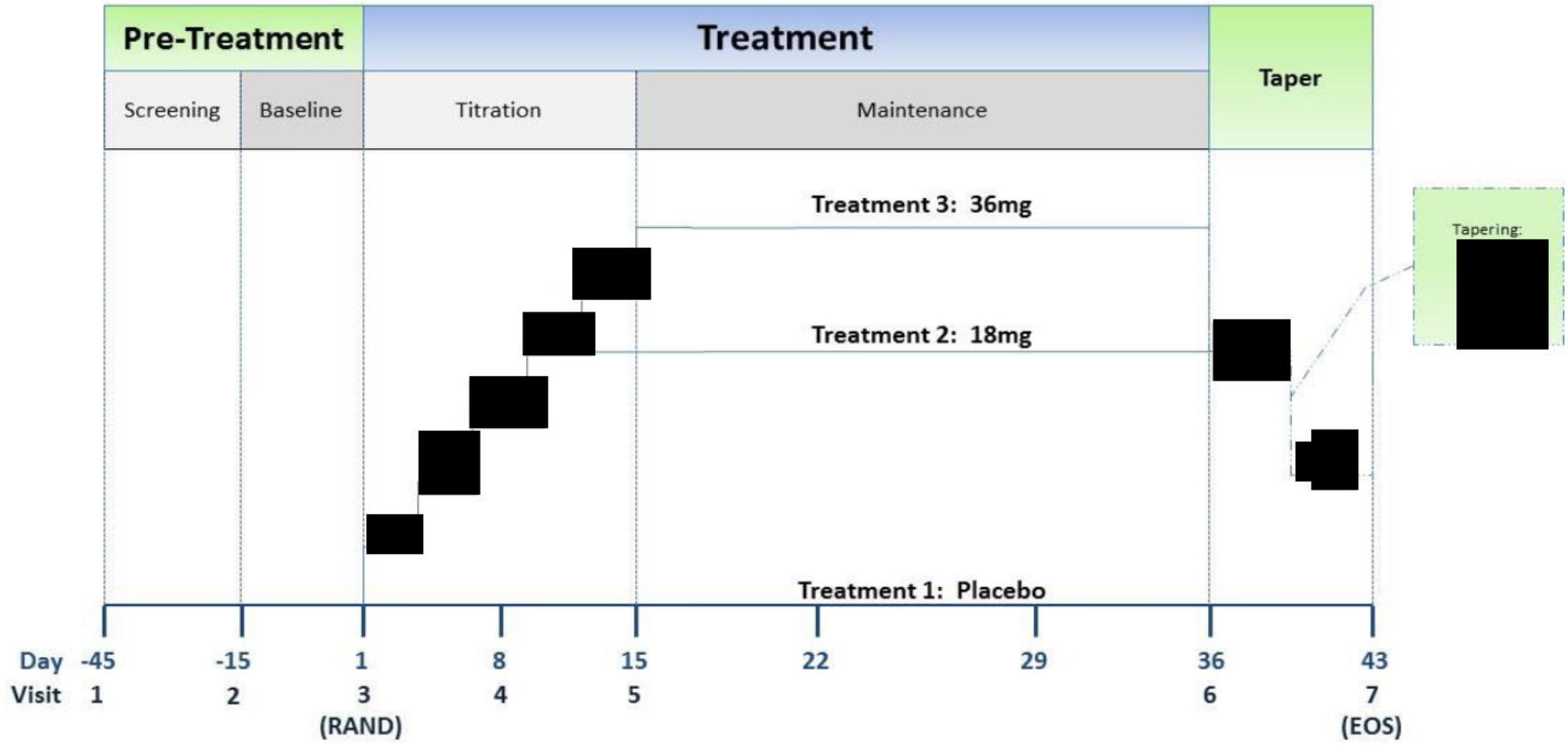
Subjects will return to the study site for a final visit, after completing the 1-week Taper/Conversion Period. Those subjects who elect to continue in the OLE study will have procedures performed for that study as well. Subject who discontinues from the study during the maintenance period will be offered a Taper kit and will return to the study site for a follow-up visit (EOS). Subjects who discontinue during the titration period will not receive a taper kit and will only complete the EOS procedures.

Figure 1: Treatment Schedule (Conversion)



NOTE: Based on the 810P301 study Interim Analysis result decision, the 18 mg dose arm was dropped partway through the study.

Figure 2: Treatment Schedule (Taper)



NOTE: Based on the 810P301 study Interim Analysis result decision, the 18 mg dose arm was dropped partway through the study.

4 STUDY METHODS

4.1 Selection of Study Population

The target population will be male and female subjects aged 6 to 12 years with IA and ADHD. SM will be administered in conjunction with the subject's standard ADHD treatment. Approximately 306 subjects will be randomized in this clinical investigation.

4.1.1 Inclusion Criteria

1. Healthy male or female subjects, age 6 to 12 years at the time of screening.
2. Diagnosis of ADHD according to the Diagnostic and Statistical Manual of Mental Disorders- 5 (DSM-5 confirmed by the Schedule for Affective Disorders and Schizophrenia for School-aged Children – Present and Lifetime Version 2013 (K-SADS-PL 2013).
3. Retrospective Modified Overt Aggression Scale (R-MOAS) score of $\geq$24 at screening.
4. CGI-S score of at least moderately ill at both Screening and Randomization.
5. Vitiello Aggression Scale score from -2 to -5 at Screening.
6. Free of antipsychotic medication for at least two weeks prior to Visit 2.
7. Monotherapy treatment with FDA-approved optimized ADHD medication (psychostimulant or non-stimulant) at an FDA-approved dose for at least one month prior to Screening, and willing to maintain that dose throughout the Baseline and Treatment period.
8. α 2- adrenergic agonists (e.g. clonidine and guanfacine) used for any other reason except for monotherapy treatment for ADHD (e.g. aggression or insomnia) must be discontinued at least two-weeks prior to Visit 2.
9. Medically healthy and with clinically normal laboratory profiles, vital signs, and electrocardiograms (ECGs).
10. Weight of at least 20 kg.
11. Able and willing to swallow tablets whole and not chewed, cut or crushed.
12. Written Informed Consent obtained from the subject's parent or legal representative, and written Informed Assent obtained from the subject if appropriate.
13. Measurement of compliance ≥ 80% for completion of IA Diary during Baseline Period.

4.1.2 Exclusion Criteria

1. Body Mass Index (BMI) in 99th percentile or above.
2. Current or lifetime diagnosis of epilepsy, major depressive disorder, bipolar disorder, schizophrenia or related disorder, personality disorder, Tourette's disorder, or psychosis not otherwise specified.
3. Currently meeting DSM-5 criteria for autism spectrum disorder, pervasive developmental disorder, obsessive compulsive disorder, post-traumatic stress disorder, or any other anxiety disorder as primary diagnosis.
4. Use of anticonvulsants including carbamazepine and valproic acid, antidepressants, mood stabilizers including lithium, benzodiazepines, cholinesterase inhibitors or any drug known to inhibit CYP2D6 activity within two weeks of Visit 2.

5. Use of herbal supplements within one week of Visit 2.
6. Known or suspected intelligence quotient (IQ) < 70.
7. Unstable endocrinological or neurological conditions which confound the diagnosis or are a contraindication to treatment with antipsychotics.
8. Suicidality, defined as either active suicidal plan/intent or active suicidal thoughts in the six months before the Screening Visit or more than one lifetime suicide attempt.
9. Pregnancy or refusal to practice contraception during the study (for female subjects of childbearing potential).
10. Substance or alcohol use during the last three months.
11. Urine drug test at screening that is positive for alcohol or drugs of abuse.
12. Known allergy or sensitivity to molindone hydrochloride.
13. Any reason which, in the opinion of the Investigator or the Sponsor, would prevent the subject and subject's caregiver from participating in the study or complying with the study procedures.
14. Use of an investigational drug or participation in an investigational study within 30 days prior to Visit 2.

4.2 Schedule of Visits and Procedures

All subjects who are randomized and take any SM will be followed according to the protocol regardless of the number of doses of SM taken, unless consent for follow-up is withdrawn. The Sponsor, or the Sponsor's designee, must be notified of all deviations from the protocol visits or procedures, and these procedures, if applicable, will be rescheduled or performed at the nearest possible time to the original schedule. Subjects will be instructed to call study personnel to report any abnormalities during the intervals in between study visits and to come to the study site if medical evaluation is needed and as the urgency of the situation indicates. Unscheduled visits may be conducted at the discretion of the investigator throughout all study periods. The medical monitor must be contacted promptly in the event that any clinically significant findings or information are obtained during the unscheduled visit. This should be captured in the appropriate eCRF. For emergency and other unscheduled visits to a medical facility other than the study site, medical records will be obtained by the Investigator or qualified designee as source data for study follow-up.

Table 1 presents the schedule of visits and procedures for the study.

Table 1: Schedule of Visits and Procedures

Phase	**Pre-treatment**		**Treatment**				**Conversion/ Taper**
Period	**Screening**	**Baseline**	**Titration**		**Maintenance**		
VISIT NUMBER	**1**	**2**	**3**	**4**	**5**	**6**	**7**
DAY	**-45**	**-15**	**1**	**8**	**15**	**36**	**43**
WINDOW (DAYS)	**≤45d prior to Visit 3**	**≥15d prior to Visit 3**	**O[c]**	**7d±2d from Visit 3**	**14d±2d from Visit 3**	**21d±3d from Visit 5**	**7d±1d from Visit 6**
Informed Consent/Assent [a]	X [b]						
R-MOAS, K-SADS-PL 2013 & Vitiello Aggression Scale	X						
Medical History	X		X [d]				
Demographics	X						
Physical Examination	X					X	
ECG (12-lead)	X			X		X	
Inclusion/Exclusion Criteria	X						
Randomization			X [b,e]				
Urine Drug Screen	X		X				
Urine Pregnancy Test [f]	X		X				X
Diary Training & Distribution or Evaluation		X	X [e]	X	X	X	
Vital Signs[g]	X						X
Weight, height, BMI	X		X	X	X	X	X
Hematology/chemistry/Urinalysis	X		X			X	X
PK Blood Sampling				X [h]	X [h]		
Columbia Suicide Severity Rating Scale (CSSRS)	X		X	X	X	X	X
Investigator CGI-S	X		X	X	X	X	
Caregiver and investigator CGI-I				X	X	X	
Efficacy scales (SNAP-IV, CHQ-PF28, PSI-4-SF)			X			X	
Safety Scales (Simpson-Angus, Barnes, AIMS)			X	X	X	X	X
Infrequent Behaviors Checklist			X	X	X	X	
Adverse Events			X	X	X	X	X
Concomitant Medications	X	X	X	X	X	X	X
Drug Dispensation			X [b]		X	X	

Phase	**Pre-treatment**		**Treatment**				**Conversion/ Taper**
Period	**Screening**	**Baseline**	**Titration**		**Maintenance**		
VISIT NUMBER	**1**	**2**	**3**	**4**	**5**	**6**	**7**
DAY	**-45**	**-15**	**1**	**8**	**15**	**36**	**43**
WINDOW (DAYS)	**≤45d prior to Visit 3**	**≥15d prior to Visit 3**	**O[c]**	**7d±2d from Visit 3**	**14d±2d from Visit 3**	**21d±3d from Visit 5**	**7d±1d from Visit 6**
Drug Return and Compliance					X	X	X
Diary Return							X

a Written consent must be obtained prior to performing any study-related procedure.
b Access IWRS.
c Visit 3 will occur at least 15 days following Visit 2
d Assess for any clinically significant change in Medical History since screening
e Diary compliance must be at least 80% (minimum of 12 days out of 15) to qualify for randomization
f To be performed for female subjects of childbearing potential prior to administration of first dose of SM and will have to be tested as negative for the subject to continue in the study.
g Heart rate (HR), blood pressure, temperature, and respiratory rate will be measured.
h Total of 5 PK blood samples will be obtained over one or two visits (Visit 4 and/or Visit 5).

4.2.1 Visit 1

Prior to conducting any screening procedures, written Informed Consent must be obtained from the parent or legal representative, and, if appropriate, Informed Assent from the subject. Subject screening procedures will be performed within 45 days prior to Visit 3 and may be done on more than one day. Abnormal results on screening laboratory tests may be repeated at the discretion of the Investigator.

The following procedures will be performed at Visit 1:

1. Obtain written informed consent and assent.
2. Obtain demographic information, medical history
3. Access Interactive Web Response System (IWRS) for subject number
4. Administer K-SADS-PL 2013 for confirmation of ADHD diagnosis
5. Administer Vitiello Aggression Scale
6. Administer R-MOAS
7. Administer Investigator CGI-S
8. Perform physical examination
9. Record vital signs (HR, BP, temperature, and RR), height, weight and BMI
10. Perform 12-lead ECG
11. Collect blood samples for hematology and chemistry
12. Administer C-SSRS
13. Collect urine sample for urinalysis and urine drug screen (all subjects), and pregnancy test (FOCBP only)
14. Assess and record concomitant medications
15. Assess inclusion/exclusion criteria

4.2.2 Visit 2

Visit 2 will occur at least 15 days prior to Visit 3. Please note that, per protocol and within the EDC, Visit 1 and Visit 2 may occur on the same day.

1. Provide training for IA diary and dosing diary module
2. Distribute device
3. Assess and record concomitant medications

4.2.3 Visit 3

Visit 3 will occur at least 15 days following Visit 2 according to the Schedule of Visits and Procedures.

1. Administer efficacy scales (SNAP-IV, CHQ-PF28, PSI-4-SF)
2. Assess IA diary compliance / review training as necessary
3. Confirm eligibility to randomize to study medication treatment
4. Randomize subject via IWRS
5. Administer Investigator CGI-S
6. Administer Infrequent Behaviors Checklist
7. Administer safety scales (Simpson-Angus, Barnes Akathisia, AIMS)

8. Record height, weight, and BMI
9. Collect blood samples for hematology/chemistry
10. Collect urine samples for urinalysis, urine drug screen (all subjects), and pregnancy test (FOCBP only)
11. Administer C-SSRS
12. Record concomitant medication
13. Assess for any clinically significant change in Medical History
14. Dispense SM via IWRS.
15. Review training on dosing diary module
16. Assess adverse events (post-dose)

4.2.4 Visit 4

Visit 4 will occur 7 (±2) days following Visit 3 according to the Schedule of Visits and Procedures.

1. Administer Investigator CGI-S
2. Administer caregiver and investigator-completed CGI-I
3. Administer Infrequent Behaviors Checklist
4. Administer safety scales (Simpson-Angus, Barnes Akathisia, AIMS)
5. Record height, weight, and BMI
6. Perform 12-lead ECG
7. Collect blood samples for PK analysis
8. Administer C-SSRS
9. Record concomitant medication
10. Review IA diary compliance and provide training as required
11. Collect AEs
12. Review dosing diary compliance and provide training as required

4.2.5 Visit 5

Visit 5 will occur 14 (±2) days following Visit 3 according to the Schedule of Visits and Procedures.

1. Administer Investigator CGI-S
2. Administer caregiver and investigator-completed CGI-I
3. Administer Infrequent Behaviors Checklist
4. Administer safety scales (Simpson-Angus, Barnes Akathisia, AIMS)
5. Record height, weight, and BMI
6. Collect blood samples for PK analysis
7. Administer C-SSRS
8. Record concomitant medication
9. Review IA diary compliance and provide training as required
10. Collect AEs
11. Collect returned SM; assess treatment compliance
12. Review dosing diary compliance and provide training as required
13. Dispense SM

4.2.6 Visit 6

Visit 6 will occur 21 (±3) days following Visit 5 according to the Schedule of Visits and Procedures.

1. Administer efficacy scales (Investigator CGI-S, caregiver and investigator CGI-I, SNAP-IV, CHQ-PF28, PSI-4-SF)
2. Administer Infrequent Behaviors Checklist
3. Administer safety scales (Simpson-Angus, Barnes Akathisia, AIMS)
4. Record height, weight, and BMI
5. Perform 12-lead ECG
6. Perform physical examination
7. Collect blood samples for hematology/chemistry
8. Collect urine sample for urinalysis
9. Administer C-SSRS
10. Record concomitant medication
11. Review IA diary compliance and provide training as required
12. Collect AEs
13. Collect returned SM; assess treatment compliance
14. Review dosing diary compliance and provide training as required
15. Determine whether subject wishes to participate in open-label extension
16. Dispense SM (either Conversion or Taper based upon subject's decision about participation in open-label extension)

4.2.7 Visit 7

Visit 7 will occur 7 (±1) days following Visit 6 according to the Schedule of Visits and Procedures. These procedures will also be performed for patients who discontinue early. Patients who discontinue early after Visit 5 will be offered a taper kit.

1. Administer safety scales (Simpson-Angus, Barnes Akathisia, AIMS)
2. Record vital signs (HR, BP, temperature, and RR), height, weight and BMI
3. Collect urine sample for pregnancy test (FOCBP only)
4. Administer C-SSRS
5. Record concomitant medication
6. Collect AEs
7. Collect SM and assess treatment compliance
8. Collect device
9. Complete/discontinue subject
10. Collect blood samples for hematology/chemistry
11. Collect urine sample for urinalysis

4.2.8 Pharmacokinetic Sample Collection

All blood samples for PK analysis will be drawn at the clinical site. A total of 5 blood samples (4 mL each) will be taken for PK analysis over the course of the study. These will include pre- and post-dose samples obtained over one visit (Visit 4 or Visit 5) or can be obtained over two visits (Visit 4 and Visit 5).

If the subject decides to complete the PK sampling over one visit then he/she will arrive at the clinic in the morning prior to taking the morning dose. A PK sample will be drawn pre-dose; then the dose will be observed in the clinic. Post-dose PK samples will be taken at approximately 1 hour, 2 hours, 4 hours and 6 hours after the time of the observed dose. PK samples should be obtained within 15 minutes of the 1 hour and 2 hour timepoints and within 30 minutes of the 4 hour and 6 hour timepoints.

If the subject decides to come for the PK sampling over two visits, then on one visit the subject will arrive at the clinic in the morning, prior to taking their morning dose. A PK sample will be drawn pre-dose; then the dose will be observed in the clinic. Post-dose PK samples will be taken at approximately 1 hour and 2 hours after the time of the observed dose. PK samples should be obtained within 15 minutes of the targeted timepoints. At the other visit, subjects will arrive at the clinic after taking their morning dose. PK samples will be taken at approximately 4 hours and 6 hours after the time that the morning dose was taken. PK samples should be obtained within 30 minutes of the targeted timepoints.

Blood samples will be collected and processed as per instructions in the Laboratory Manual.

4.3 **Treatments**

4.3.1 Treatments Administered

Subjects will take molindone hydrochloride extended-release tablet (SPN-810) or placebo twice each day (BID) with food, in the morning and in the evening, in addition to the stable dose of the optimized ADHD medication determined from the lead-in period. If initiating treatment before noon, patients should start with the morning dose; if after noon, the evening dose.

Subjects will be randomized to one of three treatments at Visit 3**.** Subjects will be titrated up to the final randomized total daily dose (TDD).

- Reference treatment
  - Treatment 1: Placebo tablets, PO, BID
- Test treatments
  - Treatment 2: Molindone extended-release tablets, 18 mg TDD, PO, BID
  - Treatment 3: Molindone extended-release tablets, 36 mg TDD, PO, BID

Based on the 810P301 study Interim Analysis result decision, the 18 mg dose arm was dropped partway through the study.

4.3.2 Identity of Investigational Product(s)

Test and reference (matching placebo) products are either purple (3mg) or yellow (9mg) round tablets printed on one side with the tablet dose strength (“3” or “9”) that will be supplied in labeled blister cards by the Sponsor. The Sponsor will package the SM in a double-blind configuration.

Each SM blister card will contain combinations of molindone extended-release and/or placebo tablets, which will supply a subject with 6 (six) to 8 (eight) days of dosing as well as some extras for lost product and/or to account for visit delays associated with patient/site schedules. The SM blister card types

include: Titration (two blister cards), Maintenance (three blister cards), Taper (one blister card), and Conversion (one blister card).

A single SM kit contains a total of 7 pre-packaged blister cards (two Titration blister cards, three Maintenance blister cards, one Tapering blister card and one Conversion blister card) and is marked with a unique 4-digit SM kit number.

4.3.3 Study Medication Handling and Accountability

All SM will be supplied to the Investigator by the Sponsor. SM supplies must be kept in an appropriate secure area (e.g., locked cabinet) and stored according to the conditions specified on the SM labels. SM must be stored between 59°F – 86°F (15°C – 30°C).

Following Sponsor instructions and in compliance with ICH E6 as well as local, state, and federal regulations, the Investigator and study staff will be responsible for the accountability of all clinical supplies (receiving, shipment, dispensing, inventory, and record keeping) in a SM accountability log, a copy of which will be collected by the Sponsor at the end of the study.

Under no circumstances will the Investigator allow the SM to be used other than as directed by this protocol. Clinical supplies will not be dispensed to any individual who is not randomized into the study.

An accurate and timely record of the receipt of all clinical supplies; dispensing of SM to the subject; collection of unused supplies returned by the subject; and subsequent return of unused SM to the Sponsor must be maintained with dates. This SM accountability log includes, but may not be limited to: (a) documentation of receipt of clinical supplies, (b) SM inventory log, (c) SM accountability log, and (d) all shipping service receipts. All forms will be provided by the Sponsor. Any comparable forms that the study site wishes to use must be approved by the Sponsor.

The supplies and inventory records must be made available, upon request, for inspection by the designated representative of the Sponsor, a representative of the FDA, or a representative of a non-US health authority. The assigned Clinical Research Associate (CRA) will review these documents along with all other study conduct documents at each and every visit to the study site once SM has been received by the study site. All used, partly used, and unused clinical supplies, including empty containers, are to be returned to the Investigator by the subject and ultimately to the Sponsor at the conclusion of the study, unless provision is made by the Sponsor for destruction of supplies and containers at the study site. Upon completion of SM accountability and reconciliation procedures by study site personnel and documentation procedures by Sponsor personnel, SM is to be returned to the Sponsor with a copy of the completed SM disposition form as outlined in the Study Medication Manual.

4.3.4 Method of Assigning Subjects to Treatment Groups

Allocation of study drug will be completed centrally through the use of an interactive web response system (IWRS) that will determine which kit to assign to the subject. The randomization schedules will be created by a designated unmasked statistician using SAS (SAS Institute, Cary, North Carolina, Version 9.2 or higher). Separate schedules for subject randomization and drug list will be created. The original randomization scheme assigns treatment to each randomization number in a 1:1:1. However, based on

the 810P301 study Interim Analysis result decision, the 18 mg arm was dropped partway through the study. As a result, subjects planned to be randomized to the 18 mg arm will be re-allocated to the 36 mg or placebo arm in a ratio of 2:1.

Upon admission to the study, subjects will be assigned site (01-99) and subject numbers (2001-2999), in the sequence that they are entered. Subjects who complete the Baseline Period and continue to meet all eligibility criteria will be assigned kit numbers, according to the randomization schedule, by using the IWRS.

4.3.5 Treatment Replacement

In the event that a subject's original kit is lost, damaged, or consumed prior to the end of treatment, the Investigator will use the IWRS which will specify a new Kit Number to be dispensed to that subject from the supplies already available at the site. Separate reserve supplies will not be provided to the Investigators.

4.3.6 Dosing Schedule

During Visit 3, subjects will be randomized to Treatments 1 , 2, or 3 and start dosing. Table 2 below presents the details of the dosing schedule for each active treatment group throughout the 6-week treatment phase for this study. Dose reduction will not be permitted in the study.

Table 2: Dosing Schedule (Total Daily Dose)

Treatment Arm	Final Dose	Study Days					
		1-2	3-5	6-8	9-11	12-14	15+
	Period*	T	T	T	T	T	M
1	Placebo	PBO	PBO	PBO	PBO	PBO	PBO
2	18 mg	[redacted]					
3	36 mg	[redacted]					

** T = titration period; M = maintenance period; PBO= Placebo*

The 18 mg dose (Treatment 2) arm was dropped partway through the study as described in section 4.3.4.

4.3.7 Method of Administration

The SM must be swallowed whole. SM must not be crushed, chewed or cut. The SM must be taken with food in the morning and in the evening, preferably within 12 hours.

4.3.8 Blinding

The subject and all personnel involved with the conduct and the interpretation of the study, including the Investigators, study site personnel, and the Sponsor and CRO clinical staff, will be blinded to the medication codes. A limited number of Supernus personnel will perform and interpret the plasma assays for the population PK analysis and will be aware of these plasma data during the study. These personnel will not have access to the randomization schedule, are not associated with the clinical conduct of the study, and will not reveal to any clinical personnel involved in the study the treatment to

which a subject is assigned. Randomization schedule data will be kept strictly confidential, filed securely by the IWRS vendor, and accessible only to authorized persons until the time of unblinding.

The test tablets have matching placebo tablets. The blind is maintained primarily through the IWRS. The blind will be maintained through the end of the Conversion/Taper period.

The Investigator must try to avoid breaking the blind. The decoding information will not be viewed unless an actual medical or medication safety emergency occurs. The Investigator can access the subject's randomized treatment information via IWRS only if knowledge of the treatment regimen will influence or assist with medical management of the subject in an acute emergency. Before breaking the blind, every effort must be made to contact the Medical Monitor to ascertain the necessity of breaking the code. If the Investigator is unsuccessful in contacting the Medical Monitor, he/she will contact the backup Medical Monitor (or other appropriate designee if the backup Medical Monitor is unavailable). If it is not possible to contact the Medical Monitor or the backup Medical Monitor (or designee), and the situation is an emergency, the Investigator may break the blind and contact the Medical Monitor as soon as possible. The Investigator is to make a careful note of the date and time of decoding, the reason that necessitated breaking the code, and the signature of the person who broke the code. Upon breaking the randomization code, the subject should be withdrawn from the study but should be followed up for safety purposes.

4.4 **Prohibited Medications:**

Subjects may not be on any prohibited medication while on study as indicated in the Inclusion/Exclusion Criteria. These medications include:

- α 2- adrenergic agonists (e.g. clonidine and guanfacine) used for any other reason except for monotherapy treatment for ADHD
- Anti-psychotics including aripiprazole, risperidone, quetiapine, and ziprasidone
- Anticonvulsants including carbamazepine and valproic acid, antidepressants, mood stabilizers including lithium, benzodiazepines, cholinesterase inhibitors or any drug known to inhibit CYP2D6 activity
- Herbal supplements

4.5 **Concomitant Medication**

The dose of the ongoing ADHD medication will not be adjusted during the study, starting at Visit 1. No additional concomitant medications are allowed during the study, with the following exceptions:

- Chronic medication for conditions not related to ADHD or IA that are allowed by Investigator at Screening
- Nutritional supplements (e.g. multivitamins, fish oil)
- Emla or other numbing cream for PK venipuncture
- Benztropine is permitted for the treatment of emerging EPS at a starting dose of 0.5mg BID up to a range of 1 to 4mg/day. Lorazepam (1 to 2 mg per dose not to exceed three times daily) and

clonazepam (0.25 to 1 mg per dose not to exceed twice daily) will also be permitted to treat emerging EPS.

- Common over-the-counter (OTC) therapies for minor transient ailments (e.g. acetaminophen for headache, ibuprofen for fever) will be allowed without exception.
- Treatment for AEs other than EPS or minor transient ailments is only permitted in consultation with the Medical Monitor.

All concomitant medications will be recorded in the eCRF.

4.6 Completion of Study and Discontinuation of Subjects

Subjects will be considered to have completed the study if they complete all visits up to and including Visit 6. All subjects who discontinue early will complete Visit 7. Any subject who discontinues from the study after Visit 5 will be offered a Taper kit.

The Investigator(s) or subjects themselves may stop SM treatment at any time for safety or personal reasons. A subject is free to withdraw from the study at any time for any reason without prejudice to their future medical care by the physician or at the institution. The Investigator or Sponsor may also withdraw the subject at any time in the interest of subject safety. The withdrawal of a subject from the study should be discussed where possible with the Medical Monitor and/or CRA before the subject stops SM. Subjects removed from the study for any reason will not be replaced.

Reasons for withdrawal may include but are not limited to subject withdrawal of consent, occurrence of unmanageable AEs, or if it is in the best interest of the subject as per Investigator's discretion.

The primary reason for withdrawal must be recorded in the subject's medical record and on the eCRF. If a subject is withdrawn for more than one reason, each reason should be documented in the source document and the most medically significant reason should be entered on the eCRF.

5 ANALYSIS VARIABLES

5.1 Primary Efficacy Variable

The primary efficacy endpoint will be based on a checklist of 15 IA behaviors collected in an electronic IA diary. The IA diary comprises two parts: 1) an episodic diary that will be used by the primary caregiver (or alternate) to enter events as soon as possible after they are observed; and 2) an evening diary that will prompt the caregiver to review events for the day and to enter any events that were not previously captured. Events can be directly observed by the caregiver or could be reported to the caregiver by another observer such as a teacher. Each event will be characterized by a checklist of 15 observed behaviors: Yelling, Screaming, Threatening, Scratching, Throwing, Slamming, Hitting Self, Arguing, Cursing, Name Calling, Shoving, Hair Pulling, Fighting, Hitting Others, Kicking Others. The checklist will indicate whether each behavior was observed (coded 1) or was not observed (coded 0) during the incidence of an event. Each day can have multiple events. A day can have no event, as can be attested

in the evening diary. In this case, if no event is reported during a day, and the evening diary confirms this, the daily event score for that subject will be 0. Behaviors not on this list will not be captured.

5.2 Secondary Efficacy Variables

The following efficacy scales will be administered at visits designated in the Schedule of Visits and Procedures (Table 1).

5.2.1 Clinical Global Impression (CGI) Scales

The CGI scale was developed to provide a brief, stand-alone assessment of the clinician's view of a subject's global functioning prior to and after administration of a SM (Guy 1976). Severity of illness (CGI-S) and global improvement (CGI-I) are both rated on a scale of 1 to 7 with 7 being "extremely ill" or "very much worse", respectively. Successful therapy is indicated by a lower overall score in subsequent testing. Investigators should consider their total clinical experience with children who have IA associated with ADHD and rate how severe the subject's condition is at the time.

- CGI-S will be evaluated by the Investigator at each visit on a 7-point scale with 1=Normal, 2=Borderline ill, 3=Mildly ill, 4=Moderately ill, 5=Markedly ill, 6=Severely ill, and 7=Extremely ill.
- CGI-I, relative to the condition at Baseline (Visit 1), will be evaluated by the caregiver and by the Investigator at each post-baseline visit on a 7-point scale with 1=Very much improved, 2=Much improved, 3=Minimally improved, 4=No change, 5=Minimally worse, 6=Much worse, and 7=Very much worse.

CGI-S will be assessed by the Investigator at Visit 1, Visit 3, Visit 4, Visit 5 and Visit 6. CGI-I will be assessed by the caregiver and the Investigator at Visit 4, Visit 5 and Visit 6.

5.2.2 Swanson, Nolan, Pelham Rating Scale- Revised (SNAP-IV)

The SNAP-IV rating scale includes 18 ADHD and 8 oppositional defiant disorder (ODD) symptoms as specified in the DSM-IV-TR and International Statistical Classification of Diseases and Health Related Problems 10th Revision (ICD-10) Classification of Mental and Behavioral Disorders. The symptoms are scored by assigning a severity estimate for each symptom on a 4-point scale (Swanson 2001). The SNAP-IV rating should be performed by the same parent or legal representative at each visit when possible.

The ratings from the SNAP-IV scale are grouped into the following 4 subscales:

- ADHD-Inattention (items #1-9),
- ADHD-Hyperactivity/Impulsivity (items #10-18)
- ODD (items #19-26)
- ADHD-Combined subscale: the first two subscales are combined

Each subscale score is the sum of the scores for the individual items included in the subscale.

The SNAP-IV rating scale will be administered at Visit 3 and Visit 6.

5.2.3 Child Health Questionnaire Parent Form 28- Item (CHQ-PF28)

The Child Health Questionnaire Parent Form 28-item (CHQ-PF28) is a short generic measure of health status and health related quality of life (Landgraf 1996). CHQ-PF28 items have four, five, or six response options, divided over eight multi-item scales (physical functioning, general behavior, mental health, self esteem, general health perceptions, parental impact: emotional, parental impact: time, and family activities) and five single item concepts (role functioning: emotional/behavior, role functioning: physical, bodily pain, family cohesion, and change in health). The CHQ-PF28 should be performed by the primary caregiver when possible.

The CHQ-PF28 will be administered at Visit 3 and Visit 6.

5.2.4 Parenting Stress Index-Short Form (PSI-4-SF)

Reduction in stress is considered important for parents of children with disruptive behavior problems, developmental disabilities, and chronic illness (Haskett 2006). The Parenting Stress Index – Short Form (PSI-4-SF) is a 36-item self-report measure of parenting stress (Abidin 1995). Three subscales (Parental Distress, Parent-Child Dysfunctional Interaction, and Difficult Child) consist of 12 items each. Parents use a 5-point scale to indicate the degree to which they agree with each statement.

The PSI-4-SF will be administered at Visit 3 and Visit 6.

5.3 Pharmacokinetic Measurements

[redacted]

5.3.1 Pharmacokinetic Variables

The pharmacokinetic variables are:

- Apparent clearance (CL/F) of molindone in the pediatric population
- Apparent volume of distribution (V/F) of molindone in pediatric population
- Effect on molindone apparent clearance (CL/F) of co-administration of amphetamines, methylphenidate, clonidine, guanfacine and atomoxetine

5.3.2 Exploratory Pharmacokinetic Variables

[redacted]

- [redacted]
- [redacted]
- [redacted]

5.4 Safety Assessments

Safety assessments will consist of monitoring of and recording of all concomitant medications and AEs, clinical laboratory tests, measurement of vital signs and 12-lead ECGs, suicidality monitoring, and the performance of physical examinations at visits designated in the Schedule of Visits and Procedures (Table 1).

Assessment of possible neurological side effects and EPS will be performed using the Simpson-Angus scale, the Barnes Akathisia scale and the AIMS. A positive rating or finding on the safety scale will be captured as an AE at the discretion of the Investigator.

5.4.1 Adverse Events

As defined by the ICH Guideline for GCP, an **adverse event (AE)** is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with treatment.

An AE can be:

- Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.
- Any new disease, intercurrent injuries, or exacerbation of an existing disease.
- Any deterioration in a laboratory value or other clinical test (e.g., ECG) that results in symptoms, a change in treatment, or discontinuation from SM.
- Recurrence of an intermittent medical condition (e.g., headache) not present at baseline.

Surgical procedures are not AEs; they are therapeutic measures for conditions that require surgery. The condition for which the surgery is required is an AE, if it occurs or is detected during the study period.

5.4.1.1 Causality

AEs may be categorized as either Adverse Drug Reactions or Suspected Adverse Drug Reactions based on their relationship to SM and the degree of certainty about causality.

Suspected adverse drug reactions (SADRs) are a subset of adverse events for which there is evidence to suggest a causal relationship between the drug and the AE, i.e., there is a reasonable possibility that the drug caused the adverse event.

Adverse drug reactions (ADRs) are a subset of all SADRs for which there is reason to conclude that the drug caused the event.

5.4.1.2 Recording and Evaluation of Adverse Events

All subjects who are enrolled (starting at Visit 3) will be questioned regarding the occurrence of AEs. At each contact with the subject, the investigator must seek information on AEs by specific questioning and, as appropriate, by examination. Information on all AEs should be recorded immediately in the source document, and also in the appropriate adverse event module of the eCRF. All clearly related

signs, symptoms, and abnormal diagnostic procedures results should be recorded in the source document, though they may be grouped under one diagnosis. For example, fever, elevated WBC, cough, abnormal chest X-ray, etc., can all be reported as "pneumonia".

All AEs occurring after enrollment and throughout the study period must be recorded. A treatment-emergent adverse event (TEAE) is defined as an AE with a start date on or after the first dose of study drug, or that worsened following first administration of study drug. For subjects who receive SM, TEAEs will be collected starting from the first dose of SM. The clinical course of each AE should be followed until resolution or until, in the medical judgment of the Investigator, the event has stabilized or is assessed as chronic.

An increase in the CSSRS, Simpson Angus Scale, Barnes Akathisia Scale, or the AIMS will not necessarily be rated as an AE unless the event meets AE criteria.

The Investigator is responsible for evaluating AEs and determining the following:

- **Serious vs. Non-serious:** Is the event a Serious Adverse Event (SAE)?
- **Causality:** Was AE related or possibly related to the SM?
- **Severity:** How pronounced is the incapacity/discomfort caused by an AE?

5.4.1.3 Criteria for Assessing Severity

The Investigator will evaluate the comments of the subject and the response to treatment in order that he or she may judge the true nature and severity of the AE. Severity refers to the accumulated intensity of discomfort/impairment of health since the last recording of AEs and will be assessed according to the following criteria:

- **Mild:** Awareness of sign, symptom, or event, but easily tolerated
- **Moderate:** Discomfort enough to interfere with usual activity and may warrant intervention
- **Severe:** Incapacitating with inability to do usual activities or significantly affects clinical status and warrants intervention

The criteria for assessing severity are different from those used for seriousness.

5.4.1.4 Criteria for Assessing Causality

The Investigator is responsible for determining the relationship between the administration of SM and the occurrence of an AE as **not suspected** or as a **suspected** reaction to SM. These are defined as follows:

Not suspected: The temporal relationship of the AE to SM administration makes a **causal relationship unlikely**, or other drugs, therapeutic interventions, or underlying conditions provide a sufficient explanation for the observed event.

- **Not related:** Temporal relationship to SM administration is missing or implausible, or there is an evident other cause.

- **Unlikely related**: Temporal relationship to SM administration makes a causal relationship improbable; and other drugs, chemicals, or underlying disease provide plausible explanations.

Suspected: The temporal relationship of the AE to SM administration makes a **causal relationship possible**, and other drugs, therapeutic interventions, or underlying conditions do not provide a sufficient explanation for the observed event.

- **Possibly related:** Temporal relationship to SM administration is plausible, but concurrent disease or other drugs or chemicals could also explain event. Information on drug withdrawal may be lacking or unclear. This will be reported as a **Suspected Adverse Drug Reaction (SADR)**.
- **Definitely related:** Temporal relationship to SM administration is plausible, and concurrent disease or other drugs or chemicals cannot explain event. The response to withdrawal of the medication (dechallenge) should be clinically plausible. The event must be definitive pharmacologically or phenomenologically, using a satisfactory rechallenge procedure if necessary. This will be reported as an **Adverse Drug Reaction (ADR)**.

5.4.2 Serious Adverse Events (SAE)

AEs are classified as serious or non-serious. An AE or ADR is considered "**serious**" if, in the view of either the investigator or Sponsor, it results in one of the following outcomes:

- death
- life-threatening AE (i.e., the subject was at immediate risk of death from the AE as it occurred. This does not include an event that, had it occurred in a more severe form or was allowed to continue, might have caused death.)
- in-patient hospitalization or prolongation of existing hospitalization
- persistent or significant disability or incapacity or substantial disruption of the ability to conduct normal life functions
- a congenital anomaly or birth defect
- an important medical event

Important medical events are those that may not be immediately life threatening or result in death or hospitalization, but are clearly of major clinical significance. They may jeopardize the subject, and may require intervention to prevent one of the other serious outcomes noted above. For example, drug dependence or abuse, blood dyscrasias, a seizure that did not result in in-patient hospitalization, or intensive treatment for allergic bronchospasm in an emergency department would typically be considered serious.

5.4.2.1 Investigator Responsibilities for Reporting SAEs

The Investigator must immediately report to the Sponsor all SAEs, regardless of whether the Investigator believes they are drug related.

All SAEs must be reported to the Drug Safety Contact within 24 hours of first becoming aware of the SAE. The Investigator must complete an SAE eCRF in EDC and include a detailed description of the SAE,

as well as other available information pertinent to the case (e.g., hospital records, autopsy reports and other relevant documents). Should the site be unable to access EDC, a paper SAE form must be completed and sent to [redacted] Drug Safety by email or fax. The investigator will keep a copy of this SAE Report form on file at the study site. Once EDC becomes available, the site must complete the SAE eCRF in EDC.

The Investigator or study physician, after thorough consideration of all facts that are available, must include an assessment of causality of an AE to SM in the report to the Sponsor.

Follow-up information, or new information available after the initial report, should be actively sought and reported to the Sponsor as it becomes available using the SAE Report Form.

The Drug Safety Contact for SAE reporting is:

[redacted]

5.4.2.2 Other Events Requiring Immediate Reporting

The Investigator must report a **pregnancy** that occurs in a subject during a clinical study to the Drug Safety Contact within 24 hours of first becoming aware of the event. Pregnancy should be reported on a Pregnancy Report Form. The Investigator should discuss the case with the Medical Monitor; the Investigator must follow any pregnant subject for 3 months after the child is born. The Investigator must complete a Pregnancy Outcome Form as a follow up. Any AEs concerning the pregnancy of the subject during pregnancy or the child after birth must be documented and reported to the Sponsor.

Treatment-emerging **EPS** (e.g. akathisia, dystonia, Parkinsonism, tardive dyskinesia) and neuroleptic malignant syndrome should be reported to the Drug Safety Contact person(s) by completing the Adverse Event of Special Interest (AESI) eCRF in EDC. Should the site be unable to access EDC, a paper AESI form must be completed and sent to [redacted] Drug Safety by email or fax within 24 hours of first becoming aware of the event. Once EDC becomes available the site must complete AESI eCRF in EDC. EPS incidence will be summarized and shared with study Investigators throughout the trial.

Overdosage of molindone presumably may be manifested by severe EPS and sedation. Coma with respiratory depression and severe hypotension resulting in a shock-like syndrome could occur. In the event of a suspected overdose, the parent or legal representative should be instructed to call 911 or their local poison control center [redacted]

Symptomatic, supportive therapy should be the rule. Gastric lavage is indicated for the reduction of absorption of molindone which is freely soluble in water. Since the adsorption of molindone by activated charcoal has not been determined, the use of this antidote must be considered of theoretical value.

Emesis in a comatose patient is contraindicated. Additionally, while the emetic effect of apomorphine is blocked by molindone in animals, this blocking effect has not been determined in humans.

5.4.2.3 Sponsor Responsibilities for Expedited Reporting of SAEs

The Sponsor will inform Investigators and regulatory authorities of reportable events, in compliance with applicable regulatory requirements, on an expedited basis (i.e., within specific timeframes). For this reason, it is imperative that study sites submit SAE information to the Sponsor in the manner described above.

Investigators must comply with the applicable regulatory requirements related to the reporting of SAEs to the IRB/IEC. Investigators must also submit the safety information provided by the Sponsor to the IRB/IEC unless the country legal regulation requires that the Sponsor should be responsible for the safety reporting to the IRB/IEC.

It is the responsibility of the Sponsor to notify all participating investigators, in a written IND safety report, of any SADR that is both serious and unexpected. The Sponsor will also notify participating investigators of any findings from other sources (other studies, animal and in vitro testing, etc.) that suggest a significant risk for human subjects. Such findings will typically lead to safety-related changes in the study protocol, Informed Consent, and/or Investigator's Brochure.

5.4.3 Management of Treatment-Emerging EPS

If a subject experiences treatment-emerging EPS (including akathisia, dystonia, Parkinsonism, or tardive dyskinesia), benztropine will be permitted at a starting dose of 0.5 mg BID up to a range of 1 to 4 mg/day. Lorazepam (1 to 2 mg per dose not to exceed three times daily) and clonazepam (0.25 to 1 mg per dose not to exceed twice daily) will also be permitted to treat emerging EPS.

A positive finding on an EPS safety assessment scale (Barnes Akathisia, Simpson-Angus, AIMS) does not necessarily equate to an EPS event. Investigators should evaluate positive findings on the EPS safety assessment scales and integrate them into a global clinical observation to determine if an AE of EPS should be recorded.

5.4.4 Laboratory Measurements

With the exception of urine pregnancy test, clinical laboratory tests will be performed by a central laboratory as specified in the reference binder.

Details for collecting, handling, and shipping samples (including shipment addresses) will be detailed in a separate laboratory manual. The Schedule of Visits and Procedures (Table 1) shows the time points at which urine samples will be collected for urinalysis and blood samples will be collected for clinical laboratory tests and plasma concentration levels.

Table 3 presents the clinical laboratory tests to be performed. Metabolic parameters (including insulin, glucose, triglycerides, and cholesterol) and prolactin will be measured. A subject will be excluded if the Screening blood test results indicates > 2 times the upper limit of normal (ULN) of alanine

aminotransferase (ALT), aspartate aminotransferase (AST), gamma glutamyl transpeptidase (GGT), and/or serum creatinine. Laboratory tests will not be repeated for these subjects.

All laboratory tests will be reviewed in a timely manner by qualified site personnel to ensure safety. Abnormal lab findings may be confirmed if necessary by one repeated testing at the discretion of the Investigator. Any repeat laboratory testing will be conducted under **fasting condition**. Any laboratory abnormality may qualify as an AE in the Investigator's judgment.

A total of approximately 42 mL of blood per subject will be drawn during the study: 22 mL is for clinical laboratory tests and 20 mL is for PK sampling.

Table 3: Clinical Laboratory Tests

Category	Parameters
Hematology	RBC, WBC, Hgb, HCT, MCH, MCHC, MCV, platelet count, and WBC with differential (neutrophils, lymphocytes, monocytes, eosinophils, basophils, large unstained cells)
Chemistry	**Electrolytes**: Na^+, K^+, chloride, bicarbonate
	Liver function tests: alkaline phosphatase, AST, ALT, total bilirubin, direct bilirubin ,indirect bilirubin
	Renal function parameters: BUN, creatinine
	Other: glucose, Ca^{+2}, albumin, phosphorus, lactate dehydrogenase, total protein, CK/CPK, globulin, uric acid, triglycerides, insulin, prolactin, cholesterol – total, HDL and LDL Amylase, gammaGT (GGT), Iron, Lipase, Magnesium
Urine	Urinalysis Urine Drug Screen Urine pregnancy test (FOCBP only)

5.4.5 Vital Sign and Height/Weight Measurements

Vital sign measurements (e.g., blood pressure, heart rate, temperature, and respiratory rate) and height, weight and BMI will be obtained at visits designated on the Schedule of Visits and Procedures (Table 1). Blood pressure and heart rate will be measured after the subject has been sitting for 5 minutes. Vital signs may be taken at any other time, as deemed necessary by the Investigator.

5.4.6 Medical History

Medical history will be collected at visits designated on the Schedule of Visits and Procedures (Table 1).

5.4.7 Physical Examinations and Electrocardiograms (ECGs)

A physical examination and a 12-lead ECG will be obtained at visits designated on the Schedule of Visits and Procedures (Table 1). Additional ECGs may be performed at other times if deemed necessary by the Investigator.

The ECG will be recorded while the subject is resting in a supine position. The ECG will electronically measure the PR, QRS, QT, and QTc intervals, and heart rate.

All ECG tracings will be reviewed within 24 hours by the Investigator or qualified Sub-Investigator. PR intervals will be determined for each of these ECGs from a single reading. Invalid measurements will be repeated. QTc will be reported as QTcF (QT corrected using Fridericia's method).

5.4.8 Other Special Tests

The following special tests will be administered in the clinic at visits designated in the Schedule of Visits and Procedures (Table 1).

5.4.8.1 K-SADS-PL 2013 Diagnostic Interview

The K-SADS-PL 2013 is a semi-structured diagnostic interview designed to diagnose current and past episodes of psychopathology in children and adolescents according to DSM-5 criteria (Kaufman 1997). We will use a version of K-SADS 2013 that was revised to be compatible to the DSM-5 criteria. It includes the parent and child DSM-5 cross-cutting symptoms measures (DSM-5 CC-SM); an unstructured Introductory Interview; the Diagnostic Screening Interview; the Supplement Completion Checklist; the Diagnostic Supplements and the Summary Lifetime Diagnostic Checklist. The K-SADS-PL 2013 will be used at screening to confirm the diagnosis of ADHD, as well as to rule out exclusionary diagnoses. The Screen Interview will assess the different diagnoses and determine which supplements should be completed. Supplement 4 (Neurodevelopment, Disruptive and Conduct Disorders) must be completed to assess ADHD, ODD, CD Tic and ASD. If an exclusionary diagnosis is confirmed, the remainder of the diagnostic will not be completed. This assessment will be administered at Visit 1.

5.4.8.2 Simpson-Angus Scale

The Simpson-Angus scale is a 10-item rating scale that is widely used for assessment of neuroleptic-induced Parkinsonism (Simpson 1970). It consists of 1 item measuring gait, 6 items measuring rigidity, and three items measuring glabella tap, tremor and salivation, respectively. This assessment will be administered at Visit 3 and all subsequent visits.

5.4.8.3 Barnes Akathisia Scale

The Barnes Akathisia scale is a rating scale for drug-induced akathisia and includes components for rating the observable, restless movements characteristic of akathisia, the awareness of restlessness, and any distress associated with the condition (Barnes 1989). This assessment will be administered at Visit 3 and all subsequent visits.

5.4.8.4 Abnormal Involuntary Movement Scale (AIMS)

The AIMS test is a rating scale used to measure tardive dyskinesia (Munetz 1988). There are 12 items that rate involuntary movements of various areas of the subject's body. This assessment will be administered at Visit 3 and all subsequent visits.

5.4.8.5 Vitiello Aggression Scale

The Vitiello Aggression Scale is a 10-item rating scale that uses a cluster analysis to categorize aggression into two subtypes, predatory (or planned) and affective (or impulsive) (Vitiello 1990). This assessment will be administered at Visit 1.

5.4.8.6 Retrospective-Modified Overt Aggression Scale (R-MOAS)

The Retrospective-Modified Overt Aggression Scale (R-MOAS) was developed to gauge the severity of aggressive behavior (Blader 2010). Parents rate the frequency over the past week of 16 aggressive behaviors in four areas: verbal aggression; physical aggression toward others; aggression toward oneself; and destruction or hostile misuse of property. Numeric weighting amplifies the seriousness of more harmful behaviors in the total score. This assessment will be administered at Visit 1.

5.4.8.7 Columbia Suicide Severity Rating Scale (C-SSRS)

The C-SSRS is a questionnaire that prospectively assesses suicidal ideation and behavior using a semi-structured interview to probe patient responses (Posner 2011). The C-SSRS versions applicable to the current study are the Baseline version and the Since Last Visit version.

The Baseline version of the scale assesses lifetime suicidal ideation and behavior. This version is suitable as part of a subject's first interview and will be used at Visit 1 to identify volunteers who must not participate in the trial due to their suicidal tendencies.

The Since Last Visit version of the scale assesses any suicidal thoughts or behaviors the subjects may have had since the last administration of the C-SSRS. This version will be used for the other study visits.

5.4.8.8 Infrequent Behaviors Checklist

The infrequent behaviors checklist is a checklist of 15 behaviors that (along with the 15 IA Diary behaviors) were qualitatively linked to IA during the development of the IA diary. These behaviors include teasing, spitting, biting, weapons, ripping, breaking, vandalizing, destroying, fire setting, hitting animal, kicking self, kicking animal, severe injury self, severe injury others, severe injury animal. Caregivers will be asked which, if any, of these behaviors have been observed since the patient's last visit. This assessment will be administered at Visit 3, Visit 4, Visit 5, and Visit 6.

6 STATISTICAL METHODS

6.1 Statistical and Analytical Plans

Tabular summaries of the data collected during the study will be presented to provide a general description of the subjects studied and an overview of the Efficacy, PK and safety results. Data from all sites will be combined in the computation of these summaries and summaries will be presented by treatment group. Continuous variables will be summarized using descriptive statistics (number of subjects, mean, standard deviation [SD], median, and minimum and maximum values). Categorical (nominal) variables will be summarized using frequency tables (number and percentage of subjects in each category).

In addition to tabular summaries, subject data listings, as specified in Sections 16.2 and 16.4 of ICH Guidance E3, will be provided. Additional subject data listings to be provided for this study are listed under the relevant subsections below. All data analyses will be performed by the CRO after the study is completed and the database is released. Statistical programming and analyses will be performed using SAS® and/or other validated statistical software as required.

Complete details of the statistical analysis will be provided in a separate statistical analysis plan (SAP), which will be written, finalized, and approved prior to database lock and will be included in the Clinical Study Report (CSR) for this protocol. The statistical analysis plan will supersede the statistical analysis methods described in this clinical protocol. Any deviation from the statistical plan will be documented and described in the final report. If changes to principal features stated in the protocol are required, these will be documented in a protocol amendment. The final SAP will take into account any amendment to the protocol.

In general, the baseline value for a variable is defined as the last observation prior to the first dose of double-blind study medication, ideally Visit 3, but including the screening value, if necessary.

6.2 **Handling Missing Data**

For the primary efficacy endpoint, the frequency of IA behaviors during the Treatment period will be calculated over the number of days with non-missing IA diary data in the Treatment period. No explicit imputation of missing data will be used, but this approach is implicitly equivalent to using the frequency of IA behaviors during the days with non-missing IA diary data to impute the frequency for days after study discontinuation and days with missing IA diary data.

6.3 **Analysis Populations**

The population of “all enrolled subjects” consists of all those screened subjects who meet the requirements for study participation and are entered in the Baseline period of the study. The population of “all randomized subjects” consists of all those enrolled subjects who complete the Baseline Period, meet the inclusion/exclusion criteria and are randomized.

Safety Population: will include all randomized subjects who received at least 1 dose of study drug.

Intent-to-Treat (ITT) Population: will include all subjects who received at least 1 dose of study drug and have a baseline and at least 1 valid post-randomization assessment of frequency of IA behaviors based on IA diary entry.

Per-Protocol (PP) Population: will include all of the subjects in the ITT population who completed the treatment period with 80% diary completion compliance and who did not have major protocol deviations.

PK population: will include all subjects in the safety population who had at least one PK sample drawn which had a quantifiable concentration for at least one analyte of interest.

The safety, ITT, PP, and PK populations are based on randomized treatment received.

6.4 **Demographic and Baseline Characteristics**

Demographic/baseline variables include age, sex, ethnicity, race, and height at screening, weight at screening and baseline, and medical history. Tabular summaries of the demographic/baseline variables will be presented for the safety, ITT, and PP populations, except for medical history, which will be summarized for the safety population only.

6.5 **Subject Disposition**

A disposition of subjects will include the number and percentage of subjects in each of the following categories:

- Subjects in the randomized population
- Subjects in the ITT population
- Subjects treated (safety population)
- Subjects in the PP study population

Within each of the previous categories, the number and percentage of subjects who completed and discontinued from the study will be summarized. The reasons for study discontinuation will also be summarized. The reason for discontinuation may include any of the following:

- Subject withdrew consent
- Lost to follow-up
- Administrative reason
- Adverse event
- Investigator decision
- Failure to follow required study procedures
- Other

Only one (primary) reason for study discontinuation will be recorded for each subject.

6.6 **Protocol Deviations**

Protocol deviations will be presented in listings. If applicable, the number and percent of subjects within each type of protocol deviation will be presented using discrete summary statistics. Protocol deviations will include, but are not limited to:

- Non-compliance with any scheduled study visit
- Non-compliance with study treatment
- Disallowed concomitant medications
- Non-compliance with study inclusion or exclusion criteria
- Non-compliance with study assessment procedures

6.7 Study Medication Exposure and Compliance

Duration of exposure is defined as the total number of days a subject is exposed to any study treatment. This will be calculated for each subject by taking the difference between the date of last dose *minus* the date of the first dose, *plus* 1 (date of last dose – date of first dose +1).

Duration of Treatment exposure will also be summarized using descriptive statistics (n, mean, SD, median, minimum, and maximum).

Percent of study drug compliance is defined as {(number of tablets dispensed – number of tablets returned) / 4*(date of last dose – date of first dose + 1)}* 100%.

Each subject is expected to take 4 tablets per day. For each treatment, SM compliance will be summarized by compliance category (<80%, 80-120%, and >120%) and number of subjects in each compliance category. Study medication compliance will also be summarized as a continuous variable using descriptive statistics (n, mean, standard deviation, median, minimum, and maximum) for each treatment.

Summaries of treatment compliance and exposure will be presented separately for the Titration Period, Maintenance Period, and combined Titration and Maintenance Periods.

6.8 Concomitant Medications

Concomitant medications will be assigned an 11-digit code using the World Health Organization Drug Dictionary (WHO DD) drug codes. Concomitant medications will be further coded to the appropriate Anatomical-Therapeutic-Chemical (ATC) code indicating therapeutic classification. A tabular summary of concomitant medications by drug class will be presented for the safety population.

6.9 Efficacy Analyses

6.9.1 Primary Efficacy Analysis

The primary efficacy endpoint is the percent change (PCH_T) in the frequency (unweighted score) of IA behaviors per 7 days in the Treatment (Titration and Maintenance) period relative to the Baseline period calculated over the number of days with non-missing IA diary data. The frequency of IA behaviors per 7 days is the sum of scores for all events in a given period of sequential days, adjusted to 7 days.

The primary efficacy endpoint PCH_T will be calculated by PCH_T= 100*(T – B)/B, where T and B are IA behavior frequencies per 7 days during the treatment period and baseline period, respectively. The IA behavior frequency per 7 days is defined as (SUM/DAY) x 7, where SUM is the sum of the IA behaviors reported in the subject IA diary, and DAY is the number of days with non-missing IA frequency data in the subject IA diary during the specified study period.

Per the adaptive design feature of protocol 810P301 that led to discontinuation of the 18 mg dose group, SPN-810 36 mg vs. placebo will be tested.

The null (H_0) and the alternative (H_a) hypotheses are as in the following:

- H_{01}: There is no difference between the median of the 36 mg dose SPN-810 and the median of placebo vs.
- H_{a1}: There is a difference between the median of the 36 mg dose SPN-810 and the median of placebo.

The primary efficacy analysis will be performed using the Wilcoxon rank-sum test to compare the median of 36 mg dose of SPN-810 with the median of the Placebo. The Hodges-Lehmann estimate and the associated 95% confidence interval (CI) will be calculated. The superiority of 36 mg dose to placebo will be claimed if the p-value from this analysis < 0.05 at alpha of 5% significance level. There is no multiplicity adjustment with respect to the primary endpoint since only 2 treatments are compared.

6.9.2 Key Secondary Efficacy Analyses

The key secondary efficacy analysis is the change from Visit 3 to Visit 6 in Investigator CGI-S score.

The Key Secondary endpoint will be analyzed using Mixed-Effect Model for Repeated Measure (MMRM) for the ITT population. The model includes treatment, visit, and interaction between treatment and visit as fixed factors, and baseline as covariate. The model parameters will be estimated using restricted maximum likelihood method with unstructured variance-covariance matrix and Kenward-Roger approximation to estimate denominator degrees of freedom. The between-group comparison will be performed using the simple contrast at the respective visits. The least squares mean of 36 mg dose and placebo, the difference in the least squares mean (36 mg dose minus placebo), and the 2-sided 95% CI for the difference will be calculated.

6.9.3 Additional Secondary Efficacy Analyses

1. Investigator CGI-I score at Visit 6
2. CHQ-28 score at Visit 6
3. PSI-4-SF scores at Visit 6 in:
    a. Parental Distress
    b. Parent-Child Dysfunctional Interaction
    c. Difficult Child
4. Caregiver CGI-I score at Visit 6
5. SNAP-IV ADHD scores at Visit 6 in:
    a. Inattention ratings
    b. Hyperactivity/Impulsivity ratings
    c. Oppositional Defiant Disorder
    d. Combined Scale ratings
6. Percentage of responders with ≥50% reduction in the frequency of IA behaviors from baseline
7. Percentage of responders with ≥30% reduction in the frequency of IA behaviors from baseline

The other secondary endpoints will be analyzed using the ITT Population as follows:

Scores of CGI-I (investigator and caregiver) will be analyzed using a Mixed-Effect Model for Repeated Measure (MMRM) similar to the key secondary outcome.

Scores for CHQ-PF28, PSI-4-SF, and SNAP-IV will be analyzed using the analysis of covariance method based on the ITT population. The model includes treatment and baseline as fixed independent covariates and Visit 6 value as a response variable. The least squares mean of each treatment group, the difference in the least squares mean (36 mg dose minus placebo), and the 2-sided 95% CI for the difference will be obtained.

The percentage of responders with at least 30% reduction and with at least 50% reduction in the frequency of IA behaviors per 7 days in the Treatment (Titration and Maintenance) period relative to the Baseline period will be derived analyzed using the logistic regression model with treatment as explanatory variables and baseline as covariate. Odds ratio (36 mg dose/placebo), and 95% CI for the odds ratio and p-value will be presented. In addition, the number and percentage of responders will also be tabulated.

If the null hypothesis for the primary analysis is not rejected, then no multiplicity adjustment will be done for the key secondary endpoint. If the key secondary endpoint hypothesis is rejected then, a sequential testing procedure to preserve the type I error rate at 0.05 will be conducted for the adiidtinal secondary endpoints as described below:

First, the first of the additional secondary endpoints (Investigator CGI-I score at Visit 6) will be used to test H_{01}: no difference between SPN-810 36 mg and Placebo in the treatment of IA in subjects with ADHD in conjunction with standard ADHD treatment. If this test is rejected, then the 2nd test using the same hypothesis will be repeated using the 2nd additional secondary endpoint (CHQ-28 score at Visit 6). If the first hypothesis is not rejected then no other additional secondary endpoint test will be performed. If the 2nd test is rejected then the 3rd test will be conducted for the 3rd additional secondary endpoint (PSI-4-SF scores) and so on until the last additional secondary endpoint is used for testing in the above pre-specified order above.

6.9.4 Sensitivity Analysis

In the presence of a high drop-out rate, performance of sensitivity analysis is crucial. The purpose of sensitivity analysis is to see whether different methods of handling missing data provide consistent and similar results for the primary efficacy analysis. To this end, two sensitivity analyses will be performed:

1. Multiple imputation under MAR using available data on the primary endpoint
2. Placebo- based imputation under MNAR

6.9.4.1 Multiple imputation under Missing at Random (MAR)

The multiple imputation (MI) method assumes that the missing data are missing at random (MAR), that is, the probability that an observation is missing may depend on the observed values but not the missing values. For example, if a subject's Diary values are available on Day 1 and Day 2 but missing on Day 3, then the missing value on Day 3 is related to the non-missing value on Day 1 and Day 2.

MI is implemented using the following three steps.

1) SAS PROC MI is applied with input dataset containing some missing values for all days during the titration and maintenance period to create 100 datasets. The data sets will include separate columns for the frequency of incidences during each day starting from baseline. The Markov Chain Monte Carlo (MCMC) method will be used to complete the missingness pattern to a monotone pattern separately by treatment arm. The monotone patterns will be achieved by applying sequential imputation based on Bayesian regression with the treatment arm included as a covariate. All copies contain identical values of the non-missing data items, but different values imputed for missing values.

2) For each of these MI data sets, the percent change will be computed as in the observed data set and the primary analysis based on the Wilcoxon rank-sum test will be conducted and asymptotic 95% confidence intervals will be constructed.

3) To produce a single confidence interval for each dose placebo comparison (e.g., Dose 1 versus placebo), PROC MIANALYZE will be used and Rubin's combination rules will be applied to the treatment effect estimates and associated asymptotic standard errors from the MI data sets (Rubin 1987). The treatment effect estimates will be defined as the midpoints of the asymptotic confidence intervals and the standard errors will be defined as the asymptotic standard errors (based on the width of the associated 95% confidence intervals) from the Hodges-Lehmann estimate of the individual datasets.

6.9.4.2 Multiple imputation under Missing Not at Random (MNAR)

This approach can be labeled "worst-case" sensitivity analyses as it assumes that after discontinuation subjects from the dosing arms would adopt the outcome model estimated from the placebo arm. To generate missing values from this "placebo-based" imputation model, PROC MI with the MNAR statement (available in SAS 9.3 and later versions) will be used or, alternatively, SAS macros available at the DIA Missing Data Working Group site (Ratitch et al., 2013; Ayele et al., 2014) can be used.

6.9.5 Supplementary Analysis

A supplementary analysis based on the per-protocol population will be performed.

6.10 Sample Size and Power Considerations

Based on results from the Phase 2 study, a 15-point average difference in favor of the SPN-810 treatment arms compared with placebo is assumed; the change from baseline to endpoint in total R-MOAS rating was used to evaluate the difference. The R-MOAS was used because there have been no prior studies with the IA diary. A common standard deviation of 34.83 was obtained from a blinded analysis of SPN-810P301 data.

Based on these parameter assumptions, a sample size of approximately 122 per arm will yield 90% power to detect a non-zero difference between the median of SPN-810 treatment and the placebo groups using the Wilcoxon rank-sum test with a 2-sided significance level α=0.05.

The original sample size of 291 was based on having 3 treatment groups (97 subjects per arm) and specific assumptions on the drug placebo difference, standard deviation and discontinuation rate.

After the 810P301 study Interim Analysis result was completed, the 18 mg dose arm was discontinued and subjects planned to be randomized to the 18 mg arm would be re-allocated to the 36 mg or placebo arm in a ratio of 2:1. As such there will be an unequal randomization between the 36 mg dose group and placebo. With this post-interim analysis un-equal randomization, the placebo arm is expected to approach approximately 121 subjects of the total of 306 subjects randomized.

The sample size was calculated using the nQuery Advisor Software, Version 7.

6.11 **Interim Analysis**

There will be no interim analysis.

6.12 **Pharmacokinetic Analyses**

[redacted]

6.13 **Safety Analyses**

Evaluation of safety will be performed for the safety population. Safety data that will be evaluated include concomitant medications, AEs, clinical laboratory results, vital signs, ECGs, and findings from the physical examinations. The occurrence of neurological side effects will be assessed by looking at any worsening in scores from Visit 3 to each subsequent visit for each of the Simpson-Angus scale, Barnes Akathisia scale, and AIMS. Suicidal ideation and suicidal behavior will be measured by C-SSRS.

All summary tables related to safety analyses will use the safety population.

6.13.1 Adverse Events

AEs will be classified into standardized medical terminology from the verbatim description (Investigator term) using the Medical Dictionary for Regulatory Activities (MedDRA). AEs will be summarized using discrete summaries at the subject and event level by system organ class and preferred term for each treatment group. Similarly, treatment-emergent AEs will be summarized by severity and relationship separately. Verbatim description and all MedDRA level terms, including the lower level terms, for all AEs will be contained in the subject data listings.

All AEs occurring after randomization and throughout the study period will be recorded. For subjects who receive SM, treatment-emergent AEs (TEAEs) will be collected starting after the first dose of SM (Visit 3) to the end of the study. These AEs include those that emerge during treatment or worsen in severity during treatment. These AEs will be tabulated, listed and analyzed.

Separate TEAE incidence tables will be presented for the three treatment groups. The incidence rates for all SADRs will also be summarized as described for all TEAEs.

In addition, these same tables will be presented by treatment period (Titration, Maintenance, and combined Titration and Maintenance). For the combined Titration and Maintenance Periods, the incidence of TEAEs will also be presented by highest severity reported and the dose of SM at first occurrence.

Listings (and tabular summaries, if warranted) of deaths, other SAEs, and other significant TEAEs, including TEAEs resulting in treatment discontinuation, will be provided.

6.13.2 Laboratory Values

Clinical laboratory values will be summarized by visit by treatment group using descriptive statistics for hematology and biochemistry. For quantitative laboratory parameters, both actual values and change from baseline values will be summarized.

Laboratory test results will be assigned a low, normal, high (LNH) classification according to whether the values were below (L), within (N), or above (H) the laboratory parameters' reference ranges provided by the central laboratory. Within-treatment comparisons will be based on three by three tables (shift tables) that, for a particular laboratory test, compare the LNH classification at baseline to the LNH classification at visit. By subject-listings of all abnormal laboratory values, i.e., those with L or H classification will be provided.

6.13.3 Vital Signs, Height and Weight

Vital signs will be summarized by visit by treatment group using descriptive statistics. Both actual values changes from baseline to visit will be summarized. Descriptive summary statistics (mean, SD, median, and range) for vital sign data, height, weight and BMI will be evaluated by treatment group.

6.13.4 ECG Results

By-visit tabular summaries of the quantitative ECG parameters and the overall ECG findings (normal, abnormal not clinically significant, or abnormal clinically significant) will be presented. The QT will be corrected using Fridericia's method.

ECG results will be summarized by visit by treatment group using descriptive statistics (for quantitative ECG parameters) and frequency tables (for qualitative ECG parameters, including the overall ECG finding). For quantitative ECG parameters, both actual values and change from screening values will be summarized.

6.13.5 Physical Examinations

Findings from the physical examinations will be listed for each system or area examined.

6.13.6 Columbia Suicide Severity Rating Scale (C-SSRS)

C-SSRS outcomes will be summarized using number and percent of subjects by categories for suicidal ideation only, suicidal behavior only and suicidality (ideation and behavior combined). The summary will be presented by treatment groups. The proportion of subjects in each treatment group will be compared with the proportion of subjects in the placebo group using Fisher's exact test or Chi-square test as applicable if appropriate.

6.13.7 Infrequent Behaviors Checklist

Infrequent behaviors will be listed for each subject by treatment group.

6.13.8 Other Special Tests

The occurrence of neurological side effects will be assessed by looking at the changes in scores from baseline to post-baseline visits for each of the Simpson-Angus scale, Barnes Akathisia scale, and AIMS. For each item on each of these scales, the number (and percentage) of subjects with a worse score at any post-baseline visit, compared to baseline, will be presented. A listing of these subjects will also be provided.

7 DOCUMENTATION

7.1 Adherence to the Protocol

The Investigator agrees, when signing the protocol, to adhere to the instructions and procedures described in the protocol and to adhere to the principles of ICH GCP to which the protocol conforms as well as all governing local regulations and principles for medical research.

The protocol, ICF, and appropriate related documents must be reviewed and approved by an IRB constituted and functioning in accordance with ICH E6 and any local regulations. Documentation of IRB compliance with the ICH and any local regulations regarding constitution and review conduct will be provided to the Sponsor.

A signed letter of study approval from the IRB Chairman must be sent to the Investigator with a copy to the Sponsor prior to study start and the release of any SM to the site by the Sponsor or its designee. If the IRB decides to suspend or terminate the study, the Investigator will immediately send the notice of study suspension or termination by the IRB to the Sponsor.

Study progress is to be reported to IRB annually (or as required) by the Investigator or Sponsor, depending on local regulatory obligations. If the Investigator is required to report to the IRB, he/she will forward a copy to the Sponsor at the time of each periodic report.

7.2 Changes to the Protocol

There are to be no changes to the protocol without written approval from the Sponsor.

Any change to the protocol requires a written protocol amendment or administrative change that must be approved by the Sponsor before implementation. Amendments specifically affecting the safety of subjects, the scope of the investigation, or the scientific quality of the study require additional approval by the applicable IRBs and, in some countries, by the regulatory authority. These requirements should in no way prevent any immediate action from being taken by the Investigator, or by the Sponsor, in the interest of preserving the safety of all subjects included in the study. If an immediate change to the protocol is warranted as per the Investigator, for safety reasons, the Medical Monitor and IRB must be notified promptly.

Changes affecting only administrative aspects of the study do not require formal protocol amendments or IRB approval, but the IRB must be kept informed of such changes. In these cases, the Sponsor will send a letter to the IRB detailing such changes.

7.3 Protocol Deviations

There are to be no Investigator-initiated deviations from the protocol. Any subject whose treatment deviates from the protocol or who is not qualified for study participation may be ineligible for analysis and may compromise the study. The date of and reason for deviations must be documented in all cases. Significant or major protocol deviations impacting the safety of the subject or the integrity of the study must be reported by the Investigator to the IRB immediately. Reporting of all other protocol deviations must adhere to the requirements of the governing IRB. Protocol assessments will continue until the end of the study, unless the protocol deviations put the subject at risk or the subject's condition requires that he/she be discontinued from the study.

7.4 Data Quality Assurance

This study will be organized, performed, and reported in compliance with the protocol, standard operating procedures (SOPs), working practice documents, and applicable regulations and guidelines. Site visit audits may be made periodically by the Sponsor's Quality Assurance team or qualified designee, which is an independent function from the study conduct team.

7.4.1 Data Collection

The primary source document will be the subject's medical record. If separate research records are maintained by the Investigator(s), both the medical record and the research record will be considered the source documents for the purposes of monitoring and auditing the study.

Electronic data collection techniques will be used to collect data directly from the study sites using eCRFs. The electronic data will be stored centrally in a fully validated clinical database.

[redacted]

Data recorded on source documents will be transcribed into the eCRFs in accordance with the eCRF Completion Instructions that are provided to the study sites. The Investigator is responsible for ensuring that all sections of each eCRF are completed correctly, and that entries can be verified against source documents. The eCRFs will be monitored for completeness and accuracy against the source documents by the CRA(s) on a regular basis. Inconsistencies between the eCRFs and source documents will be resolved in accordance with the principles of GCP.

Completed eCRFs will be extracted from the clinical database, stored as PDF files on a CD-ROM and sent to the respective study site for archiving. A CD-ROM containing all eCRFs will be kept by the Sponsor in the Sponsor's Trial Master File.

7.4.2 Clinical Data Management

Data from eCRFs and other external data (e.g., laboratory data) will be entered into or merged with a clinical database as specified in the data management plan. Quality control and data validation procedures will be applied to ensure the validity and accuracy of the clinical database.

7.4.3 Database Quality Assurance

In accordance with the vendor's procedures, the clinical database will be reviewed and checked for omissions, apparent errors, and values requiring further clarification using computerized and manual procedures. Data queries requiring clarification will be documented and returned to the study site for resolution. Only authorized personnel will make corrections to the clinical database, and all corrections will be documented in an audit trail.

7.4.4 Bioanalytical Data Management and Quality Control

[redacted]

7.5 Retention of Records

The Investigator has the responsibility to retain all study "essential documents", as described in ICH E6. Essential documents include but not limited to the protocol, copies of paper CRFs or eCRFs, source documents, laboratory test results, SM inventory records, Investigator's Brochure, regulatory agency registration documents (e.g., FDA form 1572, ICFs, and IRB/IEC correspondence). The investigator should take measures to prevent accidental or premature destruction of these documents. Study essential documents should be retained until at least two years after the last approval of a marketing application or after formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the Sponsor. The Investigator must obtain written permission from the Sponsor prior to the destruction of any study document.

It is requested that at the completion of the required retention period, or should the Investigator retire or relocate, the Investigator contact the Sponsor, allowing the Sponsor the option of permanently retaining the study records.

These records must be made available at reasonable times for inspection and duplication, if required, by a properly authorized representative of the US FDA in accordance with the US 21 CFR 312.68 or other national or foreign regulatory authorities in accordance with regulatory requirements.

7.6 Auditing Procedures

In addition to the routine monitoring procedures, the Sponsor's Corporate Quality Assurance department or qualified designee may conduct audits of clinical research activities in accordance with the Sponsor's written SOPs to evaluate compliance with the principles of ICH GCP and all applicable local regulations. A government regulatory authority may also wish to conduct an inspection (during the study or after its completion). If an inspection is requested by a regulatory authority, the Investigator must inform the Sponsor and the CRO immediately that this request has been made.

These records must be made available at reasonable times for inspection and duplication, if required, by a properly authorized representative of the US FDA in accordance with the US 21 CFR 312.68 or other national or foreign regulatory authorities in accordance with regulatory requirements.

7.7 Publication of Results

Any presentation or publication of data collected as a direct or indirect result of this trial will be considered as a joint publication by the Investigator(s) and the appropriate personnel at the Sponsor's site. Authorship will be determined by mutual agreement. All manuscripts, abstracts or other modes of presentation arising from the results of the study must be reviewed and approved in writing by the Sponsor, prior to submission for publication or presentation. No publication or presentation with respect to the study shall be made until any Sponsor comments on the proposed publication or presentation have been addressed to the Sponsor's satisfaction.

The detailed obligations regarding the publication of any data, material results, or other information, generated or created in relation to the study shall be outlined in the agreement between each Investigator and the Sponsor or designee.

7.8 Financing and Insurance

Financing and Insurance information will be set forth in a separate document between the Investigator and Sponsor (provided by the Sponsor or designee).

7.9 Disclosure and Confidentiality

The contents of this protocol and any amendments and results obtained during the course of this study will be kept confidential by the Investigator, the Investigator's staff, and IRB and will not be disclosed in whole or in part to others or used for any purpose other than reviewing or performing the study without the written consent of the Sponsor. No data collected as part of this study will appear in any written work, including publications, without the written consent of Sponsor.

All persons assisting in the performance of this study must be bound by the obligations of confidentiality and non-use set forth in the Confidentiality Agreement between the Investigator and Sponsor.

7.10 **Discontinuation of Study**

The Sponsor reserves the right to discontinue the study for medical or administrative reasons at any time. The Investigator will be reimbursed for reasonable expenses covering subjects, use of live-in facilities, laboratory tests, and other professional fees. The Investigator will refund the excess of payments made in advance.

The Investigator reserves the right to discontinue the study should his/her judgment so dictate. The Investigator will notify the IRB in case of study discontinuation. Study records must be retained as noted above.

8 ETHICS

8.1 **Institutional Review Boards / Independent Ethics Committees**

A list of the Institutional Review Board(s) (IRB) and/or Independent Ethics Committee(s) (IEC) that approved this study and the approval letters will be included in the clinical study report for this protocol.

The protocol, any protocol amendments, and the informed consent form (ICF) will be reviewed and approved by the appropriate IRB before subjects are screened for entry. Verification of the IRB unconditional approval of the protocol will be transmitted to the Sponsor prior to the shipment of study medication to the investigational site. The Investigators or Sponsor will submit, depending on local regulations, periodic reports and inform the IRB of any reportable adverse events (AEs) per International Conference on Harmonization (ICH) guidelines and local IRB standards of practice.

8.2 **Ethical Conduct of the Study**

This study will be conducted in accordance with standard operating procedures (SOPs) of the Sponsor and [redacted], the Contract Research Organizations (CRO) that will conduct the study. These SOPs are designed to ensure adherence to Good Clinical Practice (GCP) guidelines as required by:

- Declaration of Helsinki, 1964 (“Recommendations Guiding Physicians in Biomedical Research Involving Human Patients”), and all its accepted amendments to date concerning medical research in humans.
- ICH Guideline for GCP (Committee for Proprietary Medicinal Products/ICH/135/95) of the European Agency for the Evaluation of Medicinal Products, Committee for Proprietary Medicinal Products, ICH of Pharmaceuticals for Human Use.
- United States (US) Code of Federal Regulations (CFR) dealing with clinical studies (21 CFR, including parts 50 and 56 concerning Patient Informed Consent and IRB regulations).
- Local, national legal guidelines.

8.3 **Investigators and Study Personnel**

This study will be conducted by qualified Investigators under the Sponsorship of Supernus Pharmaceuticals, Inc. (Sponsor) at approximately 25 study sites in the US.

Contact persons at the Sponsor and the CROs are listed in the reference binder provided to each investigational site. The study will be monitored by qualified personnel from the designated CRO [redacted] by visiting the study sites. The Sponsor will oversee and review the monitoring activities of the [redacted] monitors. Medical writing, data management, and statistical analyses will be performed by the CROs. Laboratory tests will be conducted by a central laboratory as designated in the reference binder.

8.4 **Subject Information and Consent/Assent**

The Investigator (or designee) will inform the subject and their parent(s), or legal representative, of all aspects pertaining to the subject's participation in the study and will provide oral and written information describing the nature and duration of the study, the procedures involved, the expected duration, the potential risks and benefits involved, and any potential discomfort.

The process for obtaining informed consent/assent will be in accordance with all applicable regulatory requirements. The Investigator (or designee) and the parent (or legal representative) must sign and date the Informed Consent Form (ICF)/Informed Assent Form (IAF) before the subject can participate in the study. The parent or legal representative and the subject will be given a copy of the signed and dated consent/assent form and the original will be retained in the investigational site study records.

The decision regarding subject participation in the study is entirely voluntary. The Investigator (or designee) must emphasize to the subject and their parent(s) or legal representative that consent regarding study participation may be withdrawn at any time without penalty or loss of benefits to which the subject is otherwise entitled.

The ICF/IAF should be given by means of a standard written statement, written in non-technical language. The subject should understand the statement before signing and dating it. If written consent is not possible, oral consent may be obtained if witnessed by at least one person not involved in the study. The verbal consent will be documented and signed by the Investigator and the witness(es). No subject can enter the study before his/her ICF has been obtained.

If the ICF/IAF is amended during the study, the Investigator must follow all applicable regulatory requirements pertaining to approval of the amended ICF by the IRB and use the amended informed consent form (including ongoing subjects).

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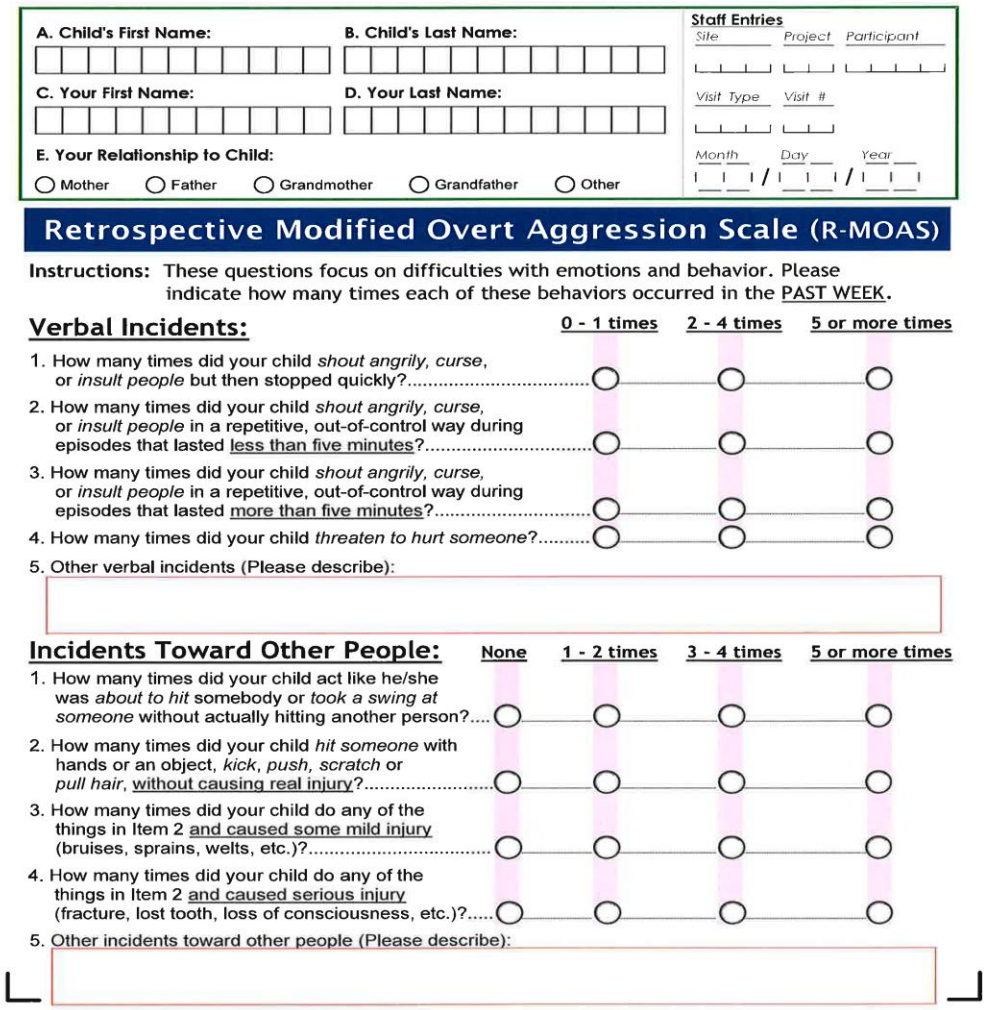
10 APPENDICES

10.1 **Retrospective Modified Overt Aggression Scale (R-MOAS)**



A. Child's First Name: B. Child's Last Name:

C. Your First Name: D. Your Last Name:

E. Your Relationship to Child:

○ Mother ○ Father ○ Grandmother ○ Grandfather ○ Other

Staff Entries

Site Project Participant

Visit Type Visit #

Month Day Year

Retrospective Modified Overt Aggression Scale (R-MOAS)

Instructions: These questions focus on difficulties with emotions and behavior. Please indicate how many times each of these behaviors occurred in the PAST WEEK.

Verbal Incidents:	0 - 1 times	2 - 4 times	5 or more times
1. How many times did your child *shout angrily, curse,* or *insult people* but then stopped quickly?	○	○	○
2. How many times did your child *shout angrily, curse,* or *insult people* in a repetitive, out-of-control way during episodes that lasted less than five minutes?	○	○	○
3. How many times did your child *shout angrily, curse,* or *insult people* in a repetitive, out-of-control way during episodes that lasted more than five minutes?	○	○	○
4. How many times did your child *threaten to hurt someone*?	○	○	○
5. Other verbal incidents (Please describe):			

Incidents Toward Other People:	None	1 - 2 times	3 - 4 times	5 or more times
1. How many times did your child act like he/she was *about to hit* somebody or *took a swing at someone* without actually hitting another person?	○	○	○	○
2. How many times did your child *hit someone* with hands or an object, *kick, push, scratch* or *pull hair*, without causing real injury?	○	○	○	○
3. How many times did your child do any of the things in Item 2 and caused some mild injury (bruises, sprains, welts, etc.)?	○	○	○	○
4. How many times did your child do any of the things in Item 2 and caused serious injury (fracture, lost tooth, loss of consciousness, etc.)?	○	○	○	○
5. Other incidents toward other people (Please describe):				

Site ___ Project ___ | Visit Type ___ Visit # ___ | Month ___ Day ___ Year ___ | Subject # ___ Initials ___

Incidents Involving Property:

	None	1 - 2 times	3 - 4 times	5 or more times
1. How many times did your child *slam a door or cabinet, rip clothing*, or *knock something over* in anger?	○	○	○	○
2. How many times did your child *throw things down, kick furniture*, or otherwise *misuse things angrily* but did not break them?	○	○	○	○
3. How many times did your child *break things, smash windows*, or *damage or deface property* on purpose?	○	○	○	○
4. How many times did your child *set a fire* or *throw things at people* in order to hurt them?	○	○	○	○

5. Other incidents involving property (Please describe):

Incidents Directed Toward Self:

	None	1 - 2 times	3 - 4 times	5 or more times
1. How many times did your child *pick at or scratch* his or her skin, *pull out hair*, or *hit himself or herself* while upset or angry?	○	○	○	○
2. How many times did your child *bang his or her head, hit his or her fists into the wall*, or *throw* himself or herself on the floor?	○	○	○	○
3. How many times did your child *cut, bruise*, or *burn* himself or herself on purpose?	○	○	○	○
4. How many times did your child *severely injure* himself or herself, or *try to kill* himself or herself?	○	○	○	○

5. Other incidents in which your child acted harmfully toward himself or herself (Please describe):

Staff Use:

VE.....
PH.....
PR.....
SE.....
Total.....

10.2 **Clinical Global Impression (CGI) Scale**

Clinical Global Impression (CGI) Scale

☐ **(1) NOT DONE**

INSTRUCTIONS: Indicate only one response for the question by placing a cross (X) in the appropriate numbered box.

SEVERITY OF ILLNESS:
Considering your total clinical experience with this particular population (*impulsive aggression comorbid with ADHD*), how severe is the subject's condition at this time?

☐ (0) NOT ASSESSED
☐ (1) Normal, not at all ill
☐ (2) Borderline mentally ill
☐ (3) Mildly ill
☐ (4) Moderately ill
☐ (5) Markedly ill
☐ (6) Severely ill
☐ (7) Among the most extremely ill patients

GLOBAL IMPROVEMENT: Rate total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at Visit 1/Baseline, how much has the subject's *impulsive aggression* changed?

☐ (0) NOT ASSESSED
☐ (1) Very much improved
☐ (2) Much improved
☐ (3) Minimally improved
☐ (4) No change
☐ (5) Minimally worse
☐ (6) Much worse
☐ (7) Very much worse

10.3 **Vitiello Scale**

Predatory-Affective Aggression Scale

Patient_____

Rater_____ Date_____

Check if any these behaviors is usual for this patient (i.e., it has occurred at least 3 times during the last month):

		YES	NO
1.	Non profitable damaging of own property	1	0
2.	Hides aggressive acts	1	0
3.	Exposes self to physical harm when aggressive	1	0
4.	Is aggressive without a purpose	1	0
5.	Can control own behavior when aggressive	1	0
6.	Aggression is unplanned, out of the blue	1	0
7.	Very careful to protect self when aggressive	1	0
8.	Completely out of control when aggressive	1	0
9.	Plans aggressive acts	1	0
10.	Steals	1	0

Scoring:

Predatory score: sum of items 2, 5, 7, 9, and 10
Affective score: sum of items 1, 3, 4, 6, and 8
Total score: difference of Predatory score minus Affective score/
Possible range of total score: from 5 (completely predatory) to –5 (completely affective)

Reference:

B. Vitiello et al. (1990), J. Neuropsychiatry Clin. Neurosciences 2:189-192.

10.4 **Kiddie-Sads-Present and Lifetime Version (K-SADS-PL) 2013**

K-SADS-PL 2013

Includes:

A. Screen Interview

B. Supplements

I. **Depressive and Bipolar Related Disorders Supplement**
II. **Schizophrenia Spectrum and Other Psychotic Disorders Supplement**
III. **Anxiety, Obsessive-Compulsive, and Trauma-Related Disorders Supplement**
IV. **Neurodevelopmental, Disruptive, and Conduct Disorders Supplement**
V. **Eating Disorders and Substance-Related Disorders Supplement**

Advanced Center for Intervention and Services Research (ACISR)
for Early Onset Mood and Anxiety Disorders
Western Psychiatric Institute and Clinic

Child and Adolescent Research and Education (CARE)
Program, Yale University

Subject

Date / / 20

Interviewer

ACKNOWLEDGEMENTS

The KSADS-PL 2013 was written by Joan Kaufman PhD, Boris Birmaher, MD, David Axelson, MD, Francheska Perepletchikova, PhD, David Brent, MD and Neal Ryan, MD. This version of the KSADS was revised to be compatible with DSM-5 diagnoses, and includes dimensional as well as categorical diagnostic assessments.

The authors extend appreciation to the many consultants who contributed to this instrument including Oscar Bukstein MD, John Campo MD, Carrie Christopher Fascetti, MSW, Andrew Gilbert MD, Benjamin Goldstein MD, Tina Goldstein PhD, Diane Goudreau, PhD, Megan Muir Grivas, MA, Ben Handen MD, Ami Klin, PhD, David Kolko PhD, Walter Kaye, MD, Rolf, Loeber, PhD, Catherine Lord, PhD, Martin Lubetsky MD, William Pelham, PhD, David Rosenberg, MD, Rita Scholle BA, Eunice Torres, MS, and John Walkup, MD. Special thanks are given to Denise Carter-Jackson and Jason Lyons, MA for the extensive reformatting of earlier version of this instrument.

The authors of the KSADS-PL 2013 acknowledge the prior authors and earlier versions of this instrument which laid the foundation of the current KSADS-PL: the K-SADS-P (Present Episode Version), which was developed by William Chambers, MD and Joaquim Puig-Antich, MD, and later revised by Joaquim Puig-Antich, MD and Neal Ryan, MD; the K-SADS-E by Helen Orvaschel, PhD and Joaquim Puig-Antich, MD, the K-SADS-PL by Joan Kaufman, PhD, Boris Birmaher, MD, David Brent, MD, Uma Rao, MD, and Neal Ryan, MD, and the KSADS-PL-2009 Working Draft was developed by David Axelson MD, Boris Birmaher MD, Jamie Belazny RN, MPH, Joan Kaufman PhD, and Mary Kay Gill MSN with support provided by the Advanced Center for Intervention and Services Research (ACISR, MH66371) PI: David Brent MD. . The current instrument is also greatly indebted to several other existing structured and semi-structured psychiatric instruments including the SADS-L (Spitzer and Endicott), the SCID (Spitzer, Williams, Gibbon, and First), the DIS (Robins and Helzer), the ISC (Kovacs), the DICA (Reich, Shayka, and Taibleson), and the DUSI (Tarter, Laird, Bukstein, and Kaminer). Guidelines for the introductory interview at the beginning of this instrument were initially provided by Michael Rutter, M.D. and Philip Graham, M.D., and refined with subsequent renditions of the KSADS.

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Screen Interview

Subject

Schedule for Affective Disorders and Schizophrenia for School Aged Children (6-18 Years)

Kiddie-SADS - Lifetime Version (K-SADS-PL 2013

The K-SADS-PL 2013 combines dimensional and categorical assessment approaches to diagnose current and past episodes of psychopathology in children and adolescents according to DSM-5 criteria. Prior to administering the interview portion of the K-SADS-PL, parents and children are to complete the DSM-5 cross-cutting 25-item symptom rating scales. Responses on these dimensional rating scales are then taken into account in completing the interview portion of the assessment. The primary diagnoses assessed with the K-SADS-PL 2013 include: Major Depression, Persistent Depression, Mania, Hypomania, Cyclothymia, Bipolar Disorders, Disruptive Mood Dysregulation Disorder, Schizoaffective Disorders, Schizophrenia, Schizophreniform Disorder, Brief Psychotic Disorder, Panic Disorder, Agoraphobia, Separation Anxiety Disorder, Simple Phobia, Social Anxiety Disorder, Selective Mutism, Generalized Anxiety, Obsessive Compulsive Disorder, Attention Deficit Hyperactivity Disorder, Conduct Disorder, Oppositional Defiant Disorder, Enuresis, Encopresis, Anorexia Nervosa, Bulimia, Binge Eating Disorder,Transient Tic Disorder, Tourette's Disorder, Chronic Motor or Vocal Tic Disorder, Alcohol Use Disorder, Substance Use Disorder, Post-Traumatic Stress Disorder, Adjustment Disorders, and Autism Spectrum Disorder.

The K-SADS-PL 2013 is a semi-structured interview. The probes that are included in the interview do not have to be, and should not be recited verbatim. Rather, they are provided to illustrate ways to elicit the information necessary to score each item. The interviewer should feel free to adjust the probes to the developmental level of the child, and use language supplied by the parent and child when querying about specific symptoms.

After reviewing parent and child responses on the DSM-5 cross-cutting rating scales, the K-SADS-PL 2013 is administered by interviewing the parent(s), the child, and finally achieving summary ratings which include all sources of information (parent, child, school, chart, and other). In general, when administering the instrument to pre-adolescents, conduct the parent interview first. In general, when working with adolescents, begin with them. There may be clinical reasons to alter the order of administration.

When there are discrepancies between different sources of information, the rater will have to use his/her best clinical judgment. In the case of discrepancies between parents' and child's reports, the most frequent disagreements occur in the items dealing with subjective phenomena where the parent does not know, but the child is very definite about the presence or absence of certain symptoms. This is particularly true for items like guilt, hopelessness, interrupted sleep, hallucinations, and suicidal ideation. If the disagreements relate to observable behavior (e.g. truancy, fire setting, or a compulsive ritual), as appropriate, the examiner should query the parent(s) and child about the discrepant information. Ultimately the interviewer will have to use his/her best clinical judgment in assigning the summary ratings.

The following guidelines should be used in coding symptoms:

1) *Current Diagnoses*: In coding current episodes (CE) of disorders, symptoms should be rated for the time period when they were the most severe during the episode. *Note in the margins if and when particular symptoms (e.g. insomnia) improved or resolved.* Patients typically present when symptoms are at the worst. In follow-up research assessments, symptoms may be in partial remission.
2) *Disorders Targeted with Medication*: In coding disorders treated with medication (e.g. ADHD), use the ratings to describe the most intense severity of symptoms experienced prior to initiation of medication, when medications wear off, or during 'drug holidays'. *Note in margins symptoms targeted effectively with medication.*
3) *Past Diagnoses*: In order for an episode to be considered 'resolved' or 'past', the child should have had a minimum of *two months* free from the symptoms associated with the disorder. Episodes rated in the past disorders section should represent the most severe past (MSP) episode experienced of that given disorder.
4) *Time Line*: For children with a history of recurrent or episodic disorders, it is recommended that a time line be generated to chart lifetime course of disorder and facilitate scoring of symptoms associated with each episode of illness.

In the process of completing the full interview, diagnoses initially believed to be 'past' may turn out to be current diagnoses in partial remission. Corrections in the coding of current and past severity ratings can be made after completion of the interview.

Administration of the K-SADS-PL 2013 requires the completion of: 1) the parent and child DSM-5 cross-cutting symptoms measures (DSM-5 CC-SM); 2) an unstructured Introductory Interview; 3) a Diagnostic Screening Interview; 4) the Supplement Completion Checklist; 5) the appropriate Diagnostic Supplements; andd6) the Summary Lifetime Diagnostic Checklist. The K-SADS-PL is initially completed with each informant separately. If there is no suggestion of current or past psychopathology, no assessments beyond the Screen Interview will be necessary. The Summary Lifetime Diagnostic Checklist is completed after synthesizing all the data and resolving discrepancies in informants' reports. Each of the phases of the KSADS-PL interview is discussed briefly below.

1) The DSM-5 Cross-Cutting Symptom Measures (DSM-5 CC-SM). The DSM-5 CC-SM are designed to be self-report measures completed independently by the parent and child before beginning the KSADS interview. Scores on these self-report scales should be reviewed and recorded in the spaced provided before beginning the interview portion of the KSADS. The DSM-5 CC-SM include 25-items that assess symptom severity over the past two weeks. The parent and child DSM-5 CC-SM are included at the end of the KSADS. The American Psychiatric Association recommends specific follow-up measures that can be completed if threshold scores are obtained on the 25-item DSM-5 CC-SM, and several disorder specific severity scales. These additional scales can be accessed at: http://www.psychiatry.org/practice/dsm/dsm5/online-assessment-measures#Level1, but do not need to be completed as part of the KSADS diagnostic assessment.

2) The Unstructured Introductory Interview. This section of the K-SADS-PL 2013 takes approximately 10 to 15 minutes to complete. In this section, the parent provides information about health, presenting complaint and prior psychiatric treatment data, and both the parent and the child are surveyed about the child's school functioning, hobbies, and peer and family relations. Discussion of these latter topics is extremely important, as it provides a context for eliciting mood symptoms (depression and irritability), and obtaining information to evaluate functional impairment. This section of the K-SADS-PL should be used to establish rapport with the parent(s) and the child, and should never be omitted.

3) The Screen Interview. The Screen Interview surveys the primary symptoms of the different diagnoses assessed in the K-SADS-PL 2013. Specific probes and scoring criteria are provided to assess each symptom. *The rater is not obliged to recite the probes verbatim, or use all the probes provided, just as many as is necessary to score each item.* Probing should be as neutral as possible, and leading questions should be avoided (e.g. "You don't feel sad, do you?")

Symptoms rated in the screen interview are surveyed for *current* (CE) and *most severe past* (MSP) episodes simultaneously. Begin by asking if the child has *ever* experienced the symptom. If the answer is no, rate the symptom negative for current and past episodes and proceed to the next question. If the answer is yes, find out when the symptom was present. If the symptom is endorsed for one time frame (e.g. currently), inquire if it was ever present at another time (e.g. past).

The diagnoses assessed with the screen interview do not have to be surveyed in order. The interviewer may begin inquiring about relevant diagnoses suggested by the presenting complaint information obtained during the unstructured interview. All sections of the Screen Interview must be completed, however, and most people find it easiest to proceed from start to finish.

Skip Out Criteria. After the primary symptoms associated with each diagnosis are surveyed in the Screen Interview, skip out criteria are delineated for current and past episodes of the disorder. A space is provided to indicate if the child met the skip out criteria, or if the child has clinical manifestations of the primary symptoms associated with the specific diagnosis. If the child failed to meet the skip out criteria for some diagnoses, the appropriate supplements should be administered after the Screen Interview is completed in its entirety.

Scoring. While interviewers are free to utilize latitude in the manner in which symptoms are queried, the scoring criteria are to be applied rigidly. The majority of the items in the K-SADS-2013 are scored using a 0–3 point rating scale. Scores of 0 indicate no information is available, scores of 1 suggest the symptom is not present, scores of 2 indicate subthreshold levels of symptomatology, and scores of 3 represent threshold criteria. The remaining items are rated on a 0-2 point rating scale on which 0 implies no information, 1 implies the symptom is not present, and 2implies the symptom is present. When determining whether a symptom meets threshold vs subthreshold level criteria, it is important to assess the severity, frequency, and duration of the symptom, as well as impairment from the symptom. It is often helpful to ask for examples of specific behaviors or symptoms. To attain a threshold score of 3, the child must meet or exceed the threshold scoring criteria. If his symptom severity falls between the threshold and subthreshold criteria, the symptom would be rated subthreshold; a score of 2.

Subthreshold Symptoms While subthreshold manifestations of symptoms are not sufficient to count toward the diagnosis of a disorder, further inquiry may be warranted in certain cases. Subthreshold scores of psychotic symptoms or clusters of other symptoms associated with a given diagnosis should be brought to the attention of the attending physician or research supervisor. If subthreshold scores are attained on multiple items within a given diagnostic section of the Screen Interview, the supplement for that section can be completed to further assess relevant clinical symptomatology.

4) Supplement Completion Checklist. The Supplement Completion Checklist is on the last page of this Screen Interview. It should be torn off before starting the interview. Supplements requiring completion should be noted in the spaces provided, together with the dates of possible current and past episodes of disorder.

5) Diagnostic Supplements. There are five Diagnostic Supplements included with the K-SADS-PL: Supplement #1: Depressive and Bipolar Related Disorders; Supplement #2: Schizophrenia Spectrum and Other Psychotic Disorders; Supplement #3: Anxiety, Obsessive Compulsive, and Trauma-Related Disorders; Supplement #4: Neurodevelopmental, Disruptive, and Conduct Disorders; Supplement #5: Eating Disorders and Substance-Related Disorders. The format of the KSADS with its Screen Interview and five Diagnostic Supplements is designed to facilitate differential diagnoses, with the Screen Interview providing a good overview of potentially relevant diagnostic categories before surveying symptoms associated with the different disorders in detail.

The diagnoses surveyed in each of these supplements are outlined in the Supplement Completion Checklist, and in the Table of Contents at the beginning of each supplement. The skip out criteria in the Screening Interview specify which supplements, if any, should be completed. Like in the Screen Interview, each supplement has a list of symptoms, probes, and criteria to assess current (CE) and most severe past (MSP) episodes of disorder.

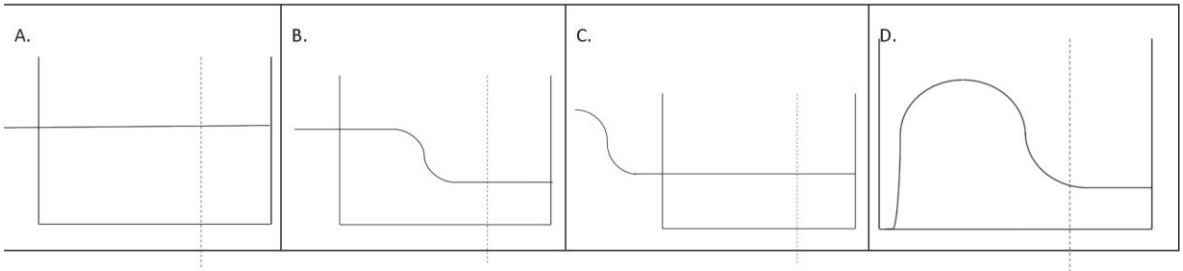
Supplements should be administered in the order that symptoms for the different diagnoses appeared. For example, if the child had evidence of Attention Deficit Hyperactivity Disorder (ADHD) beginning at age 5, and possible Major Depression (MDD) beginning at age 9, the Supplement for ADHD should be completed before the supplement for MDD. If the child had a history of attention difficulties associated with ADHD, when inquiring about concentration difficulties in assessing MDD, it is important to find out if the onset of depressive symptoms was associated with a worsening of the long standing concentration difficulties. If there was no change in attention problems with the onset of the depressive symptoms, the symptom concentration difficulties should not be rated positively in the MDD supplement.

When the time course of disorders overlap, supplements for disorders that may influence the course of other disorders should be completed first. For example, if there is evidence of substance use and possible Mania or Psychosis, the substance abuse supplement should be completed first, and care should be taken to assess the relationship between substance use and possible manic and/or psychotic symptoms.

6) The Summary Lifetime Diagnostic Checklist is a template that was designed to record basic lifetime and current diagnostic information. Clinicians / Investigators may wish to record additional, more specific information (e.g., dates of onset/offset or duration of additional episodes). The Follow-up Summary Diagnostic Checklist is a template designed to record longitudinal course of illness. These template checklists are included at the end of the supplements of the KSADS.

Using the K-SADS in Longitudinal Studies. When the KSADS is used to monitor subjects longitudinally, it is important to be sure that the symptoms and diagnoses are being scored since the last interview. The timeframe for the Current ratings needs to be defined, based on the aims of the study. For example, the Current period could be the month prior to the interview (or 2 weeks, or 2 months, etc.). Then symptoms and diagnoses are rated for the most symptomatic time during the current period. Past symptoms and diagnoses are rated based on the most severe symptomatology between the last interview and whatever time is defined as the Current rating period. These rules are more relevant for episodic disorders such as depression and mania/hypomania. It is recommended that each study define *a priori* the timeframes to be used in administering the KSADS for longitudinal assessments. Results from the follow-up interviews can then be recorded on the Longitudinal Summary Diagnostic Checklist. The longitudinal summary diagnostic checklist may require some modifications by Investigators to accommodate the aims, methodology, and outcome definitions (e.g., remission, recovery, remission, recurrence) utilized in each study.

As depicted below, the KSADS can be used to characterize subject's longitudinal course of illness. The space between the first two lines on the left side of each diagram below depicts the course of illness since the last assessment up to the "current episode" timeframe, and the space on the right side of each diagram depicts the characterization of the current (e.g., last two months) symptomatology.



Legend. A) Figure A depicts a child with a chronic course of illness from the last interview; B) Figure B depicts a child who met full criteria during the last interview and continued to meet criteria during his most severe past episode during the follow-up interval, then met partial remission criteria during the "current" time frame assessed at follow-up; C) Figure C depicts a child who was in partial remission but never went into full remission during the "past" or "current" follow-up intervals, and is currently in partial remission: D) Figure D depicts a child who had no diagnosis at the initial interview, and then had an onset of a full diagnosis during the follow-up, but met for partial remission during the "current" follow-up interval.

Guidelines for the Administration of the Introductory Unstructured Interview

The unstructured interview should take at least 15 minutes to administer. The aim of the unstructured interview is to establish rapport, obtain information about presenting complaints, prior psychiatric problems, and the child's global functioning. It is helpful to spend a few minutes in general conversation in order to make the child and parent feel at ease.

The interview opens with questions about basic demographics. This is a very easy thing for most people to talk about, and the information helps to orient the interviewer to the child's life circumstances. Health and developmental history data should also be obtained from the parent, as this information may be helpful in making differential diagnoses. The child does not need to be queried about these things.

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Subject Information *page v of xiv* ■

In discussing onset and course of symptoms, many children will be unable to provide reliable time data. This is developmentally normal. If the child does not provide such data in the first questioning, s/he will probably not provide it at all.

In interviewing the parent, modify the questions to refer to the child.

In the introductory interview and throughout the K-SADS, interviewers are encouraged to use language generated by the child and/or parent when asking about symptoms (e.g., "For how long did you feel bummed?")

After surveying the reason for referral, obtain information about treatment history. Then ask about the child's school adaptation and social relations.

In interviewing children, it is not necessary --- and usually not productive to try to complete all of the introductory interview. Review basic demographics (e.g. age, grade, family constitution, siblings' names and ages), presenting complaints (likely in less detail than with the parent), and family, school adaptation, and peer relations information. The discussion of these latter topics are extremely *important*, as it provides a context for eliciting mood symptoms (depression and irritability) from children, generate hypotehese about possible relevant diagostic areas, and obtain preliminary information to evaluate functional impairment.

SUBJECT INFORMATION

First Name: **Last Name:**

Date of Birth: / /

Gender: ○ Male ○ Female

Ethnicity: ○ Hispanic or Latino ○ Not Hispanic or Latino

Race *(Mark all that apply):* ○ Black or African American ○ Native Hawaiian or Pacific Islander
○ Asian ○ Native American or Alaskan Native
○ White or Caucasian
○ Other Specify:

With whom is subject currently living (choose one)?

○ Both biological parents	○ Biological father only	○ Group home
○ Both biological parents, but joint custody	○ Stepmother only	○ Residential institution
○ Biological mother and stepfather	○ Stepfather only	○ Boarding home
○ Biological father and stepmother	○ Grandparent	○ Runaway
○ Biological mother and boyfriend/girlfriend	○ Adoptive parent	○ College student
○ Biological father and boyfriend/girlfriend	○ Other relative/friend	○ Lives independently
○ Biological mother only	○ Foster home	○ Other

Subject

■ Date / / 2 0 Interviewer ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Caregiver Information *page v. of xiv*

PARENTAL PARTICIPATION:

Who is the informant/reporter for this interview?

O Both biological parents	O Adoptive mother	O Grandparent
O Biological mother	O Adoptive father	O Other relative
O Biological father	O Step-mother	O Other
O Both adoptive parents	O Step-father	

If Other, please specify:

SUBJECT'S PRIMARY CAREGIVER's

First Name: (lives with subject, if applicable) **Last Name:**

This is Subject's: O Biological Mother O Bio Father O Foster Mother O Foster Father
O Stepmother O Stefather O Aunt O Uncle O None O Other Specify:
O Adopted Mother O Adpted Father O Grandmother Grandfather

SUBJECT'S SECONDARY CAREGIVER's

First Name: (lives with subject, if applicable) **Last Name:**

This is Subject's: O Biological Father O Bio Mother O Foster Father O Foster Mother
O Stepfather O Stepmother O Uncle O Aunt O None O Other Specify:
O Adopted Father O Adopted Mother O Grandfather O Grandmother

BIOLOGICAL MOTHER

First Name: **Last Name:**

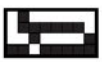
Does child live with biological mother: O Yes O No

If no, describe nature of contact/relationship:

O Mother deceased
O Mother alive, regular visitation
O Mother alive, sporadic contact
O Mother alive but no contact

Quality of Relationship:

O Excellent O Good O Fair O Poor

■ Subject [ ]  ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Caretaker / Sibling Information *page vii of xiv*

BIOLOGICAL FATHER

First Name: **Last Name:**

Does child live with biological mother: ○ Yes ○ No

If no, describe nature of contact/relationship:
- ○ Mother deceased
- ○ Mother alive, regular visitation
- ○ Mother alive, sporadic contact
- ○ Mother alive but no contact

Quality of Relationship:
○ Excellent ○ Good ○ Fair ○ Poor

SUBJECT'S SIBLINGS

First Name: **Last Name:**

Age: ○ Half sibling ○ Full sibling

Quality of Relationship between Sibling and Subject:
○ Excellent ○ Good ○ Fair ○ Poor

First Name: **Last Name:**

Age: ○ Half sibling ○ Full sibling

Quality of Relationship between Sibling and Subject:
○ Excellent ○ Good ○ Fair ○ Poor

First Name: **Last Name:**

Age: ○ Half sibling ○ Full sibling

Quality of Relationship between Sibling and Subject:
○ Excellent ○ Good ○ Fair ○ Poor

Of the people in your family, or among the people you live with, who would you say you are closet to? _____

_____

_____

■ Subject ■

2013 **KSADS-PL SCREEN INTERVIEW:**
Health Screen *page viii of xiv*

CHILD AND ADOLESCENT HEALTH SCREEN

PREGNANCY AND BIRTH:

1. Mother's age at birth of child ☐☐
2. Did mother have any illness or injury during pregnancy? O Yes O No
3. Did she take any medications other than vitamins and iron? O Yes O No
4. Did mother drink or use elicit drugs during pregnancy? O Yes O No
5. Did mother smoke during prgnancy? O Yes O No
6. Was the baby premature? (record # wks: _____) O Yes O No
7. What was the birth weight? ☐☐☐ lbs.
8. Did the baby have any trouble at birth? O Yes O No
9. Did the baby have any other trouble? (Jaundice, infections, other?) O Yes O No
10. How many days did the baby stay in the hospital after birth? ☐☐☐ days

MEDICAL AND SURGICAL HISTORY:

11. Current height: ☐ feet ☐☐ inches Weight: ☐☐☐.☐ lbs
12. Where does your child go for medical care?
13. Date of last medical exam: ☐☐ / ☐☐ / ☐☐☐☐
14. Has your child had allergic reactions to any medications? If ***YES***, please specify: O Yes O No
    Allergic reactions to foods? O Yes O No
    Allergic reactions to insect bites? O Yes O No
15. Has your child had all immunizations? O Yes O No
16. Any bad reactions to immunizations? O Yes O No

Subject ☐☐☐☐☐☐☐

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Medical / Developmental History *page ix of xiv*

MEDICAL AND SURGICAL HISTORY cont:

17. Any hospitalizations? If ***YES***, for what? O Yes O No

18. Any serious injuries? If ***YES***, what kind? O Yes O No

19. Any head injuries? (Indicate if your child lost consciousness): O Yes O No

20. Any other current or past significant medical health problems? If ***YES***, please specify: O Yes O No

DEVELOPMENTAL HISTORY:

1. Problems with social relatedness during infancy and early childhood: O Yes O No

If no, explain:

2. Developmental milestones within normal limits: O Yes O No

If no, explain:

■ Subject ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Presenting Complaint *page x of xiv* ■

_____
Clinician

_____
Supervising Physician/Supervising Researcher

☐☐ / ☐☐ / ☐☐☐☐
Date

Presenting Complaint:

2013 **KSADS-PL SCREEN INTERVIEW**
Family History for Biological Relatives *page xi of xiv*

Probe: Have you or anyone else in the family had psychiatric treatment before? For what sorts of problems?

Criteria:
0 = No Information
1 = Not Present
2 = Probable
3 = Definite

	Mother	Father	Sibling	Half-Sibling	Grandparent	Aunt/Uncle	Other
Psychiatric Tx	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Depression	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Mania	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
ADHD	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Conduct/Antisocial	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Schizophrenia	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Other Psychosis	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Alcohol Use Disorder	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Substance Use Dis.	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Autism Spectrum	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Suicide Attempt	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Suicide Completion	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Other	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Treatment / Medication Information *page xii of xiv* ■

LIFETIME TREATMENT HISTORY

		Age of first tx (in YEARS)	Age of first tx (in MONTHS)
Outpatient Treatment	○ No info ○ No ○ Yes		
Psychiatric Hosptialization	○ No info ○ No ○ Yes		
Partial Hospitalization	○ No info ○ No ○ Yes		
Residential Treatment Facility	○ No info ○ No ○ Yes		
In-Home Services Tx (e.g., Wrap Around/Family Based)	○ No info ○ No ○ Yes		

Number of Psychiatric Hospitalizations

OVERALL RELIABILITY OF INFORMATION:
☐ Good ☐ Fair ☐ Poor

Medication listing

		Past/Current				Past/Current	
1		○	○	7		○	○
2		○	○	8		○	○
3		○	○	9		○	○
4		○	○	10		○	○
5		○	○	11		○	○
6		○	○	12		○	○

■ Subject ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
School Information *page xiii of xiv*

School Information

Current Grade (or highest grade completed): ☐☐ Any Repeated Grades? List: ☐☐ ☐☐ ☐☐

Current School Setting:
- ○ Regular Public School
- ○ Regular Private School
- ○ Vocational-TechnicalSchool
- ○ Not in School
- ○ Specialized School for Youth with Emotional/Behavioral Problems
- ○ Cyber School
- ○ Home School
- ○ Other, specify: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Specialized Services:
- ○ Full-time Emotional Support Classroom
- ○ Full-time Learning Support Classroom
- ○ Full-time Aide
- ○ Tutoring Support
- ○ Other, specify: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
- ○ Special Education for specific subjects (partially mainstreamed)
- ○ Part-time Aide
- ○ Resource Room
- ○ Gifted Program

Recent Grades - Academic Classes:
Best: ○ A ○ B ○ C ○ D ○ F
Average: ○ A ○ B ○ C ○ D ○ F
Worst: ○ A ○ B ○ C ○ D ○ F

Subject Strengths: ☐

Subject Weaknesses: ☐

Concerns from teachers about behavior:
Detentions (past year): ☐☐☐
Suspensions (past year): ☐☐
Expulsions (ever): ○ yes ○ no If yes, how many? ☐☐

Reasons for Disciplinary Action (check all that apply):
_____ Fights in school
_____ Talking back to teachers
_____ Pulling fire alarm
_____ Threats of violence
_____ Other (specify)

Subject ☐☐☐☐☐☐☐

■ Date ☐☐ / ☐☐ / 2 0 ☐☐ Interviewer ☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Peer / Activities Information *page xiv of xiv* ■

Peer Relations

Best friend(s)? O yes O no

Relations with peers at school: O Excellent O Good O Fair O Poor

Relations with peers in the neighborhood: O Excellent O Good O Fair O Poor

Bullied by others? O Never/Rarely - not a problem O Sometimes - can be a problem
O Often - definite problem O Very Often - major problem

Other Activities / Interests

(Mark those that apply and specify)

O Hobbies 1 2

O Preferred Activies during free-time 1 3
2 4

O Sports 1 3
2 4

O Organizations 1 2

■ Subject ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Depression *page 1 of 52*

	P	C	S	
1. Depressed Mood	( )	( )	( )	**0 -** No information.
DSM-5 DR# 6: Felt down, depressed:	( )	( )	( )	**1 -** Not present. Not at all or less than once a week.
Parent Rating: _____ Child Rating: _____	( )	( )	( )	**2 -** Subthreshold: Depressed mood at least 2-3 days/ week, for much of the day.
	( )	( )	( )	**3 -** Threshold: Depressed mood, more days than not (4-7 days/week), most of the day (at least 50% of awake time.).

PAST: ☐ P ☐ C ☐ S

Have you ever felt sad, blue, down, or empty?
Did you feel like crying? When was that
Do you feel _____ now
Was there ever another time you felt _____
Did you have any other bad feelings
Did you have a bad feeling all the time that you couldn't get rid of
Did you cry or were you tearful? Did you feel (_____) all the time, some o the time? (Percent of awake time: summation of % of all labels if they do not occur simultaneously).
(Assessment of diurnal variation can secondarily clarify daily duration of depressive mood)
Did it come and go
How often? Every day?
How long did it last?
What do you think brought it on?
Could other people tell that you were sad?

Duration of Depressed Mood: (current) ☐☐☐

Duration of Depressed Mood: (most severe past) ☐☐☐

NOTE: SOMETIMES THE CHILD WILL INITIALLY GIVE A NEGATIVE ANSWER AT THE START OF THE INTERVIEW BUT WILL BECOME OBVIOUSLY SAD AS THE INTERVIEW GOES ON. THEN THESE QUESTIONS SHOULD BE REPEATED ELICITING THE PRESENT MOOD AND USING IT AS AN EXAMPLE TO DETERMINE ITS FREQUENCY. SIMILARLY, IF THE MOTHER'S REPORT IS THAT THE CHILD IS SAD MOST OF THE TIME AND THE CHILD DENIES IT, THE CHILD SHOULD BE CONFRONTED WITH THE MOTHER'S OPINION AND THEN ASKED WHY HE THINKS HIS MOTHER BELIEVES HE FEELS SAD SO OFTEN.

NOTE: WHEN A CHILD OR PARENT REPORTS FREQUENT SHORT PERIODS OF SADNESS THROUGHOUT THE DAY, IT IS LIKELY THAT THIS CHILD IS ALWAYS SAD AND ONLY REPORTS THE EXACERBATIONS, IN WHICH CASE THE RATING OF DEPRESSIVE MOOD WILL BE 4. THUS, IT IS ALWAYS ESSENTIAL TO ASK ABOUT THE REST OF THE TIME: "Besides these times when you felt (_____), during the rest of the time, did you feel happy or were you more sad than your friends?"

Subject ☐☐☐☐☐☐☐

■ Date ☐☐ / ☐☐ / 2 0 ☐☐ Interviewer ☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Depression *page 2 of 52*

	P	C	S
2. Irritability and Anger	( )	( )	( )
DSM-5 DR# 7: Felt more irritated than usual:	( )	( )	( )
Pamtt Rating: _____ Child Rating: _____	( )	( )	( )
	( )	( )	( )

0 - No information

1 - Not present. Not at all or less than once a week.

2 - Subthreshold: Feels definitely more angry or irritable than called for by the situation at least (2-3 days/week), for much of the day.

3 - Threshold: Feels irritable/angry, more days than not, (4-7 days/week), most of the day (at least 50% of awake time.).

PAST: ☐ ☐ ☐
P C S

Was there ever a time when you got annoyed, irritated, or cranky at little things?
Did you ever have a time when you lost your temper a lot? When was that?
Are you like that now? Was there ever another time you felt _____?
What kinds of things made you _____?
Were you feeling mad or angry also (even if you didn't show it)?
How angry?
More than before?
What kinds of things made you feel angry?
Did you sometimes feel angry and/or irritable and/or cranky and didn't know why?
Did this happen often?
Did you lose your temper?
With your family?
Your friends?
Who else?
At school?
What did you do?
Did anybody say anything about it?
How much of the time did you feel angry, irritable, and/or cranky?
All of the time?
Lots of the time?
Just now and then?
None of the time?

When you got mad, what did you think about?
Did you think about killing others or hurting yourself? Or about hurting them or torturing them? Whom? Did you have a plan? How?

NOTE: IRRITABILITY MAY BE DUE TO OTHER DISORDERS, e.g., BIPOLAR DISORDER, ADHD, ODD, CD, SUBSTANCE ABUSE, ASD.

Duration of Irritable Mood (current)
☐☐☐

Duration of Irritable Mood (most severe past)
☐☐☐

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Depression *page 3 of 52*

	P	C	S
3. Anhedonia, Lack of interest, Apathy, Low Motivation, or Boredom	( )	( )	( )
DSM-5 DR# 5: Has less fun doing things:	( )	( )	( )
Parent Rating: _____ Child Rating: _____	( )	( )	( )
	( )	( )	( )

0 - No information.

1 - Not present.

2 - Subthreshold: Several activities definitely less pleasurable or interesting. Or bored or apathetic at least 3 times a week during activities.

3 - Threshold: Most activities much less pleasurable or interesting. Or bored or apathetic daily, or almost daily, at least 50% of the time.

PAST: ☐ ☐ ☐
P C S

Boredom is a term all children understand and which frequently refers to loss of ability to enjoy (anhedonia) or to loss of interest or both. Loss of pleasure and loss of interest are not mutually exclusive and may coexist.

What are the things you do for fun? Enjoy?
(Get examples: nintendo, sports, friends, favorite games, school subjects, outings, family activities, favorite TV programs, computer or video games, music, dancing, playing alone, reading, going out, etc.).

Has there ever been a time you felt bored a lot of the time? When
Do you feel bored a lot now
Was there another time you felt bored a lot
Did you feel bored when you thought about doing the things you usually like to do for fun? (Give examples mentioned above).
Did this stop you from doing those things
Did you (also) feel bored while you were doing things you used to enjoy

Anhedonia refers to partial or complete (pervasive) loss of ability to get pleasure, enjoy, have fun during participation in activities which have been attractive to the child like the ones listed above. It also refers to basic pleasures like those resulting from eating favorite foods and, in adolescents, sexual activities.

Did you look forward to doing the things you used to enjoy? (Give examples)
Did you try to get into them
Did you have to push yourself to do your favorite activities
Did they interest you
Did you get excited or enthusiastic about doing them? Why not
Did you have as much fun doing them as you used to before you began feeling (sad, etc.)
If less fun, did you enjoy them a little less? Much less? Not at all
Did you have as much fun as your friends
How many things are less fun now than they used to be (use concrete examples provided earlier by child)
How many were as much fun? More fun
Did you do _____ less than you used to? How much less

In adolescents: (if sexually active) *Do you enjoy sex as much as you used to? Are you less sexually active than you used to be*

This item does not refer to inability to engage in activities (loss of ability to concentrate on reading, games, TV, or school subjects)

Two comparisons should be made in each assessment: Enjoyment as compared to that of peers and/or enjoyment as compared to that of child when not depressed. The second is not possible in episodes of long duration because normally children's preferences change with age. Severity is determined by the number of activities which are less enjoyable to the child, and by the degree of loss of ability to enjoy.

Do not confuse with lack of opportunity to do things which may be due to excessive parental restrictions.

Duration of Anhedonia: (current)
☐☐☐

Duration of Anhedonia: (past)
☐☐☐

■ Subject ☐☐☐☐☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Suicide *page 4 of 52*

4a. Recurrent Thoughts of Death

Sometimes children who get upset or feel bad, wish they were dead or feel they'd be better off dead.
Have you ever had these type of thoughts? When?
Do you feel that way now?
Was there ever another time you felt that way?

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Infrequent thoughts of death (e.g. less than once per month, vague, non-specific).
( )	( )	( )	**3 -** Threshold: Recurrent thoughts of death, "I would be better off dead" or "I wish I were dead."

PAST: ☐ P ☐ C ☐ S

4b. Suicidal Ideation

DSM-5 DR# 24: Thoughts of committing suicide

Parent Rating: _____ Child Rating: _____

Sometimes children who get upset or feel bad think about dying or even killing themselves.
Have you ever had such thoughts?
How would you do it?
Did you have a plan?

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not at all.
( )	( )	( )	**2 -** Subthreshold: Infrequent or vague thoughts of suicide (e.g., less than once per month).
( )	( )	( )	**3 -** Threshold: Recurrent thoughts of suicide.

PAST: ☐ P ☐ C ☐ S

4c. Suicidal Acts - Intent

DSM-5 DR# 25: Ever tried to kill self

Parent Rating: _____ Child Rating: _____

Have you actually tried to kill yourself? When?
What did you do?
Any other things?
Did you really want to die?
How close did you come to doing it?
Was anybody in the room? In the apartment?
Did you tell them in advance?
How were you found? Did you really want to die?
Did you ask for any help after you did it?

NOTE: CODE SELF-HARMING BEHAVIOR WITH NO INTENT TO DIE AS NON-SUICIDAL, SELF-INJURIOUS BEHAVIOR - NOT AS SUICIDAL BEHAVIOR.

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** No attempt.
( )	( )	( )	**2 -** Subthreshold: Preparations with no actual intent to die (e.g., held pills in hand) or planned attempt but did not follow through or engage in self harming behavior.
( )	( )	( )	**3 -** Threshold: Self injurious behavior with ANY suicidal intent. (If subject endorses even a 1% intent to die, code as threshold here).

PAST: ☐ P ☐ C ☐ S

Ever attempted suicide: ○ Yes ○ No

Number of lifetime attempts meeting threshold of (3): ☐☐☐

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Suicide *page 5 of 52*

4d. Suicidal Acts - Medical Lethality

Actual medical threat to life or physical condition following the most serious suicidal act. Take into account the method, impaired consciousness at time of being rescued, seriousness of physical injury, toxicity of ingested material, reversibility, amount of time needed for complete recovery and how much medical treatment needed.

How close were you to dying after your (most serious suicidal act)?
What did you do when you tried to kill yourself?
What happened to you after you tried to kill yourself?

NOTE: CODE SELF-HARMING BEHAVIOR WITH NO INTENT TO DIE AS NON-SUICIDAL, SELF-INJURIOUS BEHAVIOR - NOT AS SUICIDAL BEHAVIOR.

	P	C	S
	( )	( )	( )
	( )	( )	( )
	( )	( )	( )
	( )	( )	( )

0 - No information.
1 - No attempt or engaged in behavior with no intent to die (e.g., held pills in hand). No medical damage.
2 - Subthreshold: superficial cuts, scratch to wrist, took a couple of extra pills.
3 - Threshold: Medical intervention occurred or was indicated; or significant cut with bleeding, or took more than a couple of pills.

PAST: ☐ P ☐ C ☐ S

4e. Non-suicidal, Self-Injurious Behavior

Refers to intentional self-inflicted damage to the surface of the body, of a sort likely to induce bleeding or pain for purposes that are not socially sanctioned AND done without intent of killing himself, with the expectation that the injury will lead to only minor or moderate physical harm.

Did you ever try to hurt yourself?
Have you ever burned yourself with matches/candles?
Or scratched yourself with needles/ a knife? Your nails?
Or put hot pennies on your skin?
Anything else?
Why did you do it?
How often?
Do you have many accidents?
What kind?
How often?

Some kids do these types of things because they want to kill themselves, and other kids do them because it makes them feel a little better afterwards. Why do you do these things?

	P	C	S
	( )	( )	( )
	( )	( )	( )
	( )	( )	( )
	( )	( )	( )

0 - No information.
1 - Not present.
2 - Subthreshold: Once. Has engaged in the behavior on 1-4 occasions. Has never caused serious injury to self.
3 - Threshold: Repetitive. Has engaged in the behavior more than 5 times and/or has engaged in the behavior with significant injury to self (e.g., burn left scar, cut required stitches).

PAST: ☐ P ☐ C ☐ S

— **IF RECEIVED A SCORE OF 3 ON CURRENT RATING OF ANY OF THE PREVIOUS ITEMS, COMPLETE THE DEPRESSIVE/DYSTHYMIC DISORDERS (CURRENT) SECTION OF THE DEPRESSIVE AND BIPOLAR RELATED DISORDERS SUPPLEMENT, AFTER FINISHING THE SCREEN INTERVIEW.**

— **IF RECEIVED A SCORE OF 3 ON PAST RATING OF ANY OF THE PREVIOUS ITEMS, COMPLETE THE DEPRESSIVE/DYSTHYMIC DISORDERS (PAST) SECTION OF DEPRESSIVE AND BIPOLAR RELATED DISORDERS SUPPLEMENT, AFTER FINISHING THE SCREEN INTERVIEW.**

— **NO EVIDENCE OF DEPRESSIVE/DYSTHYMIC DISORDER.**

NOTE: (RECORD DATES OF POSSIBLE CURRENT AND PAST DEPRESSIVE DISORDERS).

■ Subject ☐☐☐☐☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Mania / Hypomania *page 6 of 52* ■

P C S

1. Elevated, Elated, or Expansive Mood

( ) ( ) ( ) **0 -** No information.

( ) ( ) ( ) **1 -** Not present.

( ) ( ) ( ) **2 -** Definitely elevated and optimistic outlook that is somewhat out of proportion to the circumstances (above and beyond what is expected in a child of the subject's age). Occurs less than 4 hours in a day and/or for fewer than 3 separate days.

( ) ( ) ( ) **3 -** Mood and outlook are clearly out of proportion to circumstances. Noticeable to others and perceived as odd or exaggerated. Occurs for at least 4 hours out of a day for at least 2 consecutive days or on at least 3 separate days within one week.

PAST: ☐ ☐ ☐
P C S

Elevated mood and/or excessively optimistic attitude which is out of proportion to circumstances and above and beyond what is expected in children of the same age or same developmental level. **Differentiate from normal mood in chronically depressed subjects. Do not rate positive if mild elation is reported in situations like Christmas, birthdays, going to amusement parks, which normally overstimulate and make children very excited.**

NOTE: DO NOT SCORE POSITIVELY IF ELATED MOOD IS EXCLUSIVELY DUE TO DRUGS, MEDICATIONS, OR ANY OTHER PSYCHIATRIC OR MEDICAL CONDITION.

Has there ever been a time when you felt super happy or on top-of-the world? Way more than your normal happy feeling?
Did the super-happy feeling seem to come out of the blue?
Have there been times when you were super silly, much more silly than everyone else around you?
Were you laughing about things that normally you would not find funny?
Did it feel like you couldn't stop laughing?
Did it seem like you were drunk or high, even though you weren't taking drugs or alcohol?
Did other people notice?
Have your friends ever said anything to you about being way too happy, too silly or too high?
Did you feel super-positive, like nothing could go wrong?
Did you have the feeling that everything was terrific and would turn out just the way you wanted?
Did you feel really excited or full of enthusiasm but there really was not a reason to feel this way?
Can you give me some examples?
How long did this feeling usually last?
Would it come and go throughout the day?
Did you ever have problems or get in trouble for being too happy or high?

Ask Parent/Caregiver: *Was this above and beyond what you would see in his/her friends or other kids of the same age or developmental level in the same circumstances?*

P C S

2. Explosive Irritability / Anger

( ) ( ) ( ) **0 -** No information.

( ) ( ) ( ) **1 -** Not present.

( ) ( ) ( ) **2 -** Subthreshold: Definite periods of excessively irritable/angry mood. Anger / Irritability is out of proportion for the situation and occurs for much of the day or intensely for a brief period (< 1 hour).

( ) ( ) ( ) **3 -** Threshold: Episodes of explosive irritability / anger that are far out of proportion to any stressor or stimuli - has associated aggressive behavior (e.g. threats, property destruction or physical aggression). Occurs on at least 2 consecutive days or on at least 3 separate days within one week.

PAST: ☐ ☐ ☐
P C S

DSM-5 DR# 8: Felt angry or lost your temper:

Parent Rating: _____ Child Rating: _____

Was there ever a time you were so irritable and angry that you exploded?
When you are feeling really mad, do you throw things or break things
Tear your room apart
Have you ever punched a hole in the wall when you were angry
When you got really angry, did you ever threaten or actually hurt a parent or a teacher? What about other kids or pets
What was going on at the time when this happened? What set you off?
Have there been times when you got super angry without knowing why or over little things that you normally would not get upset about?

***NOTE**: Only rate irritiability and explosiveness in this item that occurs during distinct episode(s) and represents a change from baseline. Do not rate chronic irritability of one year duration or longer unless there was a marked change in intensity during a distinct period of time.*

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Mania / Hypomania *page 7 of 52*

3. Increased Energy or Activity

DSM-5 DR #9: Starting lots more projects

. Parent Rating:_____: Child Rating::_____

Has there ever been a time where you had much more energy than usual, so much energy that it felt like too much? What kinds of things were you doing when that happened?
Was there a change in how much you were doing ?
Did it seem like you were doing too many things or were super hyper?
How long did that feeling last? Did other people notice it?
Was it different than other people around you?
Did anything seem to cause that feeling?
Was there anything else different about you during the time of high energy - your speed of talking, thinking, any thing else?

	P	C	S
0 - No information.	( )	( )	( )
1 - Not present.	( )	( )	( )
2 - Subthreshold: Brief period(s) of increased energy, or mild intensification from baseline (or) likely caused by environmental stimulus; of questionable clinical significance.	( )	( )	( )
3 - Threshold: Definite episodes of clear increased energy or activity, well beyond baseline or far in excess of same age peers in the same situation.	( )	( )	( )

PAST: ☐ P ☐ C ☐ S

NOTE: IF THE CHILD HAS ADHD OR IS VERY ACTIVE AND ENERGETIC AT BASELINE, ONLY RATE POSITIVE IF THIS IS A DISTINCT PERIOD OF SUBSTANTIAL INCREASE IN ENERGY.

NOTE: The (hypo)manic symptom of increased energy should only be rated as positive if it is associated with an abnormal mood (e.g. elation or irritability). If the symptom is only questionably associated with an abnormal mood, then it should be rated as subthreshold.

4. Decreased Need for Sleep

DSM-5 DR 3: PProblems falling asleep, staying asleep, or waking early:

Parent Rating:_____:_____Child Rating::_____

~~DSM-5 DR 10: Sleeping~~ less than usual, still have energy:

Parent Rating:_____ Child Rating::_____:_____

Less sleep than usual yet still feels rested (average for several days when needs less sleep).

Have you ever needed less sleep than usual to feel rested?
How much sleep do you ordinarily need?
How much had you been sleeping?
Did you stay up because you felt especially high or energetic? Were you with friends or by yourself? Had you taken any drugs? Were you up busy doing things?
What time did you wake up?
Were you tired the next day, or did you have plenty of energy and did not seem to need the sleep?

NOTE: DO NOT SCORE POSITIVELY IF DECREASED NEED FOR SLEEP TRIGGERED BY SOCIAL EVENT OR ACADEMIC COMMITMENTS OR DRUG USE, OR REFLECTIVE OF TYPICAL IRREGULAR ADOLESCENT SLEEP PATTERN.

	P	C	S
0 - No information.	( )	( )	( )
1 - Not present.	( )	( )	( )
2 - At least 1 1/2 hours less than usual without feeling tired, for at least 2 consecutive days, or at least 3 separate days.	( )	( )	( )
3 - At least 3 hours less than usual because he/she felt energetic or high and did not feel tired. Occurs for at least 2 consecutive days, or on at least 3 separate days within one week.	( )	( )	( )

PAST: ☐ P ☐ C ☐ S

■ Subject ☐☐☐☐☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Mania / Hypomania *page 8 of 52*

5. Hypersexuality

[Excessive Involvement in High Risk Pleasurable Activities]

NOTE: HYPERSEXUALITY IN THE ABSENCE OF SEXUAL ABUSE OR INAPPROPRIATE EXPOSURE TO SEXUAL BEHAVIOR OR MEDIA IS A SYMPTOM FAIRLY SPECIFIC TO MANIC/HYPOMANIA. IT IS NOT A SEPARATE DSM-5 DIAGNOSTIC CRITERION, BUT WHEN PRESENT, IT CAN POTENTIALLY FULFILL EITHER BOTH THE INCREASED GOAL-DIRECTED ACTIVITY AND THE RISKY, PLEASURE-SEEKING BEHAVIOR B CRITERION.

For younger children ask parent/caregiver:
Have there been times when your child was excessively focused on sex, nudity, his/her private parts or touching others' private parts?
Did your child show an unusual increase in touching their privates in public or dressing in an inappropriate or sexual manner?
Would your child kiss or touch you in a sexual way or be way too affectionate instead of their usual way of showing affection?
What was his/her mood like during these times?
Did anything happen to cause these changes?

For adolescents:
Have there been times when you suddenly got much more interested in sex than usual or that your sex drive seemed to go way up?
Did you do anything differently when this happened (dress in a revealing way, talk about sex a lot or ask other people to be intimate / have sex with you)?
Were there times when you were driven to have sex much more than usual or with many different partners?

NOTE: IF ENDORSED POSITIVE, NEED TO RULE OUT SEXUAL ABUSE OR INAPPROPRIATE EXPOSURE TO SEXUAL MATERIAL OR BEHAVIOR.

P	C	S	
( )	( )	( )	**0** - No information.
( )	( )	( )	**1** - Not present.
( )	( )	( )	**2** - Isolated, brief incidents of mildly inappropriate sexual behavior, of questionable clinical significance.
( )	( )	( )	**3** - Definite episodes of clearly inappropriate sexual behavior.

PAST: ☐ ☐ ☐
P C S

_ **IF RECEIVED A SCORE OF 3 ON THE CURRENT RATINGS FOR ANY OF THE PREVIOUS ITEMS, COMPLETE THE CURRENT MANIA/HYPOMANIA SECTION OF THE DEPRESSIVE AND BIPOLAR RELATED DISORDERS SUPPLEMENT.**

_ **IF RECEIVED A SCORE OF 3 ON THE PAST RATINGS FOR ANY OF THE PREVIOUS ITEMS, COMPLETE THE PAST MANIA/HYPOMANIA SECTION OF THE DEPRESSIVE AND BIPOLAR RELATED DISORDERS SUPPLEMENT.**

_ **NO EVIDENCE OF (HYPO) MANIA**

NOTES: (RECORD DATES OF POSSIBLE CURRENT AND PAST HYPOMANIA OR MANIA).

■ Subject ☐☐☐☐☐☐☐  ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Disruptive Mood Dysregulation Disorder *page 9 of 52*

1. Irritability

Do you often feel cranky, irritable, or angry? Have you had these feelings in the past few weeks at all? Have you felt this way most days in the past year? (If not) How often do you have these feelings? Has there been a period of time when you didn't have those feelings for as long as a couple of months at a time?
When you are feeling cranky or angry, how much of the day do you feel this way?
Do you have these feelings at home, at school, or when you are with other children? Do other people notice the way you feel? What do your parents, teachers, or peers say about how you are feeling?

NOTE: IN THIS SECTION CODE SEVERITY OF CHRONIC IRRITABILITY OF ONE YEAR DURATION OR LONGER

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Irritable mood present less than half the day or less than most days in the past 12 months, or not severe enough to be noticeable to other people
( )	( )	( )	**3 -** Threshold: Irritable and/or angry mood present at least half the day most days for at least 12 months. Severity is sufficient to be noticeable to other people (parents, teachers, peers).

PAST: ☐ ☐ ☐
P C S

2. Recurrent Temper Outbursts

Is it pretty easy or common for you to become irritable, angry, or to explode? When you are feeling very angry, do you yell or scream? Do you swear a lot, call people names or put them down? Do you throw or destroy things? Have you ever threatened or actually hurt another person? Did you punch, kick, or beat anyone?
What was going on at the time when this happened? What set you off?
Have you felt so irritable and angry for so long that you exploded at least 3 times a week for the past year or even longer?

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Verbal or physical outbursts have not occurred as often as 3 times a week or have not persisted for as long as 12 months.
( )	( )	( )	**3 -** Threshold: Subject has verbal rages, and/or displays aggressive behaviors toward people or property. Such events occur, on average, at least 3 times a week and have been consistently present over the past 12months.

PAST: ☐ ☐ ☐
P C S

_ **IF RECEIVED A SCORE OF 3 ON THE CURRENT RATINGS ON EITHER OF THE PREVIOUS ITEMS, COMPLETE THE DYSRUPTIVE MOOD DYSREGULATION DISORDER (CURRENT) SECTION OF THE DEPRESSIVE AND BIPOLAR RELATED DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.**

_ **IF RECEIVED A SCORE OF 3 ON THE PAST RATINGS ON EITHER OF THE PREVIOUS ITEMS, COMPLETE THE DYSRUPTIVE MOOD DYSREGULATION DISORDER (PAST) SECTION OF THE DEPRESSIVE AND BIPOLAR RELATED DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.**

_ **NO EVIDENCE OF DYSRUPTIVE MOOD DYSREGULATION DISORDER**

NOTES: (RECORD DATES OF POSSIBLE CURRENT AND PAST DYSRUPTIVE MOOD DYSREGULATION DISORDER)

Subject ☐☐☐☐☐☐☐

■ Date ☐☐ / ☐☐ / 2 0 ☐☐ Interviewer ☐☐☐ ■

2013 **KSADS-PL SCREEN INTERVIEW:**
Psychosis *page 10 of 52*

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Suspected or likely.
( )	( )	( )	**3 -** Threshold: Definitely present.

PAST: ☐ P ☐ C ☐ S

1. Hallucinations

DSM-5 DR# 14: Heard Voices:

Parent Rating: _____ Child Rating: _____

DSM-5 DR# 15: Had visions:

Parent Rating: _____ Child Rating: _____

Has there ever been a time when your mind played tricks on you?
Sometimes children might hear voices or see things, or smell things that other people cannot hear, see or smell.
Has this ever happened to you? Tell me about it.

Has there ever been a time when you heard voices that other people could not hear?
What did you hear? What kind of things did you hear?
Did you ever hear music which other people could not?

Has there ever been a time when you saw things like people or figures that other people could not see? If yes ... can you tell me about it
What did you see? How often did it happen? When did it happen
Did this only happen at night while you were trying to sleep, or did it happen in the daytime too

Has there ever been a time when you smelled things that other people can't smell or felt things that weren't there?

What did you think it was?
Did you think it was your imagination or real?
Did you think it was real when you (heard, saw, etc.) it?

What did you do when you (heard, saw, etc.) it
These voices you heard (or other hallucinations), did they occu
when you were awake or asleep? Could it have been a dream
Did they happen when you were falling asleep? Waking up? Only when it was dark? Did they happen at any other time also
Were you sick with fever when they occurred
Have you ever been drinking beer, wine, liquor? Or taking any drugs when it happened
Was it like a thought or more like a voice (noise) or a vision

NOTE: IF HALLUCINATIONS POSSIBLY PRESENT, PRIOR TO SCORING THIS ITEM, ASSESS THE SUBJECT'S CONVICTION OF THE REALITY IF THE HALLUCINATIONS WITH THE PROBES BELOW.

NOTE: IF HALLUCINATIONS ARE PRESENT, *CAREFULLY ASSESS* TIMELINE TO DETERMINE IF IN RELATION TO MOOD SYMPTOMS OR INDEPENDENT OF MOOD SYMPTOMS. THIS WILL FACILITATE DIFFERENTIAL DIAGNOSIS.

NOTE: DO NOT RATE AS POSITIVE IF ONLY ENDORSES HAVING HEARD SOMEONE CALLING THEIR NAME OCCURRING ONLY ONCE OR TWICE.

DON'T RATE ILLUSIONS POSITIVELY. Illusions are defined as false perceptions based on a real sensory stimuli which is momentarily transformed. They frequently occur due to poor perceptual resolution (darkness, noisy locale) or inattention and they are immediately corrected when attention is focused on the external sensory stimulus or perceptual resolution improves.

NOTE: TAKE INTO ACCOUNT CULTURAL BACKGROUND OF THE SUBJECT.

NOTE: IT IS IMPORTANT TO NOTE IF THE CHILD IS ACTING ON HALLUCINATIONS.

Subject ☐☐☐☐☐☐☐

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Psychosis *page 11 of 52*

	P	C	S	
2. Delusions	( )	( )	( )	**0 -** No information.
	( )	( )	( )	**1 -** Not present.
	( )	( )	( )	**2 -** Subthreshold: Suspected or likely delusional.
	( )	( )	( )	**3 -** Threshold: Definite delusions.

PAST: ☐ P ☐ C ☐ S

Have you ever had any ideas about things that you didn't tell anyone because you were afraid they might not understand?
What were they?
Do you have any secret thoughts? Tell me about them.
Have you ever believed in things that other people didn't believe in? Like what?

Ask about each of the delusions surveyed below:

Has there ever been a time you felt that someone was out to hurt you or that someone was following you or spying on you? Who? Why?
Does anyone control your mind or body (like a robot)?
Did you ever think you were an important or great person?
Do you have any special powers?
When you are with people you do not know, do you think that they are talking about you?
Was there ever a time when you felt something was happening to your body? Like believing it was rotting from the inside, or that something was very wrong with it?
Did you ever feel convinced that the world was coming to an end?
How often did you think about _____?

NOTE: IF DELUSIONS ARE PRESENT, CAREFULLY ASSESS THE TIMELINE TO DETERMINE IF IN RELATION TO MOOD SYMPTOMS OR INDEPENDENT OF MOOD SYMPTOMS. THIS WILL FACILITATE THE DIAGNOSIS.

_ **IF RECEIVED A SCORE OF 3 ON THE CURRENT RATINGS ON EITHER OF THE PREVIOUS ITEMS, COMPLETE THE CURRENT SECTION OF THE SCHIZOPHRENIA SPECTRUM AND OTHER PSYCHOTIC DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.**

_ **IF RECEIVED A SCORE OF 3 ON THE PAST RATINGS ON EITHER OF THE PREVIOUS ITEMS, COMPLETE THE PAST SECTION OF THE SCHIZOPHRENIA SPECTRUM AND OTHER PSYCHOTIC DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.**

_ **NO EVIDENCE OF PSYCHOSIS.**

NOTES: (RECORD DATES OF POSSIBLE CURRENT AND PAST HALLUCINATIONS AND DELUSIONS).

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Panic Disorder *page 12 of 52*

	P	C	S
1. Panic Attacks	( )	( )	( )
DSM-5 DR# 11: Felt nervous, anxious, or scared:	( )	( )	( )
Parent Rating: _____ Child Rating: _____	( )	( )	( )

Have you ever had a time when, all of a sudden, out of the blue, for no reason at all, you suddenly felt anxious, nervous, or frightened? Tell me about it.
The first time you had an attack like this, what did you think brought it on?
Did the feeling come from out of the blue?
Wha t was it like?
How long did it last?
After the first time this happened, did you worry about it happening again?

( ) ( ) ( ) **3 -** Threshold: Recurrent unexpected attacks with four or more associated symptoms.

0 - No information.

1 - Not present.

2 - Subthreshold: Occasional unanticipated attacks, or less than 4 of the associated symptoms

PAST: ☐ ☐ ☐
P C S

Note: DSM-V does not have threshold criteria for the minimum number of attacks..

If specific symptoms are not elicited spontaneously when describing attacks, ask about each of the following symptoms:

Associated Symptoms:

1. heart palpitations,
2. sweating,
3. trembling or shaking,
4. sensations of shortness of breath, or smothering sensations,
5. feelings of choking,
6. chest pains,
7. nausea or abdominal distress,
8. dizziness or lightheadedness,
9. heat sensations or chills,
10. numbing of hands or feet,
11. depersonalization or derealization,
12. fear of losing control.
13. fear of dying,

NOTE: DO NOT COUNT IF LASTS ALL DAY OR DIRECTLY CAUSED BY DRUGS OR MEDICATIONS.

— **IF A SCORE OF 3 ON CURRENT RATING OF PANIC ATTACK ITEM, COMPLETE THE PANIC DISORDER (CURRENT) SECTION OF THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.**

— **IF A SCORE OF 3 ON PAST RATING OF PANIC ATTACK ITEM, COMPLETE THE PANIC DISORDER (PAST) SECTION OF THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.**

— **NO EVIDENCE OF PANIC DISORDER.**

NOTES: (RECORD DATES OF POSSIBLE CURRENT AND PAST PANIC DISORDER).

■ Subject ☐☐☐☐☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Agoraphobia *page 13 of 52*

1. Agoraphobia

Marked fear or anxiety about at least one situation from two or more of the following five groups: 1) being outside home or alone in other situations; 2) standing in line or being in a crowd; 3) being in closed spaces (e.g., shops, theaters or cinemas); 4) open spaces (e.g., parking lots, marketplaces, bridges); 5) using public transportation.

Have you ever gone through a period when you did not want to leave your home? Have you ever been really afraid of being in a crowded place or going outside in public? Were you bothered by standing in lines? Were you ever afraid to go to the mall, movie theatres, or any other places? Did being in open spaces bother you?
Have you ever avoided public transportation including buses or subways? Did these feelings last for several months or longer?

NOTE: RATE POSITIVELY ONLY IF BEHAVIOR IS ABOVE AND BEYOND WHAT WOULD BE EXPECTED IN CHILDREN OF SAME AGE AND DEVELOPMENTAL LEVEL.

Do not rate positively if exclusively accounted for by other psychiatric disorders (i.e. psychosis, depression) separation anxiety, social anxiety or medical problems.

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Fear limited to one situation or fear only mild or transient, but more severe than a typical child his/her age.
( )	( )	( )	**3 -** Threshold: Fears two mor more situations and fears have persisted and are are clearly out of proportion to the circumstances.

PAST: ☐ ☐ ☐
P C S

2. Distress / Avoidance

How scared did ____ make you?
Did it make your stomach upset or your heart race? How long did ___ last?
Are you more scared of ____ than any of your friends?
Has there ever been a time when your fear of ____ kept you from doing anything?
Did you try to avoid ____?
Were there times you could ____?
If someone was with you, could you ____?

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Associated with only mild transient symptoms of distress. Minimal or inconsistent avoidance.
( )	( )	( )	**3 -** Threshold: Feared stimuli or situations associated with moderate to severe symptoms of distress. Stimuli or situations consistently avoided or requires presence of companion/support..

PAST: ☐ ☐ ☐
P C S

_ **IF RECEIVED A SCORE OF 3 ON THE CURRENT RATINGS ON EITHER OF THE PREVIOUS ITEMS, COMPLETE THE AGORAPHOBIA (CURRENT) SECTION OF THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.**

_ **IF RECEIVED A SCORE OF 3 ON THE PAST RATINGS ON EITHER OF THE PREVIOUS ITEMS, COMPLETE THE AGORAPHOBIA (PAST) SECTION OF THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.**

_ **NO EVIDENCE OF AGORAPHOBIA.**

NOTES: (RECORD DATES OF POSSIBLE CURRENT AND PAST AGORAPHOBIA)

Subject ☐☐☐☐☐☐☐

■ Date ☐☐ / ☐☐ / 2 0 ☐☐ Interviewer ☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Separation Anxiety *page 14 of 52*

NOTE: KEEP IN MIND THE DEVELOPMENTAL LEVEL OF THE CHILD. RATE POSITIVELY ONLY IF SYMPTOM IS ABOVE AND BEYOND WHAT WOULD BE EXPECTED IN A CHILD OF THE SAME AGE AND DEVELOPMENTAL LEVEL.

1. Fears Calamitous Event that will Cause Separation

Did you ever worry that something bad might happen to you where you would never see your parents again? Like getting lost, kidnapped, killed, or getting into an accident?
How much do you worry about this?

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Occasionally worries. Worries more severely and more often than a typical child his/her age.
( )	( )	( )	**3 -** Threshold: Frequently worries in separation situations. Persistent and excessive worry that an untoward event will lead to separation from major attachment figure.

PAST: ☐ P ☐ C ☐ S

2. Fears Harm Befalling Attachment Figure

Has there ever been a time when you worried about something bad happening to your parents? Like what?
Were you afraid of them being in an accident or getting killed?
Were you afraid that they would leave you and not come back?
How much did you worry about this?

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Occasionally worries. Worries more severely and more often than a typical child his/her age.
( )	( )	( )	**3 -** Threshold: Frequently worries in separation situations. Persistent and excessive worry about losing, or about possible harm befalling major attachment figure.

PAST: ☐ P ☐ C ☐ S

3. School Reluctance/Refusal

Was there ever a time when you had to be forced to go to school?
Did you have worries about going to school? Tell me about those feelings.
What were you afraid of?
Had you been going to school?
How often did you miss school or did you leave school early?

NOTE: ONLY COUNT IF SCHOOL AVOIDED IN ORDER TO STAY WITH ATTACHMENT FIGURE

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Frequently somewhat resistant about going to school but usually can be persuaded to go, missed no more than 1 day in 2 weeks.
( )	( )	( )	**3 -** Threshold: Protests intensely about going to school, or sent home or refuses to go at least 1 day per week. Persistent reluctance or refusal to go to school.

PAST: ☐ P ☐ C ☐ S

■ Subject ☐☐☐☐☐☐☐  ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Separation Anxiety *page 15 of 52*

	P	C	S	
4. Fears Sleeping Away From Home/Sleeping Alone	( )	( )	( )	**0 -** No information.
Has there ever been a time after the age of four, when you were afraid of sleeping alone?	( )	( )	( )	**1 -** Not present.
Did you get scary feelings if you had to sleep away from home without your parents being with you? *Do you move to your parent's bed in the middle of the night?* *Or do you need your parent to sleep in your bedroom?* *Do you avoid sleepovers?*	( )	( )	( )	**2 -** Subthreshold: Occasionally fearful. Fears of sleeping away or alone more severe and more frequent than a typical child his/her age.
	( )	( )	( )	**3 -** Threshold: Frequently fearful, some avoidance of sleeping alone or away from home. Persistent refusal to go to sleep without being near a major attachment figure or to sleep away from home.

PAST: ☐ ☐ ☐
P C S

	P	C	S	
5. Fears Being Alone at Home	( )	( )	( )	**0 -** No information.
Was there ever a time, after the age of 4, when you used to follow your mother wherever she went?	( )	( )	( )	**1 -** Not present.
Did you get upset if she was not in the same room with you? *Did you cling to your mother?* *Did you check up on your mother a lot?* *Did you always want to know where your mother was?* *How afraid were you?* *How often did this happen?*	( )	( )	( )	**2 -** Subthreshold: Occasionally fearful. Fears of being alone more severe and more frequent than a typical child his/her age.
	( )	( )	( )	**3 -** Threshold: Clings to mother; fearful, some avoidance of being alone. Persistent and excessively fearful or reluctant to be alone or without major attachment fugures at home.

PAST: ☐ ☐ ☐
P C S

_ **IF RECEIVED A SCORE OF 3 ON THE CURRENT RATINGS OF ANY OF THE PRECEDING ITEMS, COMPLETE THE SEPARATION ANXIETY DISORDER (CURRENT) SECTION IN THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.**

_ **IF RECEIVED A SCORE OF 3 ON THE PAST RATINGS OF ANY OF THE PRECEDING ITEMS, COMPLETE THE SEPARATION ANXIETY DISORDER (PAST) SECTION IN THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.**

_ **NO EVIDENCE OF SEPARATION ANXIETY DISORDER.**

NOTE: (RECORD DATES OF POSSIBLE CURRENT AND PAST SEPARATION ANXIETY DISORDER)

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Social Anxiety/Selective Mutism Disorder *page 16 of 52* ■

1. Fear of Social Situations

Are you a very shy person?
Have you ever felt nervous, self-conscious or shy around people that you didn't know very well?
Is it difficult for you to be with other kids - even kids you know?
What kind of situations make you feel uncomfortable?

__ *Speaking in front of others (e.g. answering questions in class, giving oral reports, show & tell)?*
__ *Eating in front of others (e.g. school cafeteria, fast food restaurant)?*
__ *Writing in front of others (e.g. at chalkboard, taking tests)?*
__ *Using public bathrooms when others are around?*
__ *Performance situations (e.g., gym class, recess, sports activities)?*
__ *Changing clothes when others are present (e.g., in gym/pool locker room)?*
__ *Going to parties or social events?*

How old were you when you first started to feel this way?
For how long have you been feeling this way?

NOTE: SHYNESS AND FEAR OF SOCIAL SITUATIONS MUST BE SIGNIFICANTLY AFFECTING THE CHILD. DO NOT RATE POSITIVELY IF EXCLUSIVELY ACCOUNTED FOR BY ANOTHER PSYCHIATRIC DISORDER (i.e., AUTISM SPECTRUM DISORDER)

How old were you when you first started to feel this way?
For how long have you been feeling this way?

	P	C	S
0 - No information.	( )	( )	( )
1 - Not present.	( )	( )	( )
2 - Subthreshold: Clearly self-conscious and uncomfortable in social performance situations; avoids only 1 or 2 activities that are not critical to the child's well being (e.g. avoiding large parties where child knows no one).	( )	( )	( )
3 - Threshold: Considerable self-consciousness that makes the child uncomfortable in several social settings; at least 1 activity is avoided (e.g., repeatedly and persistently refusing to answer questions in class, avoiding gatherings where child does not know everyone). A marked and persistent fear of social performance situations - fears acting in a way (or showing anxiety symptoms) that will be humiliating or embarrassing. **DO NOT CODE AS THRESHOLD IF THE CHILD'S ONLY FEAR IS GIVING ORAL PRESENTATIONS AT SCHOOL.**	( )	( )	( )

PAST: ☐ ☐ ☐
P C S

2. Failure to Speak in Specific Social Situations

Have you ever felt like you couldn't talk in school or other situations?
Have you ever felt so shy that you just couldn't say anything? Even to another kid?
Are there certain situations that you just can't talk in?

0 - No information.	( )	( )	( )
1 - Not present.	( )	( )	( )
2 - Subthreshold: Child unable to speak in novel situations, including the start of school year, but symptom does not persist.	( )	( )	( )
3 - Threshold: Consistent failure to speak in social situations when expected to speak.	( )	( )	( )

PAST:
P C S

__ **IF RECEIVED A SCORE OF 3 ON THE CURRENT RATINGS OF THE PREVIOUS ITEM, COMPLETE THE SOCIAL ANXIETY DISORDER/SELECTIVE MUTISM (CURRENT) SECTION IN THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT AFTER COMPLETING THE SCREEN INTERVIEW.**

__ **IF RECEIVED A SCORE OF 3 ON THE PAST RATINGS OF EITHER ITEM, COMPLETE THE SOCIAL ANXIETY DISORDER/SELECTIVE MUTISM (PAST) SECTION IN THEANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT AFTER COMPLETING THE SCREEN INTERVIEW.**

__ **NO EVIDENCE OF SOCIAL ANXIETY DISORDER**

NOTES: (RECORD DATES OF POSSIBLE CURRENT AND PAST SOCIAL ANXIETY OR SELECTIVE MUTISM DISORDER)

■ Subject ☐☐☐☐☐☐☐  ■

2013

KSADS-PL SCREEN INTERVIEW:
Specific Phobias

page 17 of 52

Only rate most intense phobia.

	P	C	S
1. Specific Phobias	( )	( )	( )
Are you very, very afraid of anything?	( )	( )	( )
Like really, really scared to death of spiders, other insects, dogs, horses, heights, elevators, the subway, or the dark?	( )	( )	( )
What about crowds, being outside alone, being on a bridge or traveling in a bus, train or automobile? (ask about all situations listed).			
Were you afraid of any other things?	( )	( )	( )

0 - No information.

1 - Not present.

2 - Subthreshold: Fear of stimuli or situation more severe than a typical child his/her age.

3 - Threshold: Marked and persistent fear that is excessive and unreasonable, cued by the presence or anticipation of a specific object or situation.

PAST: ☐ P ☐ C ☐ S

	P	C	S
2. Distress/Avoidance	( )	( )	( )
How scared did ___ make you?	( )	( )	( )
Did it make your stomach upset or your heart race?			
How long did ___ last?	( )	( )	( )
Are you more scared of ___ than any of your friends?			
Has there ever been a time when your fear of ___ kept you from doing anything?			
Did you try to avoid ___?	( )	( )	( )
Were there times you could ___?			
If someone was with you, could you ___?			

0 - No information.

1 - Not present.

2 - Subthreshold: Associated with only mild transient symptoms of distress. Minimal or inconsistent avoidance.

3 - Threshold: Fear of stimuli or situation associated with moderate to severe symptoms of distress. Feared stimuli or situation consistently avoided.

PAST: ☐ P ☐ C ☐ S

Specify most intense phobia:

Specify other phobias:

_ **IF RECEIVED A SCORE OF 3 ON THE CURRENT RATINGS OF EITHER OF THE PREVIOUS ITEMS, COMPLETE THE SPECIFIC PHOBIA (CURRENT) SECTION IN THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT AFTER COMPLETING THE SCREEN INTERVIEW.**

_ **IF RECEIVED A SCORE OF 3 ON THE PAST RATINGS OF EITHER OF THE PREVIOUS ITEMS, COMPLETE THE SPECIFIC PHOBIA (PAST) SECTION IN THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT AFTER COMPLETING THE SCREEN INTERVIEW.**

_ **NO EVIDENCE OF SPECIFIC PHOBIAS**

NOTES: (RECORD DATES OF POSSIBLE CURRENT AND PAST SPECIFIC PHOBIC DISORDERS)

Subject | | | | | | | |

2013 ■

KSADS-PL SCREEN INTERVIEW:
Generalized Anxiety Disorder

page 18 of 52 ■

1. Excessive worries

	P	C	S
	( )	( )	( )
	( )	( )	( )
	( )	( )	( )
	( )	( )	( )

0 - No information.

1 - Not present.

2 - Subthreshold: Frequently worries somewhat excessively (at least 3 times per week) about anticipated events or current behavior.

3 - Threshold: Most days of the week is excessively worried about at least two different life circumstances or anticipated events or current behavior.

PAST: ☐ P ☐ C ☐ S

DSM-5 DR# 12: Not been able to stop worrying:

Parent Rating: _____ Child Rating: _____

Are you a worrier? Do you worry too much?
Do you worry more than other kids your age? Have people said you worry too much?
Has there ever been a time when you worried about things before they happened?
Can you give me some examples?

NOTE: IF THE ONLY WORRIES THE CHILD BRINGS UP RELATE TO THE ATTACHMENT FIGURE OR A SIMPLE PHOBIA, DO NOT SCORE HERE. ONLY RATE POSITIVELY IF THE CHILD WORRIES ABOUT MULTIPLE THINGS.

In order to rate positively, child must worry above and beyond other children of the same age. Worries must be exaggerated and out of context.

2. Somatic Complaints

	P	C	S
	( )	( )	( )
	( )	( )	( )
	( )	( )	( )
	( )	( )	( )

0 - No information.

1 - Not present.

2 - Subthreshold: occasional worries /complaints. Symptoms/complaints more severe and more often than experienced by a typical child his/her age.

3 - Threshold: Frequent worries /complaints. Worres about health preoccupy child and cause distress.

PAST: ☐ P ☐ C ☐ S

DSM-5 DR# 1: Bothered by stomachaches, etc.:

Parent Rating: _____ Child Rating: _____

DSM-5 DR# 2: Worried about getting sick:

Parent Rating: _____ Child Rating: _____

Do you worry a lot about your health?
Do you get a lot of headaches? Stomachaches?
Have a lot of aches and pains?
Do you worry that you might have a serious illness?

NOTE: DO NOT COUNT IF SYMPTOMS ARE KNOWN TO BE CAUSED BY A REAL MEDICAL ILLNESS.

Subject ☐☐☐☐☐☐☐

■ Date ☐☐ / ☐☐ / 2 0 ☐☐ Interviewer ☐☐☐ ■

_ IF RECEIVED A SCORE OF 3 ON THE CURRENT RATINGS OF EITHER OF THE PREVIOUS ITEMS, COMPLETE THE GENERALIZED ANXIETY DISORDER (CURRENT) SECTION IN THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.

_ IF RECEIVED A SCORE OF 3 ON THE PAST RATINGS OF EITHER OF THE PREVIOUS ITEMS, COMPLETE THE GENERALIZED ANXIETY DISORDER (PAST) SECTION IN THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRA - RELATED DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.

— NO EVIDENCE OF GENERALIZED ANXIETY DISORDER.

NOTES: RECORD DATES OF POSSIBLE CURRENT AND PAST GENERALIZED ANXIETY DISORDER).

2013 **KSADS-PL SCREEN INTERVIEW:**
Obsessive-Compulsive Disorder *page 20 of 52*

P	C	S	
( )	( )	( )	0 - No information.
( )	( )	( )	1 - Not present.
( )	( )	( )	2 - Subthreshold: Suspected or likely.
( )	( )	( )	3 - Threshold: Definite obsessions, causes some effect on functioning or distress.

PAST: ☐ P ☐ C ☐ S

1. Obsessions

DSM-5 DR# 16: Recurrent thoughts that you would do something bad or something bad would happen to you or someone else:

Parent Rating: _____ Child Rating: _____

DSM-5 DR# 18: Worried a lot that things you touch were dirty, etc:

Parent Rating: _____ Child Rating: _____

Recurrent and intrusive thoughts, impulses, or images that, are distressing and debilitating and over which the person has little control.

Has there ever been a time when thoughts popped into your mind over and over and you couldn't get rid of them
Has there ever been a time when you were bothered by thoughts, "pictures" or words which kept coming into your head for no reason and that yo couldn't stop or get rid of
Did you ever worry a lot about having dirt or germs on your hands, or worry that you might get ill from dirt or germs
Did you ever worry about doing things perfectly or about making things even or arranging things in a certain way
What about thoughts that something bad might happen, or that you did something terrible, even though you knew it wasn't true
ny other types of thoughts that kept running around your mind
What about silly thoughts, words, or numbers which wouldn't go away
How often did you think about them
Were they like a hiccup that won't go away, just kept coming again and again
re these thoughts annoying to you
Did they not seem to make any sense
Do these thoughts get in your way or stop you from doing things

NOTE: DO NOT SCORE OBSESSIONS ITEMS POSITIVELY IF IDEAS /THOUGHTS ARE DELUSIONAL, OR ARE EXCLUSIVELY DUE TO ANOTHER AXIS I DISORDER (e.g. thoughts of food in the presence of an eating disorder; thoughts that parents will get harmed in the presence of a separation anxiety disorder; increased worries from GAD). DO NOT RATE POSITIVELY IF SAYS, "I cannot stop thinking about boy/girlfriend or music."

Subject ☐☐☐☐☐☐☐

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Obsessive-Compulsive Disorder *page 21 of 52*

	P	C	S
2. Compulsions	( )	( )	( )
DSM-5 DR# 17: Felt the need to check thinkgs over and over again, etc:	( )	( )	( )
Parent Rating: _____ Child Rating: _____	( )	( )	( )
DSM-5 DR# 19: Felt you had to do things in a certain way, like counting, etc	( )	( )	( )
Parent Rating: _____ Child Rating: _____			

0 - No information.
1 - Not present.
2 - Subthreshold: Suspected or likely.
3 - Threshold: Definite compulsions, causes some effect on functioning or distress.

PAST: ☐ P ☐ C ☐ S

Recurrent intrusive, repetitive, purposeful behaviors performed in response to an obsession, according to certain rules, or in stereotyped fashion that are distressing and debilitating and over which the person has little control.

Has there ever been a time when you found yourself having to do things that seemed silly over and over, or things which you could not resist repeating like touching things, or counting or washing your hands many times, or checking locks or other things?
Have you ever found yourself having to repeat certain actions over and over?
Did you feel you had any control over them? Did these things bother you?
Were there things you always felt you had to do exactly the same way or in a special way?
Did you ever have trouble finishing your school work because you had to read parts of an assignment over and over or because you were writing and re-writing your homework over and over again?
Did you ever have trouble making it to school on time because it takes too long to get ready in the morning?
If you made a mistake on your school work, did you have to start at the beginning?
What about when you went to sleep, did you have to check something several times before you fell asleep?
Or did you have to arrange things in your room in a particular way?
Have other people ever commented about these habits?

NOTE: DO NOT RATE POSITIVELY IF BEHAVIOR IS EXCLUSIVELY ACCOUNTED FOR BY ANOTHER DISORDER (e.g., PDD, Asperger's, tics, psychosis, eating disorder).

_ **IF RECEIVED A SCORE OF 3 ON CURRENT RATINGS OF EITHER OBSESSIONS OR COMPULSIONS ITEM, COMPLETE OBSESSIVE COMPULSIVE DISORDER (CURRENT) SECTION IN THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT AFTER FINISHING SCREEN INTERVIEW.**

_ **IF RECEIVED A SCORE OF 3 ON PAST RATINGS OF EITHER OBSESSIONS OR COMPULSIONS ITEM, COMPLETE OBSESSIVE COMPULSIVE DISORDER (PAST) SECTION IN THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT AFTER FINISHING SCREEN INTERVIEW.**

_ **NO EVIDENCE OF OBSESSIVE COMPULSIVE DISORDER.**

NOTES: (RECORD DATES OF POSSIBLE CURRENT AND PAST OBSESSIVE COMPULSIVE DISORDER).

■ Subject ☐☐☐☐☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Enuresis *page 22 of 52*

1. Repeated Voiding

A lot of kids sometimes have accidents and wet their beds when they sleep at night. Has there ever been a time when this happened to you?
Did you ever have accidents during the day?
What about if you laughed or sneezed real hard?

a. Night time

How often did this happen at night?

P	C	S	
( )	( )	( )	**0** - No information.
( )	( )	( )	**1** - Not present.
( )	( )	( )	**2** - At least one to four times a month for three or more months.
( )	( )	( )	**3** - At least two times a week for three consecutive months.

PAST: ☐ ☐ ☐ (P C S)

b. Daytime

How often did this happen during the day?

P	C	S	
( )	( )	( )	**0** - No information.
( )	( )	( )	**1** - Not present.
( )	( )	( )	**2** - At least one to four times a month for three or more months.
( )	( )	( )	**3** - At least two times a week for three consecutive months.

PAST: ☐ ☐ ☐ (P C S)

c. Total

Estimate frequency of combined nighttime and daytime accidents.

NOTE: Do not rate positively if enuresis due to medical condition.

P	C	S	
( )	( )	( )	**0** - No information.
( )	( )	( )	**1** - Not present.
( )	( )	( )	**2** - At least one to four times a month for three or more months.
( )	( )	( )	**3** - At least two times a week for three consecutive months.

PAST: ☐ ☐ ☐ (P C S)

_ **IF RECEIVED A SCORE OF 3 OR ABOVE ON THE CURRENT RATINGS OF ANY OF THE PREVIOUS ITEMS, COMPLETE THE QUESTIONS ON THE FOLLOWING PAGE.**

_ **IF RECEIVED A SCORE OF 3 OR ABOVE ON THE PAST RATINGS OF ANY OF THE PREVIOUS ITEMS, COMPLETE THE QUESTIONS ON THE FOLLOWING PAGE.**

_ **IF NO EVIDENCE OF ENURESIS, GO TO ENCOPRESIS SECTION ON PAGE 24.**

Subject ☐☐☐☐☐☐☐

■ Date ☐☐ / ☐☐ / 2 0 ☐☐ Interviewer ☐☐☐ ■

2013 **KSADS-PL SCREEN INTERVIEW:**
Enuresis *page 23 of 52*

Distress

What did you usually do when you had an accident? Did you tell your mom? Your teacher? What did they do? Did the kids at school know you sometimes had accidents? How much did it bother you when you had an accident?

Impairment: (home, school, peers)

Duration: (specify)

2. Evidence of Enuresis

DSM-5 Criteria

A. Repeated voiding of urine into bed or clothes, whether involuntary or intentional;
B. The behavior is clinically significant as manifested by either a frequency of twice a week for at least three consecutive months, or the presence of clinically significant distress or impairment in social, academic (occupational), or other important areas of functioning;
C. Chronological age is at least 5 years (or equivalent developmental level);
D. The behavior is not attributable physiological effect of a substance (e.g., a diuretic, an antipsychotic medication) or another medical condition (e.g., diabetes, spina bifida, a seizure disorder).

— **MEETS DSM-5 CRITERIA FOR ENURESIS (CURRENT). (Scored 3 plus impairment).**

Specify: Nocturnal Only: _____ Diurnal Only: _____ Nocturnal and Diurnal: _____

— **MEETS DSM-5 CRITERIA FOR ENURESIS (PAST). (Scored 3 plus impairment).**

Specify: Nocturnal Only: _____ Diurnal Only: _____ Nocturnal and Diurnal: _____

NOTES: (RECORD DATES OF CURRENT AND PAST ENURESIS).

Subject

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Encopresis *page 24 of 52*

1. Repeated Passage of Feces

Some kids have accidents and soil their beds when they sleep at night. Did this ever happen to you?
Has there ever been a time when you had accidents and went to the bathroom in your pants during the day?
What about when you were really scared, or for some reason couldn't get to a bathroom when you needed to?
What kinds of accidents were you having?
Number one or number two?

NOTE: ONLY RATE POSITIVELY IF THERE ARE STOOLS IN THE PATIENT'S UNDERWEAR.

a. Night time

How often did this happen at night?

P	C	S	
( )	( )	( )	**0** - No information.
( )	( )	( )	**1** - Not present.
( )	( )	( )	**2** - Subthreshold: Less than 1 time a month.
( )	( )	( )	**3** - Threshold: 1 or more times a month for at least 3 months.

PAST: ☐ P ☐ C ☐ S

b. Daytime

How often did this happen during the day?

P	C	S	
( )	( )	( )	**0** - No information.
( )	( )	( )	**1** - Not present.
( )	( )	( )	**2** - Subthreshold: Less than 1 time a month.
( )	( )	( )	**3** - Threshold: 1 or more times a month for at least 3 months.

PAST: ☐ P ☐ C ☐ S

c. Total

Estimate total number of nighttime and daytime accidents.

P	C	S	
( )	( )	( )	**0** - No information.
( )	( )	( )	**1** - Not present.
( )	( )	( )	**2** - Subthreshold: Less than 1 time a month.
( )	( )	( )	**3** - Threshold: 1 or more times a month for at least 3 months.

PAST: ☐ P ☐ C ☐ S

_ **IF RECEIVED A SCORE OF 3 OR ABOVE ON THE CURRENT RATINGS OF ANY OF THE PREVIOUS ITEMS, COMPLETE THE QUESTIONS ON THE FOLLOWING PAGE.**

_ **IF RECEIVED A SCORE OF 3 OR ABOVE ON THE PAST RATINGS OF ANY OF THE PREVIOUS ITEMS, COMPLETE THE QUESTIONS ON THE FOLLOWING PAGE.**

_ **IF NO EVIDENCE OF ENCOPRESIS, GO TO ANOREXIA NERVOSA SECTION ON PAGE 26.**

■ Subject ☐☐☐☐☐☐☐ ■

2013 **KSADS-PL SCREEN INTERVIEW:**
Encopresis *page 25 of 52*

Distress

What did you usually do when you had an accident? Did you tell your mom? Your teacher? What did they do? Did the kids at school know you sometimes had accidents? How much did it bother you when you had an accident?

Impairment: (home, school, peers)

Duration: (specify)

2. Evidence of Encopresis

DSM-5 Criteria

A. Repeated passage of feces into inappropriate places (e.g. clothing or floor) whether involuntary or intentional;
B. At least one such event occurs each month for at least 3 months;
C. Chronological age is at least 4 years (or equivalent developmental level);
D. The behavior is not attributable to the physiological effect of a substance (e.g., laxatives) or another medical condition except through a mechanism involving constipation.

— **MEETS DSM-5 CRITERIA FOR ENCOPRESIS (CURRENT).**
Specify: ___ With constipation and overflow incontinenece or ___ Without constipation and overflow incontinenece

— **MEETS DSM-5 CRITERIA FOR ENCOPRESIS (PAST).**
Specify: ___ With constipation and overflow incontinenece **or** ___ Without constipation and overflow incontinenece

NOTES: (RECORD DATES OF CURRENT AND PAST ENCOPRESIS).

Subject

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Eating Disorders *page 26 of 52*

Begin this section with a brief (2-3 minute) semi-structured interview to obtain information about eating habits:

Are you happy with your weight?
Do you eat regular meals? Are you a dieter?
Has there ever been a time when you weighed a lot more or a lot less?
What was your weight? What did you want your weight to be?

1. Fear of Becoming Obese

Has there ever been a time when you were afraid of getting fat?
Did you believe you were fat?
Have you ever been really overweight?
Did you watch what you ate and think about what you ate all the time?
Were you afraid of eating certain foods because you were afraid they'd make you fat? What foods?
How much time did you spend thinking about food and worrying about getting fat?
If you saw that you had gained a pound or two, did you change your eating habits?
Fast for a day or do anything else?

NOTE: KEEP IN MIND DIFFERENTIAL DIAGNOSES OF ANXIETY DISORDER, OCD, AND PSYCHOSIS.

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Intense and persistent fear of becoming fat, which defies prior weight history and/or present weight, reassurance, etc. Fears have only moderate impact on behavior and/or functioning (e.g., weight loss methods utilized at least once a month, but less than once a week).
( )	( )	( )	**3 -** Threshold: Intense and persistent fear of becoming fat, that has severe impact on behavior and/or functioning (e.g., constantly pre-occupied with weight concerns; or use of weight loss methods 1 time a week or more).

PAST: ☐ ☐ ☐
P C S

2. Emaciation

Weight is proportionally lower than ideal weight for height.

If, by observation, there is any suspicion of emaciation, you must weigh the child, and look at the table (see attached). If in doubt do not ask, just weigh the child.

NOTE: DO NOT RATE POSITIVELY IF WEIGHT LOSS IS DUE TO A MEDICAL CONDITION, MOOD DISORDER, OR FOOD SCARCITY RELATED TO POVERTY.

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Weight below 90% of ideal.
( )	( )	( )	**3 -** Threshold: Weight below 85% of ideal.

PAST: ☐ ☐ ☐
P C S

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Eating Disorders *page 27 of 52*

3. Weight Loss Methods

Have you ever used diet pills to control your weight?
How about laxatives, or water pills to lose weight?
Did you sometimes make yourself throw up?
Did you exercise a lot, more than was usual for you, in order to lose weight? How much? How many hours a day?
Did you have periods of at least 1 week during which you had nothing but liquids with no calories (teas, diet sodas, coffee, water)?

Criteria
0 = No Information
1 = Not present
2 = Less than one time a week
3 = One or more times a week

	Parent CE	Parent MSP	Child CE	Child MSP	Summary CE	Summary MSP
	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
a. using diet pills	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )
b. taking laxatives	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )
c. taking water pills	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )
d. throwing up	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )
e. exercising a lot	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )
f. taking only non-caloric fluids for a week or more; restricting energy (e.g., food) intake	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )
g. combined frequency weight loss methods	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )

■ Subject ☐☐☐☐☐☐☐ Date ☐☐ / ☐☐ / 2 0 ☐☐ Interviewer ☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Eating Disorders *page 28 of 52*

	P	C	S	
4. Eating Binges or Attacks	( )	( )	( )	**0 -** No information
Binge eating episode associated with three or more of the following:	( )	( )	( )	**1 -** Not present.
1. Eating much more rapidly than normal.				
2. Eating until feeling uncomfortably full.	( )	( )	( )	**2 -** Subthreshold: Eating binges that occur less than once a week or have fewer than three associated features..
3. Eating large amounts of food when not physically hungry.				
4. Eating alone because of being embarrassed.				
5. Feelng disgusted, depressed, or very guilty after overeating	( )	( )	( )	**3 -** Threshold: Eating binges once a week or more.

PAST: ☐ ☐ ☐
P C S

Has there ever been a time when you had "eating attacks" or binges?
What's the most you ever ate at one time?
Have there ever been times you ate so much you felt sick? How often did it happen?
(ascertain all details in definition)
What triggered a binge?
What did you usually eat when you binged?
What was the most food you have eaten during a binge?
Did you ever make yourself throw up after a binge?
How did you feel after you binged?
Did you usually binge alone or with other people?
Did other people know you binged?

NOTE: ONLY RATE EATING BINGES THAT ARE PATHOLOGICAL (e.g. hidden from family members and peers, followed by depressed mood, and/or throwing up behavior). DO NOT RATE TYPICAL ADOLESCENT EATING ORGIES (e.g. outings with friends for pizza and ice cream).

_ IF RECEIVED A SCORE OF 3 ON CURRENT RATINGS OF ANY OF THE EATING DISORDER ITEMS (CURRENT), COMPLETE THE EATING DISORDERS SECTION IN THE EATING DISORDERS AND SUBSTANCE-RELATED DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.

_ IF RECEIVED A SCORE OF 3 ON PAST RATINGS OF ANY OF THE EATING DISORDER ITEMS (PAST), COMPLETE THE EATING DISORDERS SECTION IN THE EATING DISORDERS AND SUBSTANCE-RELATED DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.

_ NO EVIDENCE OF AN EATING DISORDER.

NOTE: (RECORD DATES OF POSSIBLE CURRENT AND PAST EATING DISORDERS).

■ Subject ☐☐☐☐☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Attention Deficit Hyperactivity *page 29 of 52* ■

Compared to other children/adolescents this age, how would parent/adult rate this child/adolescent. Also ask if teachers or others have complained about particular symptoms or behaviors.

If the child is being treated with stimulants, rate for most severe period prior to medication or during drug holidays and note in margin which symptoms are improved with medication.

Determine the age of onset for first positively endorsed ADHD symptom. If symptom has persisted since early childhood, use the current rating to describe the symptom's most intense severity over the past year. Score symptom as 'not present' in the past unless prior episode of symptomatology was followed by a period of six months or more in which the child was free of ADHD problems.

If the symptoms are episodic, consider the presence of a mood disorder or other causes (e.g., alcohol, drugs or medical problems).

Probe: For how long has _____ been a problem? Has it been a problem since kindergarten? First grade? Did the problem start even earlier? Note: According to the DSM-5, onset of ADHD symptoms can appear up to age 12.

---

1. Difficulty Sustaining Attention on Tasks or Play Activities

DSM-5 DR# 4: Not able to pay attention:

Parent Rating: _____ Child Rating: _____

Has there ever been a time when you had trouble paying attention in school? Did it affect your school work
Did you get into trouble because of this
When you were working on your homework, did your mind wander
What about when you were playing games? Did you forget to go when it was your turn
Did teachers complain

NOTE: RATE BASED ON DATA REPORTED BY INFORMANT (e.g., parent or teacher) OR OBSERVATIONAL DATA

NOTE: DO NOT RATE POSITIVELY IF OCCURS ONLY DURING MOOD EPISODE, PSYCHOSIS, EPISODES OF DRUG USE, OR SECONDARY TO A MEDICAL CONDITION.

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Occasionally has difficulty sustaining attention on tasks or play activities. Problem has only minimal effect on functioning.
( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) has difficulty sustaining attention. Problem has significant effect on functioning.

PAST: ☐ P ☐ C ☐ S

2. Easily Distracted

Was there ever a time when little distractions would make it very hard for you to keep your mind on what you were doing?
Like if another kid in class asked the teacher a question while the class was working quietly, was it hard for you to keep your mind on your work?
When there was an interruption, like when the phone rang, was it hard to get back to what you were doing before the interruption?
Were there times when you could keep your mind on what you were doing, and little noises and things didn't bother you?
How often were they a problem?
Did teachers complain?

NOTE: RATE BASED ON DATA REPORTED BY INFORMANT OR OBSERVATIONAL DATA.

NOTE: DO NOT RATE POSITIVELY IF OCCURS ONLY DURING MOOD EPISODE, PSYCHOSIS, EPISODES OF DRUG USE, OR SECONDARY TO A MEDICAL CONDITION.

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Occasionally distractible. Problem has only minimal effect on functioning.
( )	( )	( )	**3 -** Threshold: Attention often (4-7 days/week) disrupted by minor distractions other kids would be able to ignore. Problem has significant effect on functioning.

PAST: ☐ P ☐ C ☐ S

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Attention Deficit Hyperactivity *page 30 of 52*

	P	C	S	
3. Difficulty Remaining Seated	( )	( )	( )	**0 -** No information.
	( )	( )	( )	**1 -** Not present.
	( )	( )	( )	**2 -** Subthreshold: Occasionally has difficulty remaining seated when required to do so. Problem has only minimal effect on functioning.
	( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) has difficulty remaining seated when required to do so. Problem has significant effect on functioning.

Was there ever a time when you got out of your seat a lot at school? Did you get into trouble for this? Was it hard to stay in your seat at school? What about dinner time?

Parents: *When your child was young, were you able to take him/her to church? Restaurants? Were these difficulties beyond what you would expect for a child his/her age?*

NOTE: RATE BASED ON DATA REPORTED BY INFORMANT OR OBSERVATIONAL DATA.

Take into account that these symptoms tend to improve with age. Carefully check if this symptom was present when the child was younger.

PAST: ☐ P ☐ C ☐ S

	P	C	S	
4. Impulsivity	( )	( )	( )	**0 -** No information.
	( )	( )	( )	**1 -** Not present.
	( )	( )	( )	**2 -** Subthreshold: Occasionally impulsive. Problem has only minimal effect on functioning.
	( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) impulsive. Problem has significant effect on functioning.

Do you act before you think, or think before you act? Has there ever been a time when these kinds of behaviors got you into trouble? Give some examples.

(THIS ITEM IS NOT A DSM-5 CRITERION - DO NOT INCLUDE IN SYMPTOM COUNT)

PAST: ☐ P ☐ C ☐ S

— **IF RECEIVED A SCORE OF 3 ON THE CURRENT RATINGS OF ANY OF THE PREVIOUS ITEMS, COMPLETE THE ATTENTION DEFICIT HYPERACTIVITY DISORDER (CURRENT) SECTION IN THE NEURODEVELOPMENTAL, DISRUPTIVE, AND CONDUCT DISORDERS SUPPLEMENT AFTER COMPLETING THE SCREEN INTERVIEW.**

— **IF RECEIVED A SCORE OF 3 ON THE PAST RATINGS OF ANY OF THE PREVIOUS ITEMS, COMPLETE THE ATTENTION DEFICIT HYPERACTIVITY DISORDER (PAST) SECTION IN THE NEURODEVELOPMENTAL, DISRUPTIVE, AND CONDUCT DISORDERS SUPPLEMENT AFTER COMPLETING THE SCREEN INTERVIEW.**

— **NO EVIDENCE OF ATTENTION DEFICIT DISORDER.**

NOTE: (RECORD DATES OF POSSIBLE CURRENT AND PAST ATTENTION DEFICIT HYPERACTIVITY DISORDER).

■ Subject ☐☐☐☐☐☐☐ ■

2013

KSADS-PL SCREEN INTERVIEW:
Oppositional Defiant Disorder

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The essential feature of this disorder is a recurrent pattern of negativistic, defiant, disobedient, and hostile behavior toward authority figures that persists for at least 6 months and occurs more frequently than is typically observed in individuals of comparable age and developmental level.

Keep in mind differential diagnoses of depressive disorder, bipolar disorder, anxiety disorders, ADHD, psychosis, substance use disorders or medical illness. Also consider environmental issues.

While the DSM-5 is not clear regarding this issue, consider making this diagnosis if symptoms are present in more than one setting (i.e., home and school) consider diagnosis of Parent-Child Relational Problem if symptoms occur ONLY at home.

---

1. Loses Temper

DSM-5 DR# 8: Felt angry or lost your temper:

Parent Rating: _____ Child Rating: _____

Has there ever been a time when you would get upset easily and lose your temper?
Did it take much to get you mad?
How often did you get really mad or annoyed and lose your temper?

In order to be sure this is a temper outburst, ask:
Where do you lose your temper?
What do you do when you have a temper tantrum

	P	C	S
0 - No information.	( )	( )	( )
1 - Not present.	( )	( )	( )
2 - Subthreshold: Occasional severe temper outbursts. **(less than 1 time weekly)**.	( )	( )	( )
3 - Threshold: Less severe outbursts daily or severe temper outbursts at least once a week Outbursts more severe and more often than a typical child his/her age; cause impairment.	( )	( )	( )

PAST: ☐ P ☐ C ☐ S

2. Argues A Lot With Adults/Authority Figures

Was there ever a time when you would argue, talk back, "smart mouth" a lot with adults? Your parents or teachers?
What kinds of things did you argue with them about?
Did you argue with them a lot?
How bad did the fights get?

NOTE: ARGUING INCLUDES AN UNWILLINGNESS TO COMPROMISE, GIVE IN, OR NEGOTIATE WITH ADULTS OR PEERS.

	P	C	S
0 - No information.	( )	( )	( )
1 - Not present.	( )	( )	( )
2 - Subthreshold: Occasionally argues with parents and/or teachers; less than once per week.	( )	( )	( )
3 - Threshold: Often argues with parents and/or teachers (at least one time per week). Arguments more severe and more often than a typical child his/her age.	( )	( )	( )

PAST: ☐ P ☐ C ☐ S

Subject ☐☐☐☐☐☐☐

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Oppositional Defiant Disorder *page 32 of 52* ■

	P	C	S	
3. Disobeys Rules A Lot/Defies or refuses to comply with adult requests	( )	( )	( )	**0 -** No information.
	( )	( )	( )	**1 -** Not present.
Do you ever deliberately defy or disobey the rules at home? School? How often? *Do you think that your parents/teachers ask you to do things that you shouldn't have to do? Like what?*	( )	( )	( )	**2 -** Subthreshold: Occasionally actively defies or refuses adult requests or rules; less than one time per week.
In addition ask the following for adolescents: *How often to you get away with things without getting into trouble or without getting caught? Does this get you into trouble?*	( )	( )	( )	**3 -** Threshold: Often actively defies or refuses adult requests or rules (at least once a week). Disobedient more often than a typical child his/her age.

PAST: ☐ ☐ ☐
P C S

— **IF RECEIVED A SCORE OF 3 ON THE CURRENT RATINGS OF ANY OF THE PREVIOUS ITEMS, COMPLETE THE OPPOSITIONAL DEFIANT DISORDER (CURRENT) SECTION OF THE NEURODEVELOPMENTAL, DISRUPTIVE, AND CONDUCT DISORDERS SUPPLEMENT AFTER FINISHING THE SCREENING INTERVIEW.**

— **IF RECEIVED A SCORE OF 3 ON THE PAST RATINGS OF ANY OF THE PREVIOUS ITEMS, COMPLETE THE OPPOSITIONAL DEFIANT DISORDER (PAST) SECTION OF THE NEURODEVELOPMENTAL, DISRUPTIVE, AND CONDUCT DISORDERS SUPPLEMENT AFTER FINISHING THE SCREENING INTERVIEW.**

— **NO EVIDENCE OF OPPOSITIONAL DEFIANT DISORDER.**

NOTE: (RECORD DATES OF POSSIBLE CURRENT AND PAST OPPOSITIONAL DEFIANT DISORDER).

■ Subject ☐☐☐☐☐☐☐ ■

2013 **KSADS-PL SCREEN INTERVIEW:**
Conduct Disorder *page 33 of 52*

The essential feature of Conduct Disorder is a repetitive and persistent pattern of behavior in which the basic rights of others or major age appropriate societal rules are violated. Three behaviors must have been present during the past 12 months with at least one present in the past 6 months.

Keep in mind differential diagnoses of mood disorders, ADHD, psychosis, substance abuse.

If symptoms occur only during manic episode, consider NOT giving both diagnoses.

---

1. Lies

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Occasionally lies. Lies more often than a typical child his/her age.
( )	( )	( )	**3 -** Threshold: Lies often, multiple times per week or more **(to con or cheat)**.

PAST: ☐ ☐ ☐
P C S

Everybody lies. Some kids tell lies to exaggerate, some kids tell lies to get out of trouble, while others tell lies to con/cheat others.

Do you ever tell lies?
What type of lies do you tell?
Who do you lie to?
Have people ever called you a liar?
What's the worst lie you ever told?
Did you lie to get other people to do things for you?
Did you lie to get out of paying people back money or some favor you owe them?
Has anyone ever called you a con?
Complained that you broke promises a lot?
How often did you lie?

NOTE: ONLY RATE POSITIVE EVIDENCE OF LYING TO CHEAT OR "CON."

2. Truant

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Truant on one isolated incident.
( )	( )	( )	**3 -** Threshold: Truant on numerous occasions **(e.g. 2 or more days or numerous partial days)**.

PAST: ☐ ☐ ☐
P C S

Has there ever been a time when you skipped a whole day of school when your parents didn't know about it?
Did you ever go to school and leave early when you were not really supposed to? How about going in late?
Did you sometimes miss or skip classes in the morning?
Did you get into trouble? How often?

For adolescents: *How old were you when you first started to play hooky?*

NOTE: ONLY RATE POSITIVE INCIDENTS OF TRUANCY BEGINNING BEFORE THE AGE OF 13. IN ADDITION, TRUANCY IS ACTIVELY MISSING PART OR ALL OF A SCHOOL DAY REGARDLESS OF PARENT ABILITY TO ENFORCE ATTENDANCE.

Subject ☐☐☐☐☐☐☐

Date ☐☐ / ☐☐ / 2 0 ☐☐ Interviewer ☐☐☐

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Conduct Disorder *page 34 of 52*

P C S

3. Initiates Physical Fights

( ) ( ) ( ) **0 -** No information.

( ) ( ) ( ) **1 -** Not present.

( ) ( ) ( ) **2 -** Subthreshold: Fights with peers only. No fight has resulted in serious injury to peer (e.g. no medical intervention required, stitches, etc.).

( ) ( ) ( ) **3 -** Threshold: Reports at least one physical fight involving an adult (e.g. teacher, parent) OR reports starting frequent fights, with one or more fights resulting in serious injury to a peer, or frequent fights not resulting in injury (at least 1-2 times per month).

Has there ever been a time when you got into many fist fights?
Who usually started the fights?
What's the worst fight you ever got into? What happened? Did anyone get hurt?
Who did you usually fight with?
Have you ever hit a teacher? One of your parents? Another adult?
How often did you fight?
Have you ever tried or wanted to kill someone?

NOTE: TAKE INTO ACCOUNT CULTURE, BACKGROUND, AND NEIGHBORHOOD.

PAST: ☐ ☐ ☐
P C S

INQUIRE ABOUT BOTH OF THE FOLLOWING:

1 - Gang Involvement. Are you or any of your friends in a gang? The Crips? Bloods? Another gang?

___ ___ ___ ___ ___ ___ ___ ___ ___ ___ .

○ Check here if evidence of gang involvement.

2 - Homicidal Intent. Have you ever thought about wanting to kill someone or a group of people? Do you have a gun or any other weapons?

○ Check here if evidence of homicidal intent.

P C S

4. Bullies, Threatens, or Intimidates Others

( ) ( ) ( ) **0 -** No information.

( ) ( ) ( ) **1 -** Not present.

( ) ( ) ( ) **2 -** Subthreshold: Occasionally bullies, threatens, or intimidates.

( ) ( ) ( ) **3 -** Threshold: Bullies, threatens, or intimidates others on multiple occasions, daily, almost daily, or at least several times per week.

Do you ever try to bully kids or threaten kids to get them to do something you want them to do?

How often did you do these things:
__ call names or make fun of other kids
__ threaten to hurt other kids
__ push
__ trip
__ come up from behind and slap or knock kids down
__ knock items out of kids hands
__ make other kids do things for you

PAST: ☐ ☐ ☐
P C S

NOTE: DO NOT COUNT TRIVIAL SIBLING RIVALRY.

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Conduct Disorder *page 35 of 52*

	P	C	S	
5. Nonaggressive Stealing	( )	( )	( )	**0 -** No information.
	( )	( )	( )	**1 -** Not present.
	( )	( )	( )	**2 -** Subthreshold: Has stolen without confrontation of victim on only one occasion.
	( )	( )	( )	**3 -** Threshold: Has stolen without confrontation of victim on 2 or more occasions.

In the past year, have you stolen anything?
What is the most expensive thing you stole?
What other things have you stolen? From whom? From which stores?
Have you stolen a toy from a store? Money from your mom? Anything else?
How often have you stolen things?

NOTE: ONLY COUNT THEFTS OF NON-TRIVIAL VALUE (e.g. $20.00 or more) . EXCEPTION: MULTIPLE THEFTS OUTSIDE THE HOME OF TRIVIAL VALUE.

PAST: ☐ ☐ ☐
P C S

— **IF RECEIVED A SCORE OF 3 ON THE CURRENT RATINGS OF ANY OF THE PREVIOUS ITEMS, COMPLETE THE CONDUCT DISORDER (CURRENT) SECTION IN THE NEURODEVELOPMENTAL, DISRUPTIVE, AND CONDUCT DISORDERS SUPPLEMENT AFTER FINISHING THE SCREENING INTERVIEW.**

— **IF RECEIVED A SCORE OF 3 ON THE PAST RATINGS OF ANY OF THE PREVIOUS ITEMS, COMPLETE THE CONDUCT DISORDERS (PAST) SECTION IN THE NEURODEVELOPMENTAL, DISRUPTIVE, AND CONDUCT DISORDERS SUPPLEMENT AFTER FINISHING THE SCREENING INTERVIEW.**

— **NO EVIDENCE OF CONDUCT DISORDER.**

NOTES: (RECORD DATES OF POSSIBLE CURRENT AND PAST CONDUCT DISORDER. MAKE NOTES ABOUT GANG INVOLVEMENT).

■ Subject ☐☐☐☐☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Tic Disorders *page 36 of 52*

	P	C	S	
1 Motor Tics				
Has there ever been a time when you noticed your muscles moved in a way that you did not want them to, or that you didn't expect? Like raising your eyebrows (demonstrate), blinking a whole lot (demonstrate), scrunching up your nose (demonstrate), shrugging your shoulders (demonstrate), or moving your head like this (demonstrate)? Ever blink a whole lot or real hard and not be able to stop? About how often did this happen?	( )	( )	( )	**0 -** No information.
	( )	( )	( )	**1 -** Not present.
	( )	( )	( )	**2 -** Subthreshold: Specific tic behaviors present Tics have not persisted for a full year.
	( )	( )	( )	**3 -** Threshold: Specific tic behaviors are present. The frequency may wax and wane, but tics have been present for at least a year.

NOTE: RATE BASED ON REPORT AND OBSERVATION.

Do not rate positively if due to compulsions of OCD or stereotypic movements of PDD.

PAST: ☐ ☐ ☐
P C S

	P	C	S	
2. Phonic Tics				
Has there ever been a time when you made noises that you didn't want to make, repeated sounds or words that you don't want to say? Like sniffing, coughing, or clearing your throat when you didn't have a cold? Making animal sounds or grunting sounds, or even repeating things that you or other people said?	( )	( )	( )	**0 -** No information.
	( )	( )	( )	**1 -** Not present.
	( )	( )	( )	**2 -** Subthreshold: Specific tic behaviors present Tics have not persisted for a full year.
NOTE: RATE BASED ON REPORT AND OBSERVATION.	( )	( )	( )	**3 -** Threshold: Specific tic behaviors are present. The frequency may wax and wane, but tics have been present for at least a year.

PAST: ☐ ☐ ☐
P C S

— **IF RECEIVED SCORE OF 3 ON CURRENT RATINGS OF MOTOR OR PHONIC TIC ITEMS, COMPLETE THE TIC DISORDERS (CURRENT) SECTION IN THE NEURODEVELOPMENTAL, DISRUPTIVE, AND CONDUCT DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.**

— **IF RECEIVED SCORE OF 3 ON PAST RATINGS OF MOTOR OR PHONIC TIC ITEMS, COMPLETE THE TIC DISORDERS (PAST) SECTION IN THE NEURODEVELOPMENTAL, DISRUPTIVE, AND CONDUCT DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.**

— **NO EVIDENCE OF TIC DISORDER.**

NOTE: (RECORD DATES OF POSSIBLE CURRENT AND PAST TIC DISORDERS).

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Autism Spectrum Disorders *page 37 of 52* ■

Autism Spectrum Disorders are characterized by severe and pervasive impairment in several areas of development: reciprocal social interaction skills, communication skills, and the presence of stereotyped behavior, interests, and activities. The qualitative impairments that define these conditions are distinctly deviant relative to the individual's developmental level or mental age.

1) These disorders are usually evident early in life. For each item below, remember to assess the duration of the symptom and whether it has been present by preschool or before. Also, for each item, please remember to synthesize your clinical observation of behavior observed during the interview into the Summary rating.
2) If the child denies it, but parents report and/or you also observe symptom while interviewing the child, give more weight to parents and/or your observation than the child's report because s/he may not be aware of his/her problem.
3) For all symptoms below, take into account whether they are better accounted by other psychiatric disorder (mainly OCD, ADHD, psychosis, mental retardation, severe social anxiety), or medical or neurological conditions. Also, take into account the developmental stage of the child, normal behaviors and emotions, history of abuse or neglect, and the cultural background of the family and the child.
4) Remember to rate the symptoms as positive if you observe them during the interview. For example, parents and/or child may deny that the child has odd movements and the child keeps flapping his/her hands or shows persistent toe walking in your office. Parents or child report that he/she is very personable, friendly and has good non-verbal communication; however, you do not observe this during the interview. In this case, you can bring this to the parents attention in a polite way. For example, you can tell parents, "During the interview, I noticed that your child does not or avoids looking at me (or I saw such and such movements), is this something new or have you and others observed the same?

NOTE: MOST SECTIONS OF THE K-SADS-PL HAVE SAMPLE PROBES TO ELICIT SYMPTOMS FROM CHILDREN. THIS SECTION HAS SAMPLE PROBES TO USE WITH PARENTS, AS IT IS ASSUMED PARENTS WILL BE THE BEST INFORMANTS OF THESE BEHAVIORS, AND MANY CHILDREN WITH AUTISM SPECTRUM DISORDERS WILL NOT HAVE INSIGHT REGARDING THE PRESENCE AND SIGNIFICANCE OF THESE SYMPTOMS. THESE ITEMS SHOULD BE SURVEYED WITH THE CHILDREN, BUT GREATER WEIGHT GIVEN TO PARENT REPORT AND INTERVIEWER OBSERVATIONS WHEN SCORING INDIVIDUAL ITEMS.

1. **Stereotyped or repetitive speech, motor movements, or use of objects**

Does your child have any unusual motor mannerisms like hand flapping, head weaving, body rocking, or body spinning?
What about a preoccupation with wiggling his/her fingers?

Does your child repeat what you say? Parrot your speech or the speech of others? Repeatedly use idiosyncratic phrases?

Any other repetitive habits? Maybe an unusual or odd use of a toy or household object?

Child: *Do you like to watch your hands while you wiggle your fingers?*
Does rocking back and forth calm you when you are upset?
Do people ever tell you to stay still and stop spinning?

NOTE: RATE BASED ON PARENT AND CHILD REPORT AND BEHAVIORAL OBSERVATION.

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.No odd hand of finger mannerisms..
( )	( )	( )	**2 -** Subthreshold: A few isolated incidents, rarely observed.
( )	( )	( )	**3 -** Threshold: Occassional or more frequent occurrence.

PAST: ☐ ☐ ☐
P C S

Subject ☐☐☐☐☐☐☐

■ Date ☐☐ / ☐☐ / 2 0 ☐☐ Interviewer ☐☐☐ ■

2013 **KSADS-PL SCREEN INTERVIEW:**
Autism Spectrum Disorders *page 38 of 52*

2. **Insistence on sameness, Inflexible adherence to routines, Ritualizedf patterns of verbal or nonverbal behavior**

Is your child rigid and unable to tolerate small changes in plans or routines that you would not expect to cause a problem (like driving to school a different way, going down the grocery store aisles in a different order, or having a picnic on the family room floor instead of eating at the table)?
Do you work real hard to avoid changes in schedule as to not upset your child?
Has he or she been that way since before kindergarten?

For example, when your child outgrows his/her clothes, does he resist wearing new clothes?

Does your child hate changes in routine, like if he /she usually takes a bath or get dressed at a certain time and is unable to do so for some particular reason, does your child get very upset?

Child: *Do you get really upset when there is an unexpected change in your plans or the way you usually do things, like if there is a delay in the start of school, if dinner is a little earlier than usual, or if you have to drive home a different way than usual?*

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present. Flexibility within normal range.
( )	( )	( )	**2 -** Subthreshold: Only mildly inflexible, or inflexibility not evident in early childhood.
( )	( )	( )	**3 -** Threshold: Significant and persistent rigid adherence to routines and rituals that elicit distress when interrupted. Pattern of behavior evident since early childhood.

PAST: ☐ P ☐ C ☐ S

3. **Highly restricted, fixated interests that are abnormal in intensity or focus**

Often these are primarily manifest in the development of encompassing preoccupations about a circumscribed topic or interest, about which the individual can amass a great deal of facts and information. These interests and activities are pursued with great intensity often to the exclusion of other activities. Rate focus and/or intensity.

Parent: *Does your child have interests that are not typical for other children his/her age, like an interest in ceiling fans or radiators?*
Has he or she memorized unusual facts like bus schedules, history facts, or other sorts of facts that preoccupy him or her daily?
Does your child have one specific activity that he/she is focused on?
Do you think that he/she is "too obsessed" with certain activities or interests beyond what you would expect for a child of his/her age?

Child: *Is there something special you are interested in that you really like to talk about, read about, or do? Tell me about it.*

NOTE: RATE THIS AS POSITIVE IF IT IS INAPPROPRIATE FOR THE AGE AND CULTURE OF THE CHILD, AND IT IS EXAGGERATED. DO NOT SCORE PREOCCUPATION WITH VIDEOGAMES OR COMPUTER GAMES HERE.

Do not rate positively if behavior related to other diagnosis such as OCD or a psychosis.

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Unusual preoccupations that do not cause significant impairment or take excessive amounts of time.
( )	( )	( )	**3 -** Threshold: Definitely preoccupied with one or more stereotyped and restricted patterns of interest that is abnormal either in intensity or focus. Causes significant impairment in social functioning or limits participation in other activities.

PAST: ☐ P ☐ C ☐ S

Subject ☐☐☐☐☐☐☐

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Autism Spectrum Disorders *page 39 of 52* ■

	P	C	S
4. **Deficits in nonverbal communicative behaviors used for social interaction**	( )	( )	( )

Eye to Eye Gaze: *Do you frequently have to remind your child to look at you or the person s/he is talking to?*
Facial Expressions: *Does your child show the typical range of facial expressions?*
Can you see joy on his/her face when /she is happy?
Does s/he pout when s/he is sad?
Does s/he show less common facial expressions like surprise, interest, and guilt?
Gestures: *As a toddler or preschooler, did your child use common gestures like pointing to show interest, clapping when happy, and nodding to indicate 'yes'?*
For school age children and adolescents: *Does he /she use gestures to help show how something works or while they are explaining something?*

Indicate problematic areas of non-verbal behavior:
O Gaze O Expressions O Gestures

Note: Do not rate positive if due to shyness or anxiety and more pronounced with unfamiliar others.

0 - No information.
1 - Not present. No problems in any of these areas.
2 - Subthreshold: Subtle problems in one or more area, which is evident to family members and professionals but not to teachers or classmates.
3 - Threshold: Problems with one or more aspects of non-verbal behaviors cause functional impairment.

PAST: ☐ ☐ ☐
P C S

— **IF RECEIVED A SCORE OF 3 ON CURRENT RATING OF ANY OF THE PREVIOUS ITEMS, COMPLETE THE AUTISM SPECTRUM DISORDERS (CURRENT) SECTION IN THE NEURODEVELOPMENTAL, DISRUPTIVE, AND CONDUCT DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.**

— **IF RECEIVED A SCORE OF 3 ON PAST RATING OF ANY OF THE PREVIOUS ITEMS, COMPLETE THE AUTISM SPECTRUM DISORDERS (PAST) SECTION IN THE NEURODEVELOPMENTAL, DISRUPTIVE, AND CONDUCT DISORDERS SUPPLEMENT AFTER FINISHING THE SCREEN INTERVIEW.**

— **NO EVIDENCE OF AUTISM SPECTRUM DISORDERS**

NOTE: (RECORD DATES OF POSSIBLE CURRENT AND PAST AUTISM SPECTRUM DISORDERS).

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Tobacco Use *page 40 of 52*

Codes for the Following Items: **0** = No Information **1** = No **2** = Yes

	Parent			Child			Summary		
1. Use	**0**	**1**	**2**	**0**	**1**	**2**	**0**	**1**	**2**
A. Ever smoked	( )	( )	( )	( )	( )	( )	( )	( )	( )
B. Ever chewed tobacco	( )	( )	( )	( )	( )	( )	( )	( )	( )
C. Ever smoked (or chewed) tobacco daily for 1 month or more	( )	( )	( )	( )	( )	( )	( )	( )	( )

Notes:

DSM-5 DR# 21: Smoked?

Parent Rating: _____ Child Rating: _____

— **IF EVER USED TOBACCO, COMPLETE QUESTIONS BELOW.**

— **IF NO EVIDENCE OF TOBACCO USE, GO TO ALCOHOL USE SECTION ON THE FOLLOWING PAGE.**

	Parent	Child	Summary
2. Quantity of Tobacco Use			
A. Current Use (cigarettes/day or "dips" of chew/day)	☐☐	☐☐	☐☐
B. Greatest amount of Use (cigarettes/day or "dips" of chew/day)	☐☐	☐☐	☐☐
Age (years): ☐☐			
3. Have you ever smoked or "dipped" chew at least once a day for a month or more?	**0** **1** **2** ( ) ( ) ( )	**0** **1** **2** ( ) ( ) ( )	**0** **1** **2** ( ) ( ) ( )
(1 cigarette or 1 "dip" of chew a day or more for at least 30 days)			
Age of first regular use (in months):	☐☐☐	☐☐☐	☐☐☐
4. Ever attempt to quit	**0** **1** **2** ( ) ( ) ( )	**0** **1** **2** ( ) ( ) ( )	**0** **1** **2** ( ) ( ) ( )
5. Ever quit	**0** **1** **2** ( ) ( ) ( )	**0** **1** **2** ( ) ( ) ( )	**0** **1** **2** ( ) ( ) ( )
If yes, report longest number of months:	☐☐	☐☐	☐☐

Notes:

■ Subject ☐☐☐☐☐☐☐ Date ☐☐ / ☐☐ / 2 0 ☐☐ Interviewer ☐☐☐  ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Alcohol Use *page 41 of 52*

Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

Begin this section with a brief (2-3 minute) semi-structured interview to obtain information about drinking habits.

Probes: *How old were you when you had your first drink? What's your favorite thing to drinkDo you have a group of friends you usually drink with, or do you usually drink alone? Where do you usually drink? At home? Parties? A friend's house? The street? Bars? Are there special times when you are more likely to drink than others? School dances or other parties?How old were you when you started to drink regularly, say two drinks or more per week? In the past six months has there been at least one week in which you had at least two drinks?*

DSM-5 DR# 20: Alcoholic Beverage:

Parent Rating: _____ Child Rating: _____

	Parent	Child	Summary
1. Use			
A. Drank two drinks in one week four or more times *(one drink is equivalent to a 12oz bottle of beer, 5oz glass of wine, or 1.5oz shot of spirits/hard liquor)*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
B. Age above (at first regular use - years)	☐☐	☐☐	☐☐
C. Current frequency of use (days per month)	☐☐	☐☐	☐☐
D. Have you ever had 3 or more drinks in a single day?	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
2. Problems related to alcohol *Has drinking ever caused you any problems at home? With your parents? With your schoolwork? With your teachers? With your friends? With a job? Have you ever gotten in trouble while drinking?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
3. Received treatment for alcohol problems.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

Notes:

— **IF RECEIVED A SCORE OF 2 ON ANY OF THE PREVIOUS ITEMS, CONTINUE WITH QUESTIONS ON THE FOLLOWING PAGE.**

— **IF NO EVIDENCE OF CURRENT OR PAST ALCOHOL USE, GO TO SUBSTANCE USE SECTION ON PAGE 43.**

■ Subject ☐☐☐☐☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Alcohol Use Disorders *page 42 of 52*

1. Quantity

A. How many drinks do you usually have when you sit down to drink?

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** 1 - 2 drinks.
( )	( )	( )	**2 -** 3 or more drinks.

PAST: ☐ P ☐ C ☐ S

B. What's the most you ever drank in a single day? When was that? How about in the last six months? What's the most you drank in a day?

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** 1 - 2 drinks.
( )	( )	( )	**2 -** 3 or more drinks.

PAST: ☐ P ☐ C ☐ S

2. Frequency

What's the most number of days in a given week that you had something to drink? Do you usually drink Friday and Saturday night? Midweek too?

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** 1 - 2 days.
( )	( )	( )	**2 -** 3 or more days.

PAST: ☐ P ☐ C ☐ S

3. Concern from Others about Drinking

Has anyone ever complained about your drinking? Friends? Parents? Teachers? Have you ever been worried about it at all?

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** No.
( )	( )	( )	**2 -** Yes.

PAST: ☐ P ☐ C ☐ S

— **IF RECEIVED A SCORE OF 2 ON THE CURRENT RATINGS OF ANY OF THE ABOVE ITEMS, COMPLETE THE ALCOHOL USE DISORDER (CURRENT) SECTION IN THE EATING DISORDERS AND SUBSTANCE-RELATED DISORDERS SUPPLEMENT AFTER COMPLETING THE SCREEN INTERVIEW.**

— **IF RECEIVED A SCORE OF 2 ON THE PAST RATINGS OF ANY OF THE ABOVE ITEMS, COMPLETE THE ALCOHOL USE DISORDER (PAST) SECTION IN THE EATING DISORDERS AND SUBSTANCE-RELATED DISORDERS SUPPLEMENT AFTER COMPLETING THE SCREEN INTERVIEW.**

— **NO EVIDENCE OF ALCOHOL USE DISORDER.**

NOTE: (RECORD DATE OF POSSIBLE CURRENT AND PAST ALCOHOL USE DISORDERS).

■ Subject ☐☐☐☐☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Substance Use *page 43 of 52*

Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

Prior to beginning this section, give the subject the list of drugs included in the back of this interview packet. Remind child about the confidential nature of the interview prior to beginning probes (if appropriate).

1. Drug Use *Let me know if you have used any of the drugs on this list before, even if you have only tried them once. Which ones have you used?*

DSM-5 DR# 22: Marijuana, cocaine, etc:
Parent: _____ Child: _____

DSM-5 DR# 23: Use medications without MD prescription:
Parent: _____ Child Rating: _____

	Parent Ever			Child Ever			Summary Ever		
	0	1	2	0	1	2	0	1	2
a. Cannabis *Marijuana, pot, hash, THC*	( )	( )	( )	( )	( )	( )	( )	( )	( )
b. Stimulants *Speed, uppers, amphetamines, dexedrine, diet pills, crystal meth*	( )	( )	( )	( )	( )	( )	( )	( )	( )
c. Sedatives/Hypnotics/Anxiolytics *Barbiturates (sedatives, downers), Benzodiazepine, quaalude (ludes), valium, librium, xanax*	( )	( )	( )	( )	( )	( )	( )	( )	( )
d. Cocaine *Coke, crack*	( )	( )	( )	( )	( )	( )	( )	( )	( )
e. Opioids *Heroin, morphine, codeine, methadone, demerol, percodan, oxycontin*	( )	( )	( )	( )	( )	( )	( )	( )	( )
f. PCP *Angel dust*	( )	( )	( )	( )	( )	( )	( )	( )	( )
g. Hallucinogens *Psychedelics, LSD, mescaline, peyote*	( )	( )	( )	( )	( )	( )	( )	( )	( )
h. Solvents/Inhalants *Glue, gasoline, chloroform, ether, paint*	( )	( )	( )	( )	( )	( )	( )	( )	( )
i. Other *Prescription drugs, nitrous oxide, ecstasy, MDA, etc.* Specify: _____	( )	( )	( )	( )	( )	( )	( )	( )	( )
j. Polysubstance (Assess for combined use of all listed substances)	( )	( )	( )	( )	( )	( )	( )	( )	( )

Notes:

— **IF USED ANY DRUGS, COMPLETE ITEM ON THE FOLLOWING PAGE.**

— **IF NO EVIDENCE OF CURRENT OR PAST SUBSTANCE USE, GO TO POST-TRAUMATIC STRESS DISORDER SECTION ON PAGE 46.**

■ Subject _____ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Substance Use Disorders *page 44 of 52* ■

1. Frequency

In the past six months, what is the most you have used _____?
Every day or almost every day for at least one week? Less? More?
Was there a time when you used _____ more?

Criteria:
0 = No information.
1 = Not present.
2 = Less than once a month.
3 = More than once a month.

	Parent CE	Parent MSP	Child CE	Child MSP	Summary CE	Summary MSP
a. Cannabis *Marijuana, pot, hash, THC*	0 1 2 3 ( ) ( ) ( ) ( )	0 1 2 3 ( ) ( ) ( ) ( )	0 1 2 3 ( ) ( ) ( ) ( )	0 1 2 3 ( ) ( ) ( ) ( )	0 1 2 3 ( ) ( ) ( ) ( )	0 1 2 3 ( ) ( ) ( ) ( )
b. Stimulants *Speed, uppers, amphetamines, dexedrine, diet pills, crystal meth*	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )
c. Sedatives/Hypnotics/Anxiolytics *Barbiturates (sedatives, downers), Benzodiazepine, quaalude (ludes), valium, librium, xanax*	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )
d. Cocaine *Coke, crack*	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )
e. Opioids *Heroin, morphine, codeine, oxycontin methadone, demerol, percodan*	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )
f. PCP *Angel dust*	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )
g. Hallucinogens *Psychedelics, LSD, mescaline, peyote*	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )
h. Solvents/Inhalants *Glue, gasoline, chloroform, ether, paint*	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )
i. Other *Prescription drugs, nitrous oxide, ecstasy, MDA, etc.* Specify: _____	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )
j. Polysubstance (Assess for combined use of all listed substances)	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )	( ) ( ) ( ) ( )

Notes:

■ Subject ☐☐☐☐☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Substance Use Disorders *page 45 of 52*

Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

	Parent			Child			Summary		
2. Problems related to substance use/abuse	**0**	**1**	**2**	**0**	**1**	**2**	**0**	**1**	**2**
Has your use of ___ ever caused you any problems at home? With your parents? With your schoolwork? With teachers? With friends? With the police?	( )	( )	( )	( )	( )	( )	( )	( )	( )

Notes:

— **IF RECEIVED A SCORE OF 3 ON THE CURRENT FREQUENCY ITEM FOR ANY DRUG, COMPLETE THE SUBSTANCE ABUSE (CURRENT) SECTION IN THE EATING DISORDERS AND SUBSTANCE-RELATED DISORDERS SUPPLEMENT AFTER FINISHING SCREEN INTERVIEW.**

— **IF RECEIVED A SCORE OF 3 ON THE PAST FREQUENCY ITEM FOR ANY DRUG, COMPLETE THE SUBSTANCE ABUSE (PAST) SECTION IN THE EATING DISORDERS AND SUBSTANCE-RELATED DISORDERS SUPPLEMENT AFTER FINISHING SCREEN INTERVIEW.**

— **NO EVIDENCE OF SUBSTANCE USE DISORDER.**

NOTE: (RECORD DATE OF POSSIBLE CURRENT AND PAST SUBSTANCE ABUSE).

■ Subject | | | | | | | | ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Post Traumatic Stress Disorder *page 46 of 52* ■

Codes for the Following Items: **0** = No Information **1** = No **2** = Yes

1. Traumatic Events

Probe:
I am going to ask you about a number of bad things that sometimes happen to children your age, and I want you to tell me if any of these things have ever happened to you. Be sure to tell me if any of these things have ever happened, even if they only happened one time.

	Criteria	Parent Ever	Child Ever	Summary Ever
A. Car Accident *Have you ever been in a bad car accident?* *What happened?* *Were you hurt?* *Was anyone else in the car hurt?*	Significant car accident in which child or other individual in car was injured and required medical intervention.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
B. Other Accident *Have you ever been in any other type of bad accidents?* *What about a biking accident?* *Other accidents?* *What happened?* *Were you hurt?*	Significant accident in which child was injured and required medical intervention.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
C. Fire *Were you ever in a serious fire?* *Did your house or school ever catch on fire?* *Did you ever start a fire that got out of control? What happened?* *Did anyone get hurt?* *Was there a lot of damage?*	Child close witness to fire that caused significant property damage or moderate to severe physical injuries.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
D. Witness of a Disaster *Have you ever been in a really bad storm, like a tornado or a hurricane?* *Have you ever been caught in floods with waters that were deep enough to swim in?*	Child witness to natural disaster that caused significant devastation.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

■ Subject [| | | | | | |] ■

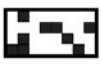
2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Post Traumatic Stress Disorder *page 47 of 52* ■

Codes for the Following Items: **0** = No Information **1** = No **2** = Yes

1. Traumatic Events (cont')

Probe:
I am going to ask you about a number of bad things that sometimes happen to children your age, and I want you to tell me if any of these things have ever happened to you. Be sure to tell me if any of these things have ever happened, even if they only happened one time.

	Criteria	Parent Ever	Child Ever	Summary Ever
E. Witness of a Violent Crime *Did you ever see someone rob someone or shoot them? Steal from a store or jump someone? Take someone hostage? What happened? Where were you when this happened? Was anyone hurt?*	Child close witness to threatening or violent crime.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
F. Victim of Violent Crime *Did anyone ever mug you or attack you in some other way? What happened? Were you hurt?*	Child victim of seriously threatening or violent crime.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
G. Confronted with Traumatic News *Have you ever gotten some really bad news unexpectedly? Like found out someone you loved just died or was sick and would never get better?*	Learned about sudden, unexpected death of a loved one, or that loved one has life-threatening disease.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
H. Terrorism Related Trauma *Were you affected by the events of Boston Marathon bombing or any other terrorist attack?*	Loved one missing for extended period of time or seriously injured or killed by terrorist attack.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

■ Subject [| | | | | | |]  ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Post Traumatic Stress Disorder *page 48 of 52* ■

Codes for the Following Items: **0** = No Information **1** = No **2** = Yes

1. Traumatic Events (cont')

Probe:
I am going to ask you about a number of bad things that sometimes happen to children your age, and I want you to tell me if any of these things have ever happened to you. Be sure to tell me if any of these things have ever happened, even if they only happened one time.

	Criteria	Parent Ever	Child Ever	Summary Ever
I. War Zone Trauma *Have you ever lived in a war zone? Had your home attacked? Witnessed the killing or rape of others? Seen everything around you set on fire?*	Lived in war zone. Witnessed death and mass destruction.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

Protective Services: Has your family ever received services from CYS/DCF? ○ **Current** ○ **Pastt**

J. Witness to Domestic Violence *Some kids' parents have a lot of nasty fights. They call each other bad names, throw things, threaten to do bad things to each other, or sometimes really hurt each other. Did your parents (or does your mother and her boyfriend) ever get in really bad fights? Tell me about the worst fight you remember your parents having. What happened?*	Child witness to explosive arguments involving threatened or actual harm to parent.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
K. Physical Abuse *When your parents got mad at you, did they hit you? Have you ever been hit so that you had bruises or marks on your body, or were hurt in some way? What happened?*	Bruises sustained on more than one occasion, or more serious injury sustained.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

■ Subject ☐☐☐☐☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Post Traumatic Stress Disorder *page 49 of 52* ■

Codes for the Following Items: **0** = No Information **1** = No **2** = Yes

1. Traumatic Events (cont')

Probe:
I am going to ask you about a number of bad things that sometimes happen to children your age, and I want you to tell me if any of these things have ever happened to you. Be sure to tell me if any of these things have ever happened, even if they only happened one time.

	Criteria	Parent Ever	Child Ever	Summary Ever
L. Sexual Abuse *Did anyone ever touch you in your private parts when they shouldn't have? What happened?* *Has someone ever touched you in a way that made you feel bad?* *Has anyone who shouldn't have ever made you undress, touch you between the legs, make you get in bed with him/her, or make you play with his private parts?* *Was CYF ever involved with your family?*	Isolated or repeated incidents of genital fondling, oral sex, or vaginal or anal intercourse.	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )
M. Other *Is there anything else that happened to you that was really bad, or something else you saw that was really scary, that you want to tell me about?* **If parental substance abuse and/or neglect known or suspected:** *Has there ever been a time when your mom or dad went on a drug binge and left you and your siblings alone for a day or longer? Were you worried they wouldn't come home or that something bad happened to them?*	Record incident below. Incident:	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )

— **IF EVIDENCE OF PAST TRAUMA (A SCORE OF "2" ON ANY ITEM), COMPLETE THE POST-TRAUMATIC STRESS DISORDER QUESTIONS ON THE FOLLOWING PAGE.**

— **IF NO EVIDENCE OF PAST TRAUMA, END THE SCREENING INTERVIEW. COMPLETE PRELIMINARY LIFETIME DIAGNOSES WORKSHEET AND APPROPRIATE SUPPLEMENTS.**

NOTE: (RECORD DATES OF PAST TRAUMATIC EVENTS).

■ Subject ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:** ■
Post Traumatic Stress Disorder *page 50 of 52*

Codes for the Following Items: **0** = No Information **1** = No **2** = Yes

***NOTE**: If more than one traumatic event was endorsed, inquire about symptom presence in relation to **ANY** of the traumas.*

NOTE: IN DISCUSSING TRAUMATIC EVENTS WITH CHILDREN, IT IS IMPORTANT TO USE THEIR LANGUAGE IN YOUR DIALOGUE. (e.g. Do you think about when he stuck his pee-pee up your bum often?)

	Parent CE	Parent MSP	Child CE	Child MSP	Summary CE	Summary MSP
1. Recurrent Memories, Thoughts, or Images *Has there ever been a time when you kept seeing _____ again and again?* *How often did this happen?* *Did what happen keep coming into your mind?* *Did you think about it a lot?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
2. Feelings of Detachment *Is it hard for you to trust other people?* *Do you feel like being alone more often than before?* *Like you just don't feel like being around people now that you used to like being around before?* *Do you feel alone even when you are with other people?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
3. Efforts to Avoid Activities or Situations that Remind you of the Trauma *Are there places or thigs that remind you of ____? Do you try to avoid them? You said before that ___ sometimes reminds you of what happened. Dio you try to avoid ___?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
4. Nightmares *Has there ever been a time when you had a lot of nightmares?* *Did you ever dream about _____? How often?* *Do you have other scary dreams?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

Note: In children content of dreams may be frightening without directly relating to trauma.

■ Subject ☐☐☐☐☐☐☐ ■

2013 ■ **KSADS-PL SCREEN INTERVIEW:**
Past Traumatic Events *page 51 of 52* ■

Codes for the Following Items: **0** = No Information **1** = No **2** = Yes

	Parent CE	Parent MSP	Child CE	Child MSP	Summary CE	Summary MSP
5. Hypervigilance	0 1 2	0 1 2	0 1 2	0 1 2	0 1 2	0 1 2
	( ) ( ) ( )	( ) ( ) ( )	( ) ( ) ( )	( ) ( ) ( )	( ) ( ) ( )	( ) ( ) ( )

Since happened, are you more careful? Do you feel like you always have to watch what's going on around you? Do you double check the doors or windows to make sure they are locked?

— IF RECEIVED A SCORE OF **2** ON CURRENT RATINGS OF ANY OF THE PRECEDING ITEMS, COMPLETE THE CURRENT AND PAST POST-TRAUMATIC STRESS DISORDER ITEMS IN THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT.

— IF RECEIVED A SCORE OF **2** ON PAST RATINGS OF ANY OF THE PRECEDING ITEMS, COMPLETE THE CURRENT AND PAST POST-TRAUMATIC STRESS DISORDER ITEMS IN THE ANXIETY, OBSESSIVE COMPULSIVE, AND TRAUMA-RELATED DISORDERS SUPPLEMENT.

— NO EVIDENCE OF POST-TRAUMATIC STRESS DISORDER .

NOTE: (RECORD DATES OF POSSIBLE CURRENT AND PAST POST-TRAUMATIC STRESS DISORDER).

■ Subject ☐☐☐☐☐☐☐ ■

2013 [redacted] **KSADS-PL SCREEN INTERVIEW:**
Supplement Completion Checklist *page 52 of 52* [redacted]

DIRECTIONS: *Check the sections to be completed in each supplement. Note dates and/or ages of onset for each current and past possible disorder.*

Supplement #1: **Depressive and Bipolar Related Disorders**

_____ Depressive Disorders - Current
_____ Depressive Disorders - Past
_____ Mania - Current
_____ Mania - Past
_____ Disruptive Mood Dysregulation Disorder - Current
_____ Disruptive Mood Dysregulation Disorder - Past

Supplement #2: **Schizophrenia Spectrum and Other Psychotic Disorders**

_____ Psychosis - Current
_____ Psychosis - Past

Supplement #3: **Anxiety, Obsessive Compulsive, and Trauma-Related Disorders**

_____ Panic Disorders - Current
_____ Panic Disorders - Past
_____ Agoraphobia - Current
_____ Agoraphobia - Past
_____ Separation Disorders - Current
_____ Separation Disorders – Past
_____ Social Anxiety/Selective Mutism - Current
_____ Social Anxiety/Selective Mutism – Past
_____ Specific Phobias - Current
_____ Specific Phobias - Past
_____ Generalized Disorders - Current
_____ Generalized Disorders - Past
_____ Obsessive Compulsive Disorder -Current
_____ Obsessive Compulsive Disorder – Past
_____ Posttraumatic Stress Disorder - Current
_____ Posttraumatic Stress Disorder - Past

Supplement #4: **Neurodevelopmental, Disruptive, and Conduct Disorders**

_____ ADHD - Current
_____ ADHD - Past
_____ Oppositional Disorder -Current
_____ Oppositional Disorder - Past
_____ Conduct Disorder - Current
_____ Conduct Disorder – Past
_____ Tic Disorders - Current
_____ Tic Disorders – Past
_____ Autism Spectrum Disorders - Current
_____ Autism Spectrum Disorders - Past

Supplement #5: **Eating Disorders and Substance-Related Disorders**

_____ Eating Disorders - Current
_____ Eating Disorders - Past
_____ Alcohol Use Disorder - Current
_____ Alcohol Use Disorder - Past
_____ Substance Use Disorders - Current
_____ Substance Use Disorders - Past

KSADS-PL 2013:

SUPPLEMENT # 4: NEURODEVELOPMENTAL, DISRUPTIVE, AND CONDUCT DISORDERS SUPPLEMENT

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Date / / 20 Interviewer

2013 ■ **Neurodevelopmental, Disruptive, and Conduct Disorders Supplement** ■

Attention Deficit Hyperactivity Disorder *page 1 of 27*

(If child is on medication for ADHD, rate behavior when not on medication)

NOTE: DO NOT RATE SYMPTOMS POSITIVELY IF THEY ARE EXCLUSIVELY ACCOUNTED FOR BY MDE, BIPOLAR DISORDER, DYSTHYMIA, AN ANXIETY DISORDER, SUBSTANCE ABUSE, PSYCHOSIS, OR ASD.

1. Makes a lot of Careless Mistakes

Do you make a lot of careless mistakes at school?
Do you often get problems wrong on tests because you didn't read the instructions right?
Do you often leave some questions blank by accident?
Forget to do the problems on both sides of a handout?
How often do these types of things happen?
Has your teacher ever said you should pay more attention to detail?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Occasionally makes careless mistakes. Problem has only minimal effect on functioning.
( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) makes careless mistakes. Problem has significant effect on functioning.

PAST: ☐ P ☐ C ☐ S

2. Doesn't Listen

Is it hard for you to remember what your parents and teachers say?
Do your parents or teachers complain that you don't listen to them when they talk to you?
Do you "tune people out"?
Do you get into trouble for not listening?

Rate based on data reported by informant or observational data.

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Occasionally doesn't listen. Problem has only minimal effect on functioning.
( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) doesn't listen. Problem has significant effect on functioning.

PAST: ☐ P ☐ C ☐ S

3. Difficulty Following Instructions

Do your teachers complain that you don't follow instructions?
When your parents or your teacher tell you to do something, is it sometimes hard to remember what they said to do?
Does it get you into trouble?
Do you lose points on your assigments for not following directions or not completing the work?
Do you forget to do your homework or forget to turn it in?
Do you get in to trouble at home for not finishing your chores or other things your parents ask you to do? How often?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Occasionally has difficulty following instructions. Problem has only minimal effect on functioning.
( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) has difficulty following instructions. Problem has significant effect on functioning.

PAST: ☐ P ☐ C ☐ S

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Attention Deficit Hyperactivity Disorder *page 2 of 27*

4. Difficulty Organizing Tasks

Is your desk or locker at school a mess?
Does it make it hard for you to find the things you need?
Does your teacher complain that your assignments are messy or disorganized?
When you do your worksheets, do you usually start at the beginning and do all the problems in order, or do you like to skip around?
Do you often miss problems?
Do you have a hard time getting ready for school in the morning?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Occasionally disorganized. Problem has only minimal effect on functioning.
( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) disorganized. Problem has significant effect on functioning.

PAST: ☐ P ☐ C ☐ S

5. Dislikes/Avoids Tasks Requiring Attention

Do you hate or dislike doing things that require a lot of concentration/effort?
Like certain assignments, homework or reading a book?
Are there some kinds of school work you hate doing more than others?
Which ones? Why?
Do you try to get out of doing your ___ assignments?
About how many times a week do you not do your ___ homework?

NOTE: IN CHILDREN/TEENS WITH ADHD, ABILITY TO SUSTAIN ATTENTION TO VERY REWARDING ACTIVITES LIKE COMPUTER OR VIDEO GAMES MAY NOT BE IMPAIRED.

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Occasionally avoids tasks that require sustained attention, and/or expresses mild dislike for these tasks. Problem has only minimal effect on functioning.
( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) avoids tasks that require sustained attention, and/or expresses moderate dislike for these tasks. Problem has significant effect on functioning.

PAST: ☐ P ☐ C ☐ S

6. Loses Things

Do you lose things a lot? Your pencils at school? Homework assignments? Things around home?
About how often does this happen?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Occasionally loses things. Problem has only minimal effect on functioning.
( )	( )	( )	**3 -** Threshold: Often loses things (e.g. once a week or more). Problem has significant effect on functioning.

PAST: ☐ P ☐ C ☐ S

Subject ☐☐☐☐☐☐☐

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Attention Deficit Hyperactivity Disorder *page 3 of 27*

7. Forgetful in Daily Activities

Do you often leave your homework at home, or your books or coats on the bus?
Do you leave your things outside by accident?
How often do these things happen?
Has anyone ever complained that you are too forgetful?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Occasionally forgetful. Problem has only minimal effect on functioning.
( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) forgetful. Problem has significant effect on functioning.

PAST: ☐ P ☐ C ☐ S

8. Fidgets

Consider restlessness, tapping fingers, chewing things, squirming, "ants in pants", etc.

Do people often tell you to sit still, to stop moving, or stop squirming in your seat? Your teachers? Parents?
Do you sometimes get into trouble for squirming in your seat or playing with little things at your desk?
Do you have a hard time keeping your arms and legs still? How often?

For parents about children: *When you take your child to church or to a restaurant, do you have to bring a lot of games or toys?*
About adolescents: *When your child was younger, were you able to take him/her to church? Restaurants?*
Were these difficulties beyond what you would expect for a child his/her age?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Occasionally fidgets with hands or feet or squirms in seat. Problem has only minimal effect on functioning.
( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) fidgets with hands or feet or squirms in seat. Problem has significant effect on functioning.

PAST: ☐ P ☐ C ☐ S

Take into account that these symptoms tend to improve with age. Carefully check if this symptom was present when the child was younger.

NOTE: RATE BASED ON DATA REPORTED BY INFORMANT OR OBSERVATIONAL DATA.

9. Runs or Climbs Excessively

Do you get into trouble for running down the hall in school?
Does your mom often have to remind you to walk instead of run when you are out together?
Do your parents or your teacher complain about you climbing things you shouldn't?
What kinds of things? How often does this happen?

Adolescents: *Do you feel restless a lot? Feel like you have to move around, or that it is very hard to stay in one place?*

Rate based on data reported by informant (parent/teacher) or observational data.

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Occasionally runs about or climbs excessively. Problem has only minimal effect on functioning. (In adolescents, may be limited to a subjective feeling of restlessness)
( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) runs about or climbs excessively. Problem has significant effect on functioning. (In adolescents, may be limited to a subjective feeling of restlessness)

PAST: ☐ P ☐ C ☐ S

2013 **Neurodevelopmental, Disruptive, and Conduct Disorders Supplement**

Attention Deficit Hyperactivity Disorder *page 4 of 27*

10. On the Go/Acts like Driven by Motor

Do people tell you that your motor is always running?
Is it hard for you to slow down?
Can you stay in one place for long, or are you always on the go?
How long can you sit and watch TV or play a game?
Do people tell you to slow down a lot?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Occasionally, minimal effect on functioning.
( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) acts as if "driven by a motor." Significant effect on functioning.

PAST: ☐ P ☐ C ☐ S

11. Difficulty Playing Quietly

Do your parents or teachers often tell you to quiet down when you are playing?
Do you have a hard time playing quietly?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Occasionally has difficulty playing quietly. Problem has only minimal effect on functioning.
( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) has difficulty playing quietly. Problem has significant effect on functioning.

PAST: ☐ P ☐ C ☐ S

12. Blurts Out Answers

At school, do you sometimes call out the answers before you are called on?
Do you talk out of turn at home?
Answer questions your parents ask your siblings? How often?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Occasionally talks out of turn. Problem has only minimal effect on functioning.
( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) talks out of turn. Problem has significant effect on functioning.

PAST: ☐ P ☐ C ☐ S

13. Difficulty Waiting Turn

Is it hard for you to wait your turn in games?
What about in line in the cafeteria or at the water fountain?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Occasionally has difficulty waiting his/her turn. Problem has only minimal effect on functioning.
( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) has difficulty waiting his/her turn. Problem has significant effect on functioning.

PAST: ☐ P ☐ C ☐ S

Subject ☐☐☐☐☐☐☐

2013 **Neurodevelopmental, Disruptive, and Conduct Disorders Supplement**

Attention Deficit Hyperactivity Disorder *page 5 of 27*

	P	C	S	
14. Interrupts or Intrudes	( )	( )	( )	**0 -** No Information.
Do you get into trouble for talking out of turn at school?	( )	( )	( )	**1 -** Not Present.
Do your parents, teachers, or any of the kids you know complain that you cut them off when they are talking?	( )	( )	( )	**2 -** Subthreshold: Occasionally interrupts others.
Do kids complain that you break in on games? Does this happen a lot?	( )	( )	( )	**3 -** Threshold: Often (4-7 days/week) interrupts others.
Rate based on data reported by informant (parent/teacher) or observational data.				**PAST:** ☐ P ☐ C ☐ S

	P	C	S	
15. Talks Excessively	( )	( )	( )	**0 -** No Information.
Do people say you talk too much?	( )	( )	( )	**1 -** Not Present.
Do you get into trouble at school for talking when you are not supposed to?	( )	( )	( )	**2 -** Subthreshold: Occasionally talks excessively.
Do people in your family complain that you talk too much?	( )	( )	( )	**3 -** Threshold: Often talks excessively.
What about humming or always making noises?				
Do not rate vocal tics positively.				**PAST:** ☐ P ☐ C ☐ S
Rate based on data reported by informant (including parent/teacher) or observational data.				

Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

	Criteria	Parent CE	Parent MSP	Child CE	Child MSP	Summary CE	Summary MSP
16. Duration	6 months or more	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
For how long have you had trouble (list symptoms that were positively endorsed)?							
17. Age of onset	Some symptoms present before age 12.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
How old were you when you started to have these problems?							
Did you have these problems in kindergarten? First Grade? Middle school?							
Specify: _____							
18. Impairment (Must be present in two settings)		0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
A. Socially (with peers):							
B. With family:		0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
C. In school:		0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

Subject ☐☐☐☐☐☐☐

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Attention Deficit Hyperactivity Disorder *page 6 of 27*

Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

	Summary CE	Summary MSP
19. *DSM-5 Criteria:* Evidence of ADHD	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

A. A persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development, as characterized by (1) and/or (2):

1. Inattention: Six (or more) of the following symptoms have persisted for at least 6 months to a degree that is inconsistent with developmental level and that negatively impacts directly on social and academic/occupational activities.
   a. Makes a lot of Careless Mistakes
   b. Difficulty Sustaining Attention on Tasks or Play Activities
   c. Doesn't Listen
   d. Difficulty Following Instructions
   e. Difficulty Organizing Tasks
   f. Dislikes/Avoids Tasks Requiring Attention
   g. Loses Things
   h. Easily Distracted
   i Forgetful in Daily Activities
2. Hyperactivity / Impulsivity: Six or more of the following nine symptoms have persisted for at least 6 months:
   NOTE: For older adolescents and adults (age 17 and older), only five symptoms are required.
   a. Fidgets
   b. Difficulty Remaining Seated
   c. Runs or Climbs Excessively
   d. Difficulty Playing Quietly
   e. On the Go/Acts as if Driven by a Motor
   f. Talks Excessively
   g. Blurts Out Answers
   h. Difficulty Waiting Turn
   i. Often Interrupts or Intrudes

B. Some symptoms that caused impairment present before the age of 12;
C. Several symptoms must be present in two or more situations (e.g. school and home);
D. Clinically significant impairment;
E. Symptoms do not occur exclusively during the course of psychotic disorder and not better accounted for by another mental disorder (e.g., mood disorder, anxiety disorder, dissociation, personality disorder).

NOTE: Autism Spectrum Disorder is no longer a rule out for the diagnosis of ADHD.

20. **Predominantly Inattentive Presentation** Meets criterion A (I), but not criterion A (II) for past six months.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
21. Predominantly Hyperactive-Impulsive Type Meets criterion A (II), but not criterion A (I) for past six months.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

■ Subject _____ ■

2013 ■ **Neurodevelopmental, Disruptive, and Conduct Disorders Supplement** ■

Attention Deficit Hyperactivity Disorder *page 7 of 27*

Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

	Summary CE	Summary MSP
22. Combined Type Both criteria A (I) and A (II) are met for past six months.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
23. Other Specified Attention Deficit Hyperactivity Disorder Prominent symptoms of inattention or hyperactivity-impulsivity that do not meet criteria for Attention Deficit Hyperactivity Disorder .	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

■ Subject ☐☐☐☐☐☐☐ ■

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Oppositional Defiant Disorder *page 8 of 27*

NOTE: A CHILD CANNOT MEET DSM-5 CRITERIA FOR ODD IF THEY MEET CRITERIA FOR DDMD. IF CHILD MEETS CRITERIA FOR DMDD, THIS SUPPLEMENT DOES NOT NEED TO BE COMPLETED, BUT MAY BE COMPLETED FOR RESEARCH PURPOSES..

When assessing for ODD, keep in mind that the essential feature of this disorder is a recurrent pattern of negativistic, defiant, disobedient, and hostile behavior toward authority figures that persists for at least 6 months and occurs more frequently than is typically observed in individuals of comparable age and developmental level. If ODD symptoms are only evident in the home setting, consider a parent-child relationshp diagnosis.

1. Easily Annoyed

Do you have a short fuse?
Do people bug you and get on your nerves a lot?
What kinds of things bug you or set you off?
Do you get really annoyed when your parents tell you that you can't do something you want to do? Like what?
What other things really get on your nerves?
What do you do when you are feeling annoyed or bugged?
How often would you say this happens?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Easily annoyed or touchy on occasion, but less than once a week)
( )	( )	( )	**3 -** Threshold: Easily annoyed or touchy. Annoyed more often than a typical child his/her age; at least one time per week.

PAST: ☐ P ☐ C ☐ S

2. Angry or Resentful

Do you get angry or cranky with your parents a lot?
How about your teachers? brothers? sisters? friends?
Do other people tell you that you get cranky a lot? Who?
How often does it happen?

Parent: *Is your child often resentful when you ask him/her to follow your rules or requests?*

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Occasionally angry or resentful;. less than one time per week
( )	( )	( )	**3 -** Threshold: Angry or resentful at least once per week. Angry more often than a typical child his/her age.

PAST: ☐ P ☐ C ☐ S

3. Spiteful and Vindictive

When someone does something unfair to you, do you try or plan to try to get back at them? Do you go through with the plan? Give me some examples?
What if your brother or a friend did something to get you into trouble or make you mad. Would you do something back to them?
Has this happened before? How often?
Are there times when people do something to you and you let it slide?
Does this happen a lot?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Sometimes lets things slide / occasionally gets back at people. (1-3 times a week)
( )	( )	( )	**3 -** Threshold: Spiteful and/or vindictive once a week or more; Spiteful more often than a typical child his/her age.

PAST: ☐ P ☐ C ☐ S

NOTE: DO NOT RATE ODD SYMPTOMS POSITIVELY IF SYMPTOMS OCCUR EXCLUSIVELY DURING A MOOD EPISODE,OR EXCLUSIVELY WHEN USING ALCOHOL OR ELICIT SUBSTANCES.

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4. Annoys People on Purpose

Do you or do people say you do things on purpose to annoy or bug them?
Your parents?
Do you enjoy pushing your mom/dad's buttons? Teachers? Siblings? Peers?
How often do you like to do this?
What kinds of things do they complain about? Do you think that it's true?
Are you a "pain in the neck"?

Do not score teasing of a sibling.

	P	C	S
	( )	( )	( )
	( )	( )	( )
	( )	( )	( )
	( )	( )	( )

0 - No Information.
1 - Not Present.
2 - Subthreshold: Occasionally has deliberately done things to annoy other people.
3 - Threshold: Often does things to annoy other people. (at least once per week)

PAST: ☐ P ☐ C ☐ S

5. Blames Others for Own Mistakes

When you get into trouble, is it ever your fault?
If you know that you did something wrong and you got caught, do you admit to it? Pretend that someone else did it? Blame someone else?
Is it usually your fault or someone else?
Do you think most of your troubles are caused by other people or are they your own fault?

	P	C	S
	( )	( )	( )
	( )	( )	( )
	( )	( )	( )
	( )	( )	( )

0 - No Information.
1 - Not Present.
2 - Subthreshold: On occasion blames others or denies responsibility for own mistakes.
3 - Threshold: Often blames others or denies responsibility for own mistakes .

PAST: ☐ P ☐ C ☐ S

Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

Criteria	Parent CE	Parent MSP	Child CE	Child MSP	Summary CE	Summary MSP
6. Duration — 6 months or more *For how long have you had trouble (list symptoms that were positively endorsed)?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
7. Impairment						
A. Socially (with peers):	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
B. With family:	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
C. In school:	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

■ Subject ☐☐☐☐☐☐☐ HT ■

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Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

	Parent CE	Parent MSP	Child CE	Child MSP	Summary CE	Summary MSP
8. Evidence of Precipitant (Specify):	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
9. Are ODD symptoms present in the following environments:						
A. With parents	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
B. With other adult family members (e.g. grandparents, aunts, uncles, etc.)	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
C. In school	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
D. In community settings (e.g. coaches, police, heathcare provider, etc.)	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
E. With peers	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

10. DSM-5 Criteria:Evidence of Oppositional Defiant Disorder

A. A pattern of angry/irritable mood,argumentative/defiant behavior, or vindictiveness lasting at least 6 months, as evidenced by four (or more) symptoms from any of the following categories, and exhibited with at least one individual who is not a sibling. — 0 1 2 ( ) ( ) ( ) | 0 1 2 ( ) ( ) ( )

Angry/Irritable Mood:

1. Often loses temper.
2. Often touchy or easily annoyed.
3. Often angry and resentful.

Argumentative/Defiant Behavior:

4. Often argues with authority figures or, for children and adolescents, with adults.
5. Often actively defies or refuses to comply with adults' requests from authority figures or with rules
6. Often deliberately annoys others
7. Often blames others for his/her mistakes or behavior

Vindictiveness:

8. Often spiteful or vindictive at least twice within the past 6 months

B. The disturbance in behavior causes distress in the individual or others, causes clinically significant impairment in social, academic, or occupation functioning.
C. The behaviors do not occur exclusively during a Psychotic, Substance Use, or Mood Disorder. Criteria are not met for Disruptive Mood Dysregulation Disorder.

NOTE: Conduct Disorder is no longer a rule out for the diagnosis of ODD.

NOTE: CONSIDER CRITERION (A) MET ONLY IF THE BEHAVIOR OCCURS MORE FREQUENTLY THAN IS TYPICALLY OBSERVED IN INDIVIDUALS OF COMPARABLE AGE AND DEVELOPMENTAL LEVEL.

Specify (current):
_____Mild (one setting)
_____Moderate (two settings)
_____Severe (three+ settings)

Specify (past):
_____Mild (one setting)
_____Moderate (two settings)
_____Severe (three+ settings)

■ Subject [| | | | | | |] ■

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Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

	Summary CE	Summary MSP
11. Evidence of Unsepcified Disruptive Behavior Disorder If criteria is not met for CD or ODD, but symptoms are present. For example, there are multiple symptoms present, in addition to clinical impairment.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
12. Evidence of Parent-Child Relational Problems Consider this diagnosis if symptoms are present with parent(s) only (and not with friends, teachers, coaches and other relatives) and symptoms are not severe. However, if parents are consistent with limit setting OR if oppostional/defiant symptoms are very severe, consider giving ODD diagnosis.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

■ Subject | | | | | | | | ■

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The essential feature of Conduct Disorder is a repetitive and persistent pattern of behavior in which the basic rights of others or major age-appropriate social rules are violated. Three behaviors must have been present during the past 12 months with at least one present in the past 6 months. **Keep in mind differential diagnoses of bipolar disorder, MDE, ADHD, psychosis, substance abuse.**

If symptoms occur only during mood disorders, consider NOT giving both diagnoses. However, in persistent depression/dysthymia, it may be impossible to disentangle and you might consider giving both diagnoses.

1. Vandalism, Destroyed others' Property

Do you ever break other people's things on purpose? Like breaking windows? Kicking in doors, smashing windows, destroying school property? Have you ever destroyed furniture, walls, floors, doors, etc. at home or school?
How about when you were very angry?
How often do you destroy others' property?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Minor acts of deliberate destruction of other people's property on rare occasions (e.g., breaks another's toy on purpose) OR one or two occasions of significant destruction of property.
( )	( )	( )	**3 -** Threshold: Three or more instances of moderate to severe vandalism/destruction of property.

PAST: ☐ P ☐ C ☐ S

2. Breaking and Entering

In the past six months, have you or any of your friends broken into any cars? Houses? Any stores? Warehouses? Other buildings?
About how many times have you broken into a house, car, store, or other building?
Have you or any of your friends done any of the following:
Broken into houses; cars; other vehicles; abandoned houses or buildings; a store(s); a building(s)?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Has been with friends who broke into a house, car, store, or building, but did not actively participate.
( )	( )	( )	**3 -** Threshold: Has broken into a house, car, store, or building 1 or more times.

PAST: ☐ P ☐ C ☐ S

3. Aggressive Stealing

Have you or any of your friends robbed anyone?
Snatched their purse?
Held them up?
How often?

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Has been with friends who aggressively stole, but did not actively participate.
( )	( )	( )	**3 -** Threshold: Mugging, purse-snatching, extortion, armed robbery, etc. on 1 or more occasions.

PAST: ☐ P ☐ C ☐ S

■ Subject ☐☐☐☐☐☐☐ ■

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P C S

4. Firesetting

( ) ( ) ( )

Have you set any fires?
Why did you set the fire?
Were you playing with matches and did you start the fire by accident, or did you start it on purpose?
Were you angry?
Were you trying to cause a lot of damage or to get back at someone?
What's the most damage you ever caused by starting a fire?
About how many fires have you set?

0 - No Information.
1 - Not Present.
2 - Subthreshold: Match/lighter play. No intent to cause damage, and fire(s) not started out of anger.
3 - Threshold: Set 1 or more fires with the intent to cause damage, or out of anger.

PAST: ☐ P ☐ C ☐ S

P C S

5. Often Stays out at Night

( ) ( ) ( )

What time are you supposed to come home at night?
Do you often stay out past your curfew?
What is the latest you ever stayed out?
Have you ever stayed out all night?
How many times have you done that?

NOTE: ONLY RATE POSITIVE INCIDENTS OF STAYING OUT IF IT BEGINS BEFORE THE AGE OF 13.

0 - No Information.
1 - Not Present.
2 - Subthreshold: Stayed out all night, or several hours past curfew, on 1-2 isolated occasions (despite parent's prohibitions).
3 - Threshold: Stayed out all night, or several hours past curfew, on several occasions (3 or more times).

PAST: ☐ P ☐ C ☐ S

P C S

6. Ran Away Overnight

( ) ( ) ( )

Have you ever run away? Why?
Was there something going on at home that you were trying to get away from?
How long did you stay away?
How many times did you do this?

NOTE: DO NOT SCORE POSITIVELY IF CHILD RAN AWAY TO AVOID PHYSICAL OR SEXUAL ABUSE.

0 - No Information.
1 - Not Present.
2 - Subthreshold: Ran away overnight only one time, or ran away for shorter periods of time on several occasions.
3 - Threshold: Ran away overnight 2 or more times or once for at least 2 or more nights (lengthy period of time).

PAST: ☐ P ☐ C ☐ S

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P C S

7. Use of a Weapon

( ) ( ) ( ) **0 -** No Information.

( ) ( ) ( ) **1 -** Not Present.

( ) ( ) ( ) **2 -** Subthreshold: Has threatened use of a weapon, but has never used one.

( ) ( ) ( ) **3 -** Threshold: Used a weapon that can cause serious harm on 1 or more occasions (e.g., knife, brick, broken bottle, gun).

Have you ever used an object or item to hit/hurt someone?
Have you ever carried a weapon?
Have you ever used or threatened to use:
____kitchen knife or pocket knife
____gun
____brick, rocks
____broken bottles
____bat
____brick
What about in self defense?

PAST: ☐ P ☐ C ☐ S

P C S

8. Physical Cruelty to Persons

( ) ( ) ( ) **0 -** No Information.

( ) ( ) ( ) **1 -** Not Present.

( ) ( ) ( ) **2 -** Subthreshold: Has been physical cruelty on one or two occasions. No significant injuries.

( ) ( ) ( ) **3 -** Threshold: Has been physically cruel to an individual on 3 or more occasions, or on one occasion intentionally causing significant injury.

Have you ever beaten someone up for no reason?
How bad?
Was it just because the other person was different than you or because of the way they looked?
Did they get hurt?

NOTE: DO NOT COUNT TRIVIAL SIBLING RIVALRY.

PAST: ☐ P ☐ C ☐ S

P C S

9. Forced Sexual Activity

( ) ( ) ( ) **0 -** No Information.

( ) ( ) ( ) **1 -** Not Present.

( ) ( ) ( ) **2 -** Subthreshold: Forced or attempted to force someone to participate in mild sexual activity (e.g., non-genital fondling) on one or more occasions.

( ) ( ) ( ) **3 -** Threshold: Forced someone to participate in severe sexual activity (e.g. genital fondling, oral sex, vaginal intercourse and/or anal intercourse) on one or more occasions.

Have you ever forced anyone to kiss you or touch you in your private parts?
Have you every forced another kid to touch you outside your clothes?
Has anyone ever said you forced another kid/person to go farther than they wanted? What did they say?

PAST: ☐ P ☐ C ☐ S

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10. Cruelty to Animals

Some kids like to hurt or torture animals. Have you hurt or tried to hurt an animal on purpose? What did you do?
About how many times have you hurt an animal on purpose in the last six months?

NOTE: DO NOT SCORE TRADITIONAL HUNTING OUTINGS. PAY CAREFUL ATTENTION TO THE COMMUNITY SETTING (RURAL, FARM, ETC.).

P	C	S	
( )	( )	( )	**0 -** No Information.
( )	( )	( )	**1 -** Not Present.
( )	( )	( )	**2 -** Subthreshold: Has repeatedly been mildly cruel to an animal (e.g., kick dog).
( )	( )	( )	**3 -** Threshold: Has killed or tortured an animal on one or more occasions, or repeatdly caused moderate to severe injuries to an animal.

PAST: ☐ P ☐ C ☐ S

Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

Criteria		Parent CE	Parent MSP	Child CE	Child MSP	Summary CE	Summary MSP
11. Impairment							
A. Socially (with peers):		**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )
B. With family:		**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )
C. In school:		**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )
12. Duration *For how long did you (list positively endorsed conduct symptoms)?* **NOTE: PER THE DSM-5, "the Conduct Disorder diagnosis should be applied only when the behavior in question is symptomatic of an underlying dysfunction within the individual and not simply a reaction to the immediate social context."**	6 months or more	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )
13. Childhood Onset Type *How old were you when you first started to (list positively endorsed items)?*	Onset of at least one conduct problem prior to age 10	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )
14. Adolescent Onset Type *You didn't do any of these things before you were 10?*	No conduct problems prior to age 10	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )	**0 1 2** ( ) ( ) ( )

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Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

	Summary CE	Summary MSP
15. Evidence of Conduct Disorder	0 1 2	0 1 2
DSM-5 Criteria	( ) ( ) ( )	( ) ( ) ( )

A. A repetitive and persistent pattern of behavior in which the basic rights of others or major age-appropriate societal norms or rules are violated, as manifested by the presence of three (or more) of the following criteria in the past 12 months, with at least one criterion present in the past 6 months:

Aggression to People and Animals

1) Often bullies, threatens or intimidates others
2) Often initiates physical fights
3) Has used a weapon that can cause serious physical harm to others (e.g., a bat, brick, broken bottle, knife,gun).
4) Has been physically cruel to people
5) Has been physically cruel to animals
6) Has stolen while confronting a victim (e.g., mugging, purse snatching, extortion, armed robbery)
7) Has forced someone into sexual activity

Destruction of Property

8) Has deliberately engaged in fire setting with the intention of causing serious damage
9) Has deliberately destroyed others' property (other than by firesetting)

Deceitfulness or Theft

10) Has broken into someone else's house, building, or car
11) Often lies to obtain goods or favors or to avoid obligations (i.e., "cons" others)
12) Has stolen items of nontrivial value without confronting a victim (e.g., shoplifting, but without breaking and entering, forgery).

Serious Violation of Rules

13) Often stays out at night despite parental prohibitions, beginning before age 13 years.
14) Has run away overnight at least twice while living in parental or parental surrogate home (or once without returning for a lengthy period).
15) Is often truant from school, beginning before age 13 years

B. The disturbance in behavior causes clinically significant impairment in social, academic, or occupational functioning.

C. If the individual is age 18 years or older, criteria are not met for Antisocial Personality Disorder.

Specify (Current): With Limited Prosocial Emotion _____ **Specify (Past):** With Limited Prosocial Emotion _____

Criteria: Displays at least two of the following characteristics persistently over at least 12 months and in multiple relationships and settings: 1) Lack of remorse or guilt; 2) Callous, lack of empathy; 3) Unconcerned about performance at school, work, or in other important activities; 4) Shallow or deficient affect.

Specify Severity (Current): Mild _____ Moderate _____ Severe _____
Specify Severity (Past): Mild _____ Moderate _____ Severe _____

Criteria: Mild: Few problems in excess of those required for the diagnosis; problems cause relatively minor problems to others (e.g, lying, truancy); Moderate: Intermediate severity (e.g., stealing without confronting a victim, vandalism); Severe: Many problems in excess of those required for the diagnosis, or problems cause considerable harm to others (e.g, forced sex, physical cruelty, use of weapon, stealing while confronting victim, breaking and entering).

■ Subject | | | | | | | | ■

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Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

	Summary CE	Summary MSP
16. Group Type Predominance of conduct problems occur as group activity with peers.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
17. Solitary Aggressive Type Most conduct disorder activities initiated by the person (not as group activity).	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
18. Undifferentiated Type Conduct symptoms cannot be classified as either group or solitary aggressive type.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
19. Callous and Unemotional At least 2 of the following: ____1. Lack of Remorse or Guilt ____2. Lack of Empathy ____3. Unconcerned about Performance ____4. Shallow or Deficient Affect	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
20. Severity (Code): 0 Mild; Few if any conduct problems in excess of those required to make the diagnosis and conduct problems only cause minor harm to others (e.g., lying, truancy, staying out late). 1 Moderate; Number of conduct problems and effect on others intermediate between mild and severe (e.g., stealing without confronting victim, vandalism). 2 Severe; Many conduct problems in excess of those required to make diagnosis or conduct problems cause considerable harm to others (e.g., forced sex, use of a weapon, stealing while confronting victim, breaking and entering	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

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Simple and Complex Motor Disorders *page 18 of 27*

Criteria for Items: **0** = No Information **1** = No **2** = Yes

NOTE: FOR SYMPTOMS TO BE RATED POSITIVELY THEY MUST OCCUR MANY TIMES A DAY, OR HAVE OCCURRED INTERMITTENTLY FOR ONE YEAR OR LONGER AND NOT BE BETTER ACOUNTED FOR BY ANOTHER NEUROLOGICAL DISORDER

SIMPLE MOTOR (Rate based on report and observation)	Parent CE	Parent MSP	Child CE	Child MSP	Summary CE	Summary MSP
1. Eye Blinking *Do your eyes blink a lot like this for no reason?* (demonstrate)	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
2. Other Facial Tics *Do other parts of your face sometimes move unexpectedly like this?* (demonstrate facial grimaces, nose scrunching, and opening mouth as if to yawn)	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
3. Head Jerks *Do you sometimes nod your head, shake your head, or turn your head to the side for no special reason?* (demonstrate)	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
4. Shoulder Jerks *What about your shoulders, do your shoulders sometimes move unexpectedly like this (shrug shoulder or roll shoulder)?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
5. Arm Movements *Do you sometimes flap your arms or throw your arms out as if to hit something that isn't there?* (demonstrate)	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
6. Stomach Twitches *Does your stomach sometimes move for no special reason?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
7. Leg Movements *Do you ever stomp your feet or kick your legs out and you're not sure why you do it?* *Do you sometimes bang your legs up under your desk when you weren't planning on moving them?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

■ Subject ☐☐☐☐☐☐☐ ■

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Simple and Complex Motor Disorders *page 19 of 27*

Code for Remaining Items: **0** = No Information **1** = No **2** = Yes

	Parent CE	Parent MSP	Child CE	Child MSP	Summary CE	Summary MSP
8. Other *Are there any other types of movements that you notice that I haven't asked you about?* Specify:	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
9. Summation of all above Simple motor tics occur many times a day or have occurred intermittently for 1 year or longer.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
COMPLEX MOTOR						
1. Touching/Tapping Things *Do you ever touch your own body, your nose, your ear, or feel ike you have to touch other people, or other things...like having to touch the phone every time you walk by it, touch walls, or all the furniture in your room?* *Do you often tap your pencil or your fingers against your desk?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
2. Hopping/Spinning *When you are walking down the hall at school, do you sometimes find that you have to hop or spin rather than keep walking straight?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
3. Echokinesis *Do you ever find that you have to imitate other people's actions like pushing your hair back or rubbing your nose? Anything else?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
4. Hurts Self *Do you ever feel like you have to hit yourself in the face, pull your hair or bite your hand?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
5. Other *Are there any other types of movements that you notice that haven't asked you about?* Specify.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
6. Summation of all above Complex motor tics occur many times a day, or have occurred intermittently for 1 year or longer.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

■ Subject | | | | | | | | ■

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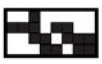
Simple and Complex Vocal Disorders *page 20 of 27*

Code for Remaining Items: **0** = No Information **1** = No **2** = Yes

SIMPLE VOCAL PHONIC	Parent CE	Parent MSP	Child CE	Child MSP	Summary CE	Summary MSP
1. Sniffing/Coughing/Throat Clearing *Do you ever sniff, cough, or clear your throat when you don't have a cold? Does this happen over and over again?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
2. Snorting/Grunting *Do you ever make noises through your nose or in your throat like this?* (demonstrate)	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
3. Other *Are there any other types of sounds that you make that I haven't asked you about? What about tongue clicking, lip smacking, or making popping sounds?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
4. Summation of all above Simple vocal tics occur many times a day or intermittently for a year or longer.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
COMPLEX VOCAL PHONIC						
1. Repeat Own Words/Sentences *Do you ever notice that you have to repeat yourself, not because someone didn't hear you, but because it didn't sound right, or maybe for no special reason at all?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
2. Repeat Others Speech *Do you find yourself sometimes repeating things other people have said for no special reason at all?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
3. Coprolalia (Obscene Words) *Do bad words ever pop out of your mouth in the middle of a sentence for no reason, or do you find yourself saying bad things under your breath and find you can't stop yourself?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
4. Insults/Racial Slurs *Do you sometimes find yourself saying bad things to people about how they look or something else about them when you didn't really mean it?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

■ Subject [ ][ ][ ][ ][ ][ ][ ]  ■

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Simple and Complex Vocal Disorders *page 21 of 27*

Code for Remaining Items: **0** = No Information **1** = No **2** = Yes

	Parent CE	Parent MSP	Child CE	Child MSP	Summary CE	Summary MSP
5. Other *Are there any other things you sometimes find yourself saying?* *Are you afraid you might have one of these attacks?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
6. Summation of all above Vocal tics occur many times a day or intermittently for a year or longer.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
7. Impairment A. Socially (with peers):	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
B. With family:	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
C. In school:	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
8. Criteria for Tourette's Disorder					0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

DSM-5 Criteria

A. Both multiple motor and one or more vocal tics have been present at some time during the illness, although not necessarily concurrently. (A tic is a sudden, rapid, recurrent, nonrhythmic, stereotyped motor movement or vocalization).

B. The tics may wax and wane in frequency, by have persisted for more than 1 year since first tic onset.

C. Onset before age 18 years.

D. The disturbance is not exclusively due to the direct physiological effects of a substance (e.g., stimulants) or a general medical condition (e.g., Huntington's disease or postviral encephalitis).

Subject

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Tic Disorders *page 22 of 27*

Code for Remaining Items: **0** = No Information **1** = No **2** = Yes

	Summary CE	Summary MSP
9. Evidence of Persistent (Chronic) Motor or Vocal Tic Disorders	0 1 2	0 1 2
	( ) ( ) ( )	( ) ( ) ( )

DSM-5 Criteria

A. Single or multiple motor or vocal tics have been present during the illness, but not both motor and vocal.

B. The tics may wax and wane in frequency, by have persisted for more than 1 year since first tic onset.

C. The onset is before age 18.

D. The disturbance is not exclusively due to the direct physiological effects of a substance (e.g., stimulants) or a general medical condition (e.g., Huntington's disease or postviral encephalitis).

E. Criteria have never been met for Tourette's Disorder.

Specify (Current): With motor tics only: _____ With vocal tics only: _____

Specify (Past): With motor tics only: _____ With vocal tics only: _____

10. Evidence of Provisional Tic Disorder	0 1 2	0 1 2
	( ) ( ) ( )	( ) ( ) ( )

DSM-5 Criteria

A. Single or multiple motor and/or vocal tics.

B. The tics have been present for less than 1 year since first tic onset.

C. Onset before age 18

D. The disturbance is not exclusively due to the direct physiological effects of a substance (e.g., stimulants) or a general medical condition (e.g., Huntington's disease or postviral encephalitis).

E. Criteria have never been met for Tourette's Disorder or Chronic Motor or Vocal Tic Disorder.

Specify (Current): With motor tics only: _____ With vocal tics only: _____

Specify (Past): With motor tics only: _____ With vocal tics only: _____

11. Tic Disorder Not Otherwise Specified	0 1 2	0 1 2
	( ) ( ) ( )	( ) ( ) ( )

DSM-5 Criteria

This category is for disorders characterized by tics that do not meet criteria for a Specific Tic Disorder. Examples include tics lasting less than 4 weeks or tics with an onset after age 18 years.

Subject

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Autism Spectrum

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Note: Assess symptoms with an onset in early childhood.

1. Deficits in social-emotional reciprocity

Parent: *s a young child, did your child show you toys and other things that interested him or her, or did he or she play on his/her own with little or no referencing to you*

If something good happens to your child now, like a good grade at school o having some other success, will your child spontaneously share it with you? Will s/he share the good news with friends?

Child: *If something good happens to you, like you get a good grade at school or have some other success, do you keep it to yourself, or do you tell mom, dad, or someone else?*

NOTE: DO NOT RATE POSITIVE IF IT IS ACCOUNTED FOR BY OTHER CONDITIONS SUCH AS ANXIETY, PSYCHOSIS, DEPRESSION, BEHAVIOR DISORDERS, OR NORMAL TEEN BEHAVIORS.

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Sometimes seeks to share, but not frequently or spontaneously.
( )	( )	( )	**3 -** Threshold: Does not spontaneously seek to share enjoyment, interests or achievements with other people, or only shares when related to preoccupation.

PAST: ☐ P ☐ C ☐ S

2. Deficits in developing and maintaining relationships, appropriate to developmental level

This may take different forms at different ages. Very young children may have little or no interest in establishing friendships. Older children may have an interest in friendship but lack understanding of the conventions of social interaction.

Parent: *Does your child have any good friends his/her age?*
Does your child get together with other children after school and on weekends?
Does your child do better with younger kids or with adults than with kids his/her own age?
Does s/he prefer to be by him or herself?
Does your child wish to be social but fails to make relationships with peers?
Does your child want to make friends, but says s/he does not know why other children do not want to be his/her friend?
Is your child able to understand how other kids react in social situations? Or does s/he misinterpret or not "tune in" to peers' reactions in social situations?
Is he/she taken advantage of?
Can your child only be with other kids on his/her terms?

Child: *Do you like to be with other kids your age or would you rather be by yourself most of the time?*
Do you have a best friend?
Do you get together after school or on the weekends?

NOTE: BE CAREFUL TO WEIGH CHILD'S REPORT WITH COLLATERAL INFORMATION. DO NOT RATE THIS AS POSITIVE IF IT IS EXCLUSIVELY DUE TO OTHER CONDITIONS SUCH AS ADHD, SOCIAL ANXIETY, SCHIZOPHRENIA, OR SCHIZOID PERSONALITY.

P	C	S	
( )	( )	( )	**0 -** No information.
( )	( )	( )	**1 -** Not present.
( )	( )	( )	**2 -** Subthreshold: Some personal relationships, mostly in group situations or primarily in restricted interest areas.
( )	( )	( )	**3 -** Threshold: Failure to develop peer relationships appropriate to developmental level. Unable to interpret peer reactions in social situations.

PAST: ☐ P ☐ C ☐ S

■ Subject ☐☐☐☐☐☐☐ ■

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3. Hyper-or hypo-reactivity to sensory input or unusual interest in sensory aspects of environment

Is you child especially sensitive to sensory inputs? Is s/he sensitive to tags in clothes or the feel of different fabrics? Is you child very reactive to a change in lighting or sounds in the home? Alternatively, does you child seem oblivious to aspects of the environment around him/her? Does your child sometimes seem oblivious to pain or extreme chagnes in temperature? Are there any things your child likes to touch or smell?

Child: *Do you hate wearing certain clothing because the tags or fabric really bother you?*

P	C	S	
( )	( )	( )	**0** - No information.
( )	( )	( )	**1** - Not present.
( )	( )	( )	**2** - Subthreshold: Mild hyper- or hypo-reactivity to sensory inputs
( )	( )	( )	**3** - Threshold: Notable and impairing hyper- or hypo-reactivity to sensory inputs

PAST: ☐ P ☐ C ☐ S

4. Motor deficits in performance of skilled movement not limited to social communication

Parent: *Is your child coordinated? Does s/he have trouble playing with a ball or doing other sport-like activities? How is his/her manual dexterity? Does s/he have trouble holding a pen or pencil? Using scissors? How is her/his balance?*

P	C	S	
( )	( )	( )	**0** - No information.
( )	( )	( )	**1** - Not present.
( )	( )	( )	**2** - Subthreshold: Mild motor deficits.
( )	( )	( )	**3** - Threshold: Moderate to severe motor deficits.

PAST: ☐ P ☐ C ☐ S

NOTE: FOR ALL THE ABOVE QUESTIONS, NOTE WHETHER THEY STARTED WHEN THE CHILD WAS YOUNG (e.g., BEFORE PRESCHOOL), OR CURRENTLY. FOR AUTISM SPECTRUM DISORDERS, ALL THESE BEHAVIORS SHOULD HAVE STARTED WHEN THE CHILD WAS YOUNG. TAKE INTO ACCOUNT WHETHER THE CHILD HAS OCD, SEVERE SOCIAL PHOBIA, MENTAL RETARDATION, A SEVERE HISTORY OF ABUSE OR NEGLECT, OR IF THERE ARE CULTURAL ISSUES THAT CAN BETTER ACCOUNT FOR THE SYMPTOMS.

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Autism Spectrum *page 25 of 27*

Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

	Parent CE	Parent MSP	Child CE	Child MSP	Summary CE	Summary MSP
5. Communication and Social Deficits Common Among Patients with Autism Spectrum Disorders						
a. One Sided Verbosity *Does your child often go on and on talking about one thing, almost like s/he is giving a speech rather than having a conversation? Have people ever said he seems like a "little professor"?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
b. Speech Pragmatic Deficits *Does your child have trouble understanding the more subtle aspects of language, like how to take turns when having a conversation, or knowing what someone means when they use sarcasm or make analogies (e.g."She's as heavy as a house")?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
c. Abnormalities in Voice Modulation/Prosody *Is there anything unusual about your child's intonation? Is his/her voice monotone? Overly sing-songy? Does s/he have poor volume control or unusual patterns of emphasis in speech?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
d. Incessant and Insensitive Pursuit of Others *Does your child relentlessly pursue contact with others, even when they don't seem interested in talking or being with him/her? Does s/he have a hard time reading others' social cues?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
NOTE: RATE BASED ON REPORT AND OBSERVATION.						
6. Features of Patients with High Functioning Autism						
a. Social Isolation *From the time your child was young, did your child prefer to be alone? What about now, does s/he seem uninterested in friends and other social contacts?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
b. Echolalic Speech *Does your child repeat phrases s/he has heard other's say, or nonsensical phrases over and over?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
NOTE: RATE BASED ON REPORT AND OBSERVATION.						

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Autism Spectrum *page 26 of 27*

Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

	Parent CE	Parent MSP	Child CE	Child MSP	Summary CE	Summary MSP
7. Developmental History a. Symptoms present in early childhood.	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
b. Speech Pragmatic Deficits *Does your child have trouble understanding the more subtle aspects of language, like how to take turns when having a conversation, or knowing what someone means when they use sarcasm or make analogies (e.g."She's as heavy as a house")?*	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
8. Impairment A. Socially (with peers):	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
B. With family:	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )
C. In school:	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )	0 1 2 ( ) ( ) ( )

Subject

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Autism Spectrum Disorder *page 27 of 27*

Codes for Remaining Items: **0** = No Information **1** = No **2** = Yes

9. Evidence of Autism Spectrum Disorders

DSM-5 Criteria

Summary CE			Summary MSP		
0	**1**	**2**	**0**	**1**	**2**
( )	( )	( )	( )	( )	( )

A. Persistent deficits in social communication and social interaction across multiple contexts, as manifest by the following, currently or by history:

1. Deficits in social-emotional reciprocity, ranging for example, from abnormal social approach or failure of back and forth conversation, to reduced sharing of interests, emotions. affect; to failure to initiate or respond to social interactions.
2. Deficits in nonverbal communicative behaviors used for social interaction, ranging from poorly integrated verbal and nonverbal communication, to abnormalities in eye contact and body-language, or deficits in understanding and use of gestures; to a total lack of facial expression and non-veral communication.
3. Deficits in developing, maintaining, and understanding relationships, ranging from difficulties adjusting behavior to suit different social contexts,to difficulties in sharing imaginative play and in making friend; to absence of interest in peers.

B. Restricted, repetitive patterns of behavior, interests, or activities as manifested by at least two of the following:

1. Stereotyped or repetitive speech, motor movements, or use of objects; (such as simple motor stereotypies, echolalia, repetitive use of objects, lining up of toys or flipping objects, or idiosyncratic phrases).
2. Insistence on sameness, inflexible adherence to routines, or ritualized patterns of verbal or nonverbal behavior (e.g. extreme distress at small changes, difficulties with transitions, need to take the same route or eat the same food every day).
3. Highly restricted, fixated interests that are abnormal in intensity or focus; (such as strong attachment to or preoccupation with unusual objects, excessively circumscribed or perseverative interests).
4. Hyper-or hypo-reactivity to sensory input or unusual interest in sensory aspects of environment; (such as apparent indifference to pain/heat/cold, adverse response to specific sounds or textures, excessive smelling or touching of objects, visual fascination with lights or movement.

C. Syptoms must be present in early childhood (but may not become fully manifest until social demands exceed limited capacities, or may become masked by learned behavior or other mitigating measures).

D. Symptoms cause clinically significant impairment in social, occupational, or other important areas of functioning.

E. These disturbances are not better explained by intellectual disability or global developmental delay. Intellectual disability and autism spectrum disorder frequently co-occur; to make comorbid diagnoses of autism spectrum disorder and intellectual disability, social communication should be below that expected for general developmental level.

Specify:

_____ With accompanying intellectual impairment _____ Without accompanying intellectual impairment
_____ With accompanying language impairment _____ Without accompanying language impairment
_____ Associated with a known medical or geneic condition or environental factor
_____ Associated with another neurodevelopmental, mental, or behavioral disorder

Specify Severity:

_____ Level One - Requiring Support (e.g. decreased social interactions, to-and-fro conversations with others fail).
_____ Level Two - Requiring Substantial Support (e.g., speaks simple sentences, limited, narrow, special interests, odd non-veral communication).
_____ Level Three - Requiring Very Substantial Support (e.g., child with few intelligible words, rarely initiates interaction, makes unusual approaches).

■ Subject | | | | | | | | ■

SUMMARY DIAGNOSTIC CHECKLISTS

TEMPLATES

SUMMARY LIFETIME DIAGNOSES CHECKLIST-

Date of Assessment: _____/_____/_____

0 = NO INFORMATION 3 = DEFINITE
1 = NOT PRESENT 4 = IN PARTIAL REMISSION*
2 = PROBABLE
*(where applicable, according to the DSM-5)

Probable Diagnosis:
1. Meets criteria for core symptoms of the disorder.
2. Meets all but one, or a minimum of 75% of the remaining criteria required for the diagnosis
3. Evidence of functional impairment

Ages: Score in years	DIAGNOSIS MOST SEVERE PAST (MSP) EPISODE	AGE OF ONSET MSP EPISODE	DIAGNOSIS CURRENT EPISODE	AGE OF ONSET OF CURRENT EPISODE
1. Major Depressive Episode	0 1 2 3		0 1 2 3 4	
2. Dysthymia	0 1 2 3		0 1 2 3 4	
3. Unspecified Depressive Disorder	0 1 2 3		0 1 2 3 4	
4. Adjustment Disorder w Depressed Mood	0 1 2 3		0 1 2 3 4	
5. Mania	0 1 2 3		0 1 2 3 4	
6. Hypmania	0 1 2 3		0 1 2 3 4	
7. Cyclothymia	0 1 2 3		0 1 2 3 4	
8. Bipolar Mixed Episode (MDE & Mania)	0 1 2 3		0 1 2 3 4	
9. Hypomania/Mixed Episode	0 1 2 3		0 1 2 3 4	
10. Unspecified Bipolar Disorder	0 1 2 3		0 1 2 3 4	
11. Unspecified Mood Disorder	0 1 2 3		0 1 2 3 4	
12. Primary Mood Disorder w Psychotic Features	0 1 2 3		0 1 2 3 4	
13. Disruptive Mood Dysregulation Disorder	0 1 2 3		0 1 2 3 4	
14. Schizoaffective Disorder	0 1 2 3		0 1 2 3 4	
1.` Schizophrenia	0 1 2 3		0 1 2 3 4	
1.` Schizophreniform Disorder	0 1 2 3		0 1 2 3 4	
17. Brief Reactive Psychosis	0 1 2 3		0 1 2 3 4	
1.` Unspecified Psychotic DO	0 1 2 3		0 1 2 3 4	

8962154 YEAR ID DATE / /

SUMMARY LIFETIME DIAGNOSES CHECKLIST

Ages:
Score in years.

	DIAGNOSIS MOST SEVERE PAST (MSP) EPISODE	AGE OF ONSET MSP EPISODE	DIAGNOSIS CURRENT EPISODE	AGE OF ONSET CURRENT EPISODE
19. Panic Disorder	0 1 2 3		0 1 2 3 4	
20. Agorophobia Disorder	0 1 2 3		0 1 2 3 4	
21. Separation Anxiety DO	0 1 2 3		0 1 2 3 4	
22. Social Anxiety DO	0 1 2 3		0 1 2 3 4	
23. Selective Mutism	0 1 2 3		0 1 2 3 4	
24. Specific Phobia	0 1 2 3		0 1 2 3 4	
25. Generalized Anxiety DO	0 1 2 3		0 1 2 3 4	
26. Obsessive Compulsive DO	0 1 2 3		0 1 2 3 4	
27. Posttaumatic Stress DO	0 1 2 3		0 1 2 3 4	
28. Acute Stress Disorder	0 1 2 3		0 1 2 3 4	
29. Unspecified Anxiety DO	0 1 2 3		0 1 2 3 4	
30. Adjustment Disorder w Anxious Mood	0 1 2 3		0 1 2 3 4	
31. Enuresis	0 1 2 3		0 1 2 3 4	
32. Encopresis	0 1 2 3		0 1 2 3 4	
33. Anorexia Nervosa	0 1 2 3		0 1 2 3 4	
34. Bulimia	0 1 2 3		0 1 2 3 4	
35. Binge Eating DO	0 1 2 3		0 1 2 3 4	
36. Eating DO NOS	0 1 2 3		0 1 2 3 4	

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SUMMARY LIFETIME DIAGNOSES CHECKLIST

Ages: Score in years	DIAGNOSIS MOST SEVERE PAST (MSP) EPISODE	AGE OF ONSET MSP EPISODE	DIAGNOSIS CURRENT EPISODE	AGE OF ONSET CURRENT EPISODE
37. ADHD	0 1 2 3		0 1 2 3 4	
	○ Combined (1) ○ Inattentive (2) ○ Impulsive/Hyperactive (3)		○ Combined (1) ○ Inattentive (2) ○ Impulsive/Hyperactive (3)	
38. Unspecified ADHD	0 1 2 3		0 1 2 3 4	
39. Conduct Disorder	0 1 2 3		0 1 2 3 4	
40. Oppositional Defiant DO	0 1 2 3		0 1 2 3 4	
41. Unspecified Disruptive Behav	0 1 2 3		0 1 2 3 4	
42. Adj. Disorder w/Dist. of Conduct	0 1 2 3		0 1 2 3 4	
43. Adj. Disorder w/Mixed Mood & Conduct	0 1 2 3		0 1 2 3 4	
44. Tourettes	0 1 2 3		0 1 2 3 4	
45. Chronic Motor or Vocal Tic Disorder	0 1 2 3		0 1 2 3 4	
46. Transient Tic DO	0 1 2 3		0 1 2 3 4	
47. Autism Spectrum DO	0 1 2 3		0 1 2 3 4	
48. Alcohol Use Disorder	0 1 2 3		0 1 2 3 4	
49. Substance Use Disorder	0 1 2 3		0 1 2 3 4	
50. Other Diagnoses (specify)	0 1 2 3		0 1 2 3 4	
51. Other Diagnoses (specify)	0 1 2 3		0 1 2 3 4	

SUBSTANCE INDUCED MOOD AND ANXIETY

Substance Induced Mood DO	0 1 2 3 4		0 1 2 3 4	
Specify MOOD	○ Mania ○ Hypomania ○ Mixed ○ Depression ○ Other/ Unknown			
Substance Induced Anxiety DO	0 1 2 3 4		0 1 2 3 4	

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TREATMENT HISTORY: Score: 0=No Information, 1=No, 2=Yes

Outpatient Treatment	0 1 2	**Psychiatric Hospitalization**	0 1 2
Age of First Outpatient Treatment (years)		**Age of First Psychiatric Hospitalization** (years)	
Total Duration of Outpatient Treatment (weeks)		**Number of Psychiatric Hospitalizations**	
		Total Duration of Inpatient Treatment (weeks)	

SUICIDAL BEHAVIOR:

Ideation: 0 1 2
Gesture: 0 1 2
Attempt: 0 1 2

RELIABILITY OF INFORMATION: ☐ Good (2) ☐ Fair (1) ☐ Poor (0)

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FOLLOW-UP SUMMARY DIAGNOSES CHECKLIST

Date of Last Assessment: ____/____/_____

0 = NO INFORMATION 3 = DEFINITE
1 = NOT PRESENT 4 = IN PARTIAL REMISSION*
2 = PROBABLE
*(where applicable, according to the DSM-5)

1. Meets criteria for core symptoms of the disorder.
2. Meets all but one, or a minimum of 75% of the remaining criteria required for the diagnosis
3. Evidence of functional impairment

Ages: Score in years	DIAGNOSIS MOST SEVERE PAST (MSP) EPISODE SINCE LAST INTERVIEW	AGE OF ONSET MSP EPISODE SINCE LAST INTERVIEW	DIAGNOSIS CURRENT EPISODE	AGE OF ONSET OF CURRENT EPISODE
1. Major Depressive Episode	0 1 2 3		0 1 2 3 4	
2. Dysthymia	0 1 2 3		0 1 2 3 4	
3. Unspecified Depressive Disorder	0 1 2 3		0 1 2 3 4	
4. Adjustment Disorder w Depressed Mood	0 1 2 3		0 1 2 3 4	
5. Mania	0 1 2 3		0 1 2 3 4	
6. Hypmania	0 1 2 3		0 1 2 3 4	
7. Cyclothymia	0 1 2 3		0 1 2 3 4	
8. Bipolar Mixed Episode (MDE & Mania)	0 1 2 3		0 1 2 3 4	
9. Hypomania/ Mixed Episode	0 1 2 3		0 1 2 3 4	
10. Unspecified Bipolar Disorder	0 1 2 3		0 1 2 3 4	
11. Unspecified Mood Disorder	0 1 2 3		0 1 2 3 4	
12. Primary Mood Disorder w Psychotic Features	0 1 2 3		0 1 2 3 4	
13. Disruptive Mood Dysregulation Disorder	0 1 2 3		0 1 2 3 4	
14. Schizoaffective Disorder	0 1 2 3		0 1 2 3 4	
15. Schizophrenia	0 1 2 3		0 1 2 3 4	
16. Schizophreniform Disorder	0 1 2 3		0 1 2 3 4	
17 Brief Reactive Psychosis	0 1 2 3		0 1 2 3 4	
18. Unspecified Psychotic DO	0 1 2 3		0 1 2 3 4	

8962154 YEAR ID DATE ____/____/____

FOLLOW-UP SUMMARY DIAGNOSES CHECKLIST

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Ages: Score in years	DIAGNOSIS MOST SEVERE PAST (MSP) EPISODE SINCE LAST INTERVIEW	AGE OF ONSET MSP EPISODE SINCE LAST INTERVIEW	DIAGNOSIS CURRENT EPISODE	AGE OF ONSET CURRENT EPISODE
19. Panic Disorder	0 1 2 3		0 1 2 3 4	
20. Agorophobia Disorder	0 1 2 3		0 1 2 3 4	
21. Separation Anxiety DO	0 1 2 3		0 1 2 3 4	
22. Social Anxiety DO	0 1 2 3		0 1 2 3 4	
23. Selective Mutism	0 1 2 3		0 1 2 3 4	
24. Specific Phobia	0 1 2 3		0 1 2 3 4	
25. Generalized Anxiety DO	0 1 2 3		0 1 2 3 4	
26. Obsessive Compulsive DO	0 1 2 3		0 1 2 3 4	
27. Posttaumatic Stress DO	0 1 2 3		0 1 2 3 4	
28. Acute Stress Disorder	0 1 2 3		0 1 2 3 4	
29. Unspecified Anxiety DO	0 1 2 3		0 1 2 3 4	
30. Adjustment Disorder w Anxious Mood	0 1 2 3		0 1 2 3 4	
31. Enuresis	0 1 2 3		0 1 2 3 4	
32. Encopresis	0 1 2 3		0 1 2 3 4	
33. Anorexia Nervosa	0 1 2 3		0 1 2 3 4	
34. Bulimia	0 1 2 3		0 1 2 3 4	
35. Binge Eating DO	0 1 2 3		0 1 2 3 4	
36. Eating DO NOS	0 1 2 3		0 1 2 3 4	

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FOLLOW-UP SUMMARY DIAGNOSES CHECKLIST

53

Ages: Score in years	DIAGNOSIS MOST SEVERE PAST (MSP) EPISODE SINCE LAST INTERVIEW	AGE OF ONSET MSP EPISODE SINCE LAST INTERVIEW	DIAGNOSIS CURRENT EPISODE	AGE OF ONSET CURRENT EPISODE
37. ADHD	0 1 2 3		0 1 2 3 4	
	○ Combined (1) ○ Inattentive (2) ○ Impulsive/Hyperactive (3)		○ Combined (1) ○ Inattentive (2) ○ Impulsive/Hyperactive (3)	
38. Unspecified ADHD	0 1 2 3		0 1 2 3 4	
39. Conduct Disorder	0 1 2 3		0 1 2 3 4	
40. Oppositional Defiant DO	0 1 2 3		0 1 2 3 4	
41. Unspecified Disruptive Behav	0 1 2 3		0 1 2 3 4	
42. Adj. Disorder w/Dist. of Conduct	0 1 2 3		0 1 2 3 4	
43. Adj. Disorder w/Mixed Mood & Conduct	0 1 2 3		0 1 2 3 4	
44. Tourettes	0 1 2 3		0 1 2 3 4	
45. Chronic Motor or Vocal Tic Disorder	0 1 2 3		0 1 2 3 4	
46. Transient Tic DO	0 1 2 3		0 1 2 3 4	
47. Autism Spectrum DO	0 1 2 3		0 1 2 3 4	
48. Alcohol Use Disorder	0 1 2 3		0 1 2 3 4	
49. Substance Use Disorder	0 1 2 3		0 1 2 3 4	
50. Other Diagnoses (specify)	0 1 2 3		0 1 2 3 4	
51. Other Diagnoses (specify)	0 1 2 3		0 1 2 3 4	

SUBSTANCE INDUCED MOOD AND ANXIETY

Substance Induced Mood DO	0 1 2 3		0 1 2 3 4	
Specify MOOD	○ Mania ○ Hypomania ○ Mixed ○ Depression ○ Other/ Unknown			
Substance Induced Anxiety DO	0 1 2 3		0 1 2 3 4	

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TREATMENT HISTORY (since last assessment): Score: 0=No Information, 1=No, 2=Yes

Outpatient Treatment	0 1 2	**Psychiatric Hospitalization**	0 1 2
Age of First Outpatient Treatment (years)		**Age of First Psychiatric Hospitalization** (years)	
Total Duration of Outpatient Treatment (weeks)		**Number of Psychiatric Hospitalizations**	
		Total Duration of Inpatient Treatment (weeks)	

SUICIDAL BEHAVIOR:

Ideation: 0 1 2
Gesture: 0 1 2
Attempt: 0 1 2

RELIABILITY OF INFORMATION: ☐ Good (2) ☐ Fair (1) ☐ Poor (0)

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AMERICAN PSYCHIATRIC ASSOCIATION

DSM-5 CROSS-CUTTING SYMPTOM MEASURES

http://www.psychiatry.org/practice/dsm/dsm5/online-assessment-measures#Level1

DSM-5 Parent/Guardian-Rated Level 1 Cross-Cutting Symptom Measure—Child Age 6–17

Child's Name: _____ **Age:** ____ **Sex:** ☐ **Male** ☐ **Female** **Date:**_____

Relationship with the child: _____

Instructions *(to the parent or guardian of child):* The questions below ask about things that might have bothered your child. For each question, circle the number that best describes how much (or how often) your child has been bothered by each problem during the **past TWO (2) WEEKS.**

		During the past **TWO (2) WEEKS,** how much (or how often) has your child...	None Not at all	Slight Rare, less than a day or two	Mild Several days	Moderate More than half the days	Severe Nearly every day	Highest Domain Score (clinician)
I.	1.	Complained of stomachaches, headaches, or other aches and pains?	0	1	2	3	4	
	2.	Said he/she was worried about his/her health or about getting sick?	0	1	2	3	4	
II.	3.	Had problems sleeping—that is, trouble falling asleep, staying asleep, or waking up too early?	0	1	2	3	4	
III.	4.	Had problems paying attention when he/she was in class or doing his/her homework or reading a book or playing a game?	0	1	2	3	4	
IV.	5.	Had less fun doing things than he/she used to?	0	1	2	3	4	
	6.	Seemed sad or depressed for several hours?	0	1	2	3	4	
V. & VI.	7.	Seemed more irritated or easily annoyed than usual?	0	1	2	3	4	
	8.	Seemed angry or lost his/her temper?	0	1	2	3	4	
VII.	9.	Started lots more projects than usual or did more risky things than usual?	0	1	2	3	4	
	10.	Slept less than usual for him/her, but still had lots of energy?	0	1	2	3	4	
VIII.	11.	Said he/she felt nervous, anxious, or scared?	0	1	2	3	4	
	12.	Not been able to stop worrying?	0	1	2	3	4	
	13.	Said he/she couldn't do things he/she wanted to or should have done, because they made him/her feel nervous?	0	1	2	3	4	
IX.	14.	Said that he/she heard voices—when there was no one there—speaking about him/her or telling him/her what to do or saying bad things to him/her?	0	1	2	3	4	
	15.	Said that he/she had a vision when he/she was completely awake—that is, saw something or someone that no one else could see?	0	1	2	3	4	
X.	16.	Said that he/she had thoughts that kept coming into his/her mind that he/she would do something bad or that something bad would happen to him/her or to someone else?	0	1	2	3	4	
	17.	Said he/she felt the need to check on certain things over and over again, like whether a door was locked or whether the stove was turned off?	0	1	2	3	4	
	18.	Seemed to worry a lot about things he/she touched being dirty or having germs or being poisoned?	0	1	2	3	4	
	19.	Said that he/she had to do things in a certain way, like counting or saying special things out loud, in order to keep something bad from happening?	0	1	2	3	4	
		In the past **TWO (2) WEEKS,** has your child ...						
XI.	20.	Had an alcoholic beverage (beer, wine, liquor, etc.)?	☐ Yes	☐ No	☐ Don't Know			
	21.	Smoked a cigarette, a cigar, or pipe, or used snuff or chewing tobacco?	☐ Yes	☐ No	☐ Don't Know			
	22.	Used drugs like marijuana, cocaine or crack, club drugs (like ecstasy), hallucinogens (like LSD), heroin, inhalants or solvents (like glue), or methamphetamine (like speed)?	☐ Yes	☐ No	☐ Don't Know			
	23.	Used any medicine without a doctor's prescription (e.g., painkillers [like Vicodin], stimulants [like Ritalin or Adderall], sedatives or tranquilizers [like sleeping pills or Valium], or steroids)?	☐ Yes	☐ No	☐ Don't Know			
XII.	24.	In the past **TWO (2) WEEKS,** has he/she talked about wanting to kill himself/herself or about wanting to commit suicide?	☐ Yes	☐ No	☐ Don't Know			
	25.	Has he/she EVER tried to kill himself/herself?	☐ Yes	☐ No	☐ Don't Know			

Instructions to Clinicians

The DSM-5 Parent/Guardian-Rated Level 1 Cross-Cutting Symptom Measure—Child Age 6–17 assesses mental health domains that are important across psychiatric diagnoses. It is intended to help clinicians identify additional areas of inquiry that may have significant impact on the child's treatment and prognosis. The measure may also be used to track changes in the child's symptom presentation over time.

The measure consists of 25 questions that assess 12 psychiatric domains, including depression, anger, irritability, mania, anxiety, somatic symptoms, inattention, suicidal ideation/attempt, psychosis, sleep disturbance, repetitive thoughts and behaviors, and substance use. Each item asks the parent or guardian to rate how much (or how often) his or her child has been bothered by the specific symptom during the past 2 weeks. The measure was found to be clinically useful and had good test-retest reliability in the DSM-5 Field Trials in pediatric clinical samples across the United States.

Scoring and Interpretation

Nineteen of the 25 items on the measure are each rated on a 5-point scale (0=none or not at all; 1=slight or rare, less than a day or two; 2=mild or several days; 3=moderate or more than half the days; and 4=severe or nearly every day). The suicidal ideation, suicide attempt, and substance abuse items are each rated on a "Yes, No, or Don't Know" scale. The score on each item within a domain should be reviewed. Because additional inquiry is based on the highest score on any item within a domain, the clinician is asked to indicate that score in the "Highest Domain Score" column. Table 1 (below) outlines threshold scores that may be used to guide further inquiry for each domain. With the exception of inattention and psychosis, a rating of mild (i.e., 2) or greater on any item within a domain that is scored on the 5-point scale may serve as a guide for additional inquiry and follow-up to determine if a more detailed assessment for that domain is needed. A parent or guardian's rating of "Don't Know" on the suicidal ideation, suicide attempt, and any of the substance use items, especially for a child age 11–17, may be used as a guide for additional inquiry of the issues with the child. The DSM-5 Level 2 Cross-Cutting Symptom measures in Table 1 may be used as a resource to provide more detailed information on the symptoms associated with some of the Level 1 domains.

Frequency of Use

To track change in the child's symptom presentation over time, the measure may be completed at regular intervals as clinically indicated, depending on the stability of the child's symptoms and treatment status, and preferably by the same parent or guardian. Consistently high scores on a particular domain may indicate significant and problematic symptoms for the child that might warrant further assessment, treatment, and follow-up. Clinical judgment should guide decision making.

Table 1: DSM-5 Parent/Guardian-Rated Level 1 Cross-Cutting Symptom Measure—Child Age 6–17: domains, thresholds for further inquiry, and associated Level 2 measures

Domain	Domain Name	Threshold to guide further inquiry	DSM-5 Level 2 Cross-Cutting Symptom Measure available online
I.	Somatic Symptoms	Mild or greater	LEVEL 2—Somatic Symptom—Parent/Guardian of Child Age 6–17 (Patient Health Questionnaire 15 Somatic Symptom Severity (PHQ-15)
II.	Sleep Problems	Mild or greater	LEVEL 2—Sleep Disturbance—Parent/ Guardian of Child Age 6–17 (PROMIS—Sleep Disturbance—Short Form)[1]
III.	Inattention	Slight or greater	LEVEL 2—Inattention—Parent/Guardian of Child Age 6–17 (SNAP-IV)
IV.	Depression	Mild or greater	LEVEL 2—Depression—Parent/Guardian of Child Age 6–17 (PROMIS Emotional Distress—Depression—Parent Item Bank)
V.	Anger	Mild or greater	LEVEL 2—Anger—Parent/Guardian of Child Age 6–17 (PROMIS Emotional Distress—Calibrated Anger Measure—Parent)
VI.	Irritability	Mild or greater	LEVEL 2—Irritability—Parent/Guardian of Child Age 6–17 (Affective Reactivity Index)
VII.	Mania	Mild or greater	LEVEL 2—Mania—Parent/Guardian of Child Age 6–17 (adapted from the Altman Self-Rating Mania Scale)
VIII.	Anxiety	Mild or greater	LEVEL 2—Anxiety—Parent/Guardian of Child Age 6–17 (adapted from PROMIS Emotional Distress—Anxiety—Parent Item Bank)
IX.	Psychosis	Slight or greater	None
X.	Repetitive Thoughts and Behaviors	Mild or greater	None
XI.	Substance Use	Yes/ Don't Know	LEVEL 2—Substance Use—Parent/Guardian of Child Age 6–17 (adapted from the NIDA-modified ASSIST)/LEVEL 2—Substance Use—Child Age 11–17 (adapted from the NIDA-modified ASSIST)
XII.	Suicidal Ideation/ Suicide Attempts	Yes/ Don't Know	None

[1]Not validated for children by the PROMIS group but found to have acceptable test-retest reliability with parent informants in the DSM-5 Field Trial.

DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure—Child Age 11–17

Name: _____ **Age:** ____ **Sex:** ❑ **Male** ❑ **Female** **Date:**_____

Instructions: The questions below ask about things that might have bothered you. For each question, circle the number that best describes how much (or how often) you have been bothered by each problem during the **past TWO (2) WEEKS.**

		During the past **TWO (2) WEEKS,** how much (or how often) have you...	None Not at all	Slight Rare, less than a day or two	Mild Several days	Moderate More than half the days	Severe Nearly every day	Highest Domain Score (clinician)
I.	1.	Been bothered by stomachaches, headaches, or other aches and pains?	0	1	2	3	4	
	2.	Worried about your health or about getting sick?	0	1	2	3	4	
II.	3.	Been bothered by not being able to fall asleep or stay asleep, or by waking up too early?	0	1	2	3	4	
III.	4.	Been bothered by not being able to pay attention when you were in class or doing homework or reading a book or playing a game?	0	1	2	3	4	
IV.	5.	Had less fun doing things than you used to?	0	1	2	3	4	
	6.	Felt sad or depressed for several hours?	0	1	2	3	4	
V. & VI.	7.	Felt more irritated or easily annoyed than usual?	0	1	2	3	4	
	8.	Felt angry or lost your temper?	0	1	2	3	4	
VII.	9.	Started lots more projects than usual or done more risky things than usual?	0	1	2	3	4	
	10.	Slept less than usual but still had a lot of energy?	0	1	2	3	4	
VIII.	11.	Felt nervous, anxious, or scared?	0	1	2	3	4	
	12.	Not been able to stop worrying?	0	1	2	3	4	
	13.	Not been able to do things you wanted to or should have done, because they made you feel nervous?	0	1	2	3	4	
IX.	14.	Heard voices—when there was no one there—speaking about you or telling you what to do or saying bad things to you?	0	1	2	3	4	
	15.	Had visions when you were completely awake—that is, seen something or someone that no one else could see?	0	1	2	3	4	
X.	16.	Had thoughts that kept coming into your mind that you would do something bad or that something bad would happen to you or to someone else?	0	1	2	3	4	
	17.	Felt the need to check on certain things over and over again, like whether a door was locked or whether the stove was turned off?	0	1	2	3	4	
	18.	Worried a lot about things you touched being dirty or having germs or being poisoned?	0	1	2	3	4	
	19.	Felt you had to do things in a certain way, like counting or saying special things, to keep something bad from happening?	0	1	2	3	4	
		In the past **TWO (2) WEEKS,** have you...						
XI.	20.	Had an alcoholic beverage (beer, wine, liquor, etc.)?	❑ Yes			❑ No		
	21.	Smoked a cigarette, a cigar, or pipe, or used snuff or chewing tobacco?	❑ Yes			❑ No		
	22.	Used drugs like marijuana, cocaine or crack, club drugs (like Ecstasy), hallucinogens (like LSD), heroin, inhalants or solvents (like glue), or methamphetamine (like speed)?	❑ Yes			❑ No		
	23.	Used any medicine without a doctor's prescription to get high or change the way you feel (e.g., painkillers [like Vicodin], stimulants [like Ritalin or Adderall], sedatives or tranquilizers [like sleeping pills or Valium], or steroids)?	❑ Yes			❑ No		
XII.	24.	In the last 2 weeks, have you thought about killing yourself or committing suicide?	❑ Yes			❑ No		
	25.	Have you EVER tried to kill yourself?	❑ Yes			❑ No		

Instructions to Clinicians

The DSM-5 Level 1 Cross-Cutting Symptom Measure is a self-rated measure that assesses mental health domains that are important across psychiatric diagnoses. It is intended to help clinicians identify additional areas of inquiry that may have significant impact on the child's treatment and prognosis. In addition, the measure may be used to track changes in the child's symptom presentation over time.

This child-rated version of the measure consists of 25 questions that assess 12 psychiatric domains, including depression, anger, irritability, mania, anxiety, somatic symptoms, inattention, suicidal ideation/attempt, psychosis, sleep disturbance, repetitive thoughts and behaviors, and substance use. Each item asks the child, age 11–17, to rate how much (or how often) he or she has been bothered by the specific symptom during the past 2 weeks. The measure was found to be clinically useful and had good test-retest reliability in the DSM-5 Field Trials conducted in pediatric clinical samples across the United States.

Scoring and Interpretation

Nineteen of the 25 items on the measure are each rated on a 5-point scale (0=none or not at all; 1=slight or rare, less than a day or two; 2=mild or several days; 3=moderate or more than half the days; and 4=severe or nearly every day). The suicidal ideation, suicide attempt, and substance abuse items are each rated on a "Yes or No" scale. The score on each item within a domain should be reviewed. Because additional inquiry is based on the highest score on any item within a domain, the clinician is asked to indicate that score in the "Highest Domain Score" column. Table 1 (below) outlines threshold scores that may be used to guide further inquiry for the domains. With the exception of inattention and psychosis, a rating of mild (i.e., 2) or greater on any item within a domain that is scored on the 5-point scale may serve as a guide for additional inquiry and follow-up to determine if a more detailed assessment for that domain is needed. The DSM-5 Level 2 Cross-Cutting Symptom measures listed in Table 1 may be used as a resource to provide more detailed information on the symptoms associated with some of the Level 1 domains.

Frequency of Use

To track change in the child's symptom presentation over time, it is recommended that the measure be completed at regular intervals as clinically indicated, depending on the stability of the child's symptoms and treatment status. Consistently high scores on a particular domain may indicate significant and problematic symptoms for the child that might warrant further assessment, treatment, and follow-up. Clinical judgment should guide decision making.

Table 1: DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure—Child Age 11–17: domains, thresholds for further inquiry, and associated Level 2 measures

Domain	Domain Name	Threshold to guide further inquiry	DSM-5 Level 2 Cross-Cutting Symptom Measure available online
I.	Somatic Symptoms	Mild or greater	LEVEL 2—Somatic Symptom—Child Age 11–17 (Patient Health Questionnaire Somatic Symptom Severity [PHQ-15])
II.	Sleep Problems	Mild or greater	LEVEL 2—Sleep Disturbance—Child Age 11-17 (PROMIS—Sleep Disturbance—Short Form)[1]
III.	Inattention	Slight or greater	None
IV.	Depression	Mild or greater	LEVEL 2—Depression—Child Age 11–17 (PROMIS Emotional Distress—Depression—Pediatric Item Bank)
V.	Anger	Mild or greater	LEVEL 2—Anger—Child Age 11–17 (PROMIS Emotional Distress—Calibrated Anger Measure—Pediatric)
VI.	Irritability	Mild or greater	LEVEL 2—Irritability—Child Age 11–17 (Affective Reactivity Index [ARI])
VII.	Mania	Mild or greater	LEVEL 2—Mania—Child Age 11–17 (Altman Self-Rating Mania Scale [ASRM])
VIII.	Anxiety	Mild or greater	LEVEL 2—Anxiety—Child Age 11–17 (PROMIS Emotional Distress—Anxiety—Pediatric Item Bank)
IX.	Psychosis	Slight or greater	None
X.	Repetitive Thoughts & Behaviors	Mild or greater	LEVEL 2—Repetitive Thoughts and Behaviors—Child 11–17 (adapted from the Children's Florida Obsessive-Compulsive Inventory [C-FOCI] Severity Scale)
XI.	Substance Use	Yes/ Don't Know	LEVEL 2—Substance Use—Child Age 11–17 (adapted from the NIDA-modified ASSIST)
XII.	Suicidal Ideation/ Suicide Attempts	Yes/ Don't Know	None

[1]Not validated for children by the PROMIS group but found to have acceptable test-retest reliability with child informants in the DSM-5 Field Trial.

10.5 **Columbia-Suicide Severity Rating Scales (C-SSRS)**

COLUMBIA-SUICIDE SEVERITY RATING SCALE (C-SSRS)

Lifetime Recent - Clinical

Version 1/14/09

Posner, K.; Brent, D.; Lucas, C.; Gould, M.; Stanley, B.; Brown, G.; Fisher, P.; Zelazny, J.; Burke, A.; Oquendo, M.; Mann, J.

Disclaimer:

This scale is intended to be used by individuals who have received training in its administration. The questions contained in the Columbia-Suicide Severity Rating Scale are suggested probes. Ultimately, the determination of the presence of suicidal ideation or behavior depends on the judgment of the individual administering the scale.

Definitions of behavioral suicidal events in this scale are based on those used in ***The Columbia Suicide History Form****, developed by John Mann, MD and Maria Oquendo, MD, Conte Center for the Neuroscience of Mental Disorders (CCNMD), New York State Psychiatric Institute, 1051 Riverside Drive, New York, NY, 10032. (Oquendo M. A., Halberstam B. & Mann J. J., Risk factors for suicidal behavior: utility and limitations of research instruments. In M.B. First [Ed.]* Standardized Evaluation in Clinical Practice*, pp. 103 -130, 2003.)*

For reprints of the C-SSRS contact Kelly Posner, Ph.D., New York State Psychiatric Institute, 1051 Riverside Drive, New York, New York, 10032; inquiries and training requirements contact posnerk@nyspi.columbia.edu

SUICIDAL IDEATION		
Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.	**Lifetime: Time He/She Felt Most Suicidal**	**Past 1 month**
1. Wish to be Dead Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up. ***Have you wished you were dead or wished you could go to sleep and not wake up?*** If yes, describe:	Yes ☐ No ☐	Yes ☐ No ☐
2. Non-Specific Active Suicidal Thoughts General non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period. ***Have you actually had any thoughts of killing yourself?*** If yes, describe:	Yes ☐ No ☐	Yes ☐ No ☐
3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it... and I would never go through with it."* ***Have you been thinking about how you might do this?*** If yes, describe:	Yes ☐ No ☐	Yes ☐ No ☐
4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."* ***Have you had these thoughts and had some intention of acting on them?*** If yes, describe:	Yes ☐ No ☐	Yes ☐ No ☐
5. Active Suicidal Ideation with Specific Plan and Intent Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out. ***Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?*** If yes, describe:	Yes ☐ No ☐	Yes ☐ No ☐
INTENSITY OF IDEATION		
The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe). Ask about time he/she was feeling the most suicidal. Lifetime - ***Most Severe Ideation:*** _____ *Type # (1-5)* _____ *Description of Ideation* Recent - ***Most Severe Ideation:*** _____ *Type # (1-5)* _____ *Description of Ideation*	Most Severe	Most Severe
Frequency ***How many times have you had these thoughts?*** (1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day	____	____
Duration ***When you have the thoughts how long do they last?*** (1) Fleeting - few seconds or minutes (2) Less than 1 hour/some of the time (3) 1-4 hours/a lot of time (4) 4-8 hours/most of day (5) More than 8 hours/persistent or continuous	____	____
Controllability ***Could/can you stop thinking about killing yourself or wanting to die if you want to?*** (1) Easily able to control thoughts (2) Can control thoughts with little difficulty (3) Can control thoughts with some difficulty (4) Can control thoughts with a lot of difficulty (5) Unable to control thoughts (0) Does not attempt to control thoughts	____	____
Deterrents ***Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?*** (1) Deterrents definitely stopped you from attempting suicide (2) Deterrents probably stopped you (3) Uncertain that deterrents stopped you (4) Deterrents most likely did not stop you (5) Deterrents definitely did not stop you (0) Does not apply	____	____
Reasons for Ideation ***What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?*** (1) Completely to get attention, revenge or a reaction from others (2) Mostly to get attention, revenge or a reaction from others (3) Equally to get attention, revenge or a reaction from others and to end/stop the pain (4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling) (5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling) (0) Does not apply	____	____

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	**Lifetime**	**Past 3 months**
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or Did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe:	Yes ☐ No ☐ Total # of Attempts _____	Yes ☐ No ☐ Total # of Attempts _____
Has subject engaged in Non-Suicidal Self-Injurious Behavior?	Yes ☐ No ☐	Yes ☐ No ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	Yes ☐ No ☐ Total # of interrupted _____	Yes ☐ No ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	Yes ☐ No ☐ Total # of aborted or self-interrupted _____	Yes ☐ No ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	Yes ☐ No ☐ Total # of preparatory acts _____	Yes ☐ No ☐ Total # of preparatory acts _____

	Most Recent Attempt Date:	Most Lethal Attempt Date:	Initial/First Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____	*Enter Code* _____	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____	*Enter Code* _____	*Enter Code* _____

COLUMBIA-SUICIDE SEVERITY RATING SCALE (C-SSRS)

Since Last Visit - Clinical

Version 1/14/09

Posner, K.; Brent, D.; Lucas, C.; Gould, M.; Stanley, B.; Brown, G.; Fisher, P.; Zelazny, J.; Burke, A.; Oquendo, M.; Mann, J.

Disclaimer:

This scale is intended to be used by individuals who have received training in its administration. The questions contained in the Columbia-Suicide Severity Rating Scale are suggested probes. Ultimately, the determination of the presence of suicidal ideation or behavior depends on the judgment of the individual administering the scale.

Definitions of behavioral suicidal events in this scale are based on those used in ***The Columbia Suicide History Form****, developed by John Mann, MD and Maria Oquendo, MD, Conte Center for the Neuroscience of Mental Disorders (CCNMD), New York State Psychiatric Institute, 1051 Riverside Drive, New York, NY, 10032. (Oquendo M. A., Halberstam B. & Mann J. J., Risk factors for suicidal behavior: utility and limitations of research instruments. In M.B. First [Ed.]* Standardized Evaluation in Clinical Practice*, pp. 103 -130, 2003.)*

For reprints of the C-SSRS contact Kelly Posner, Ph.D., New York State Psychiatric Institute, 1051 Riverside Drive, New York, New York, 10032; inquiries and training requirements contact posnerk@nyspi.columbia.edu

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead
Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?
Yes ☐ No ☐
If yes, describe:

2. Non-Specific Active Suicidal Thoughts
General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?
Yes ☐ No ☐
If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act
Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it...and I would never go through with it."*
Have you been thinking about how you might do this?
Yes ☐ No ☐
If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan
Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?
Yes ☐ No ☐
If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent
Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?
Yes ☐ No ☐
If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____
Type # (1-5) ***Description of Ideation***

Frequency
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day
____

Duration
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous
____

Controllability
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts
____

Deterrents
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply
____

Reasons for Ideation
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply
____

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes No** ☐ ☐ Total # of Attempts _____ **Yes No** ☐ ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes No** ☐ ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged inany self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes No** ☐ ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes No** ☐ ☐ Total # of preparatory acts _____
Suicide: Death by suicide occurred since last assessment.	**Yes No** ☐ ☐
	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

10.6 **Swanson, Nolan and Pelham Rating Scale-Revised (SNAP IV)**

THE MTA SNAP-IV TEACHER AND PARENT RATING SCALE James M. Swanson, Ph.D., University of California, Irvine, CA 92715				
For each item, check the column which best describes this child	Not At All	Just A Little	Pretty Much	Very Much
1. Fails to give close attention to details or makes careless mistakes in schoolwork or tasks	____	____	____	____
2. Has difficulty sustaining attention in tasks or play activities	____	____	____	____
3. Does not seem to listen when spoken to directly	____	____	____	____
4. Does not follow through on instructions and fails to finish schoolwork, chores, or duties	____	____	____	____
5. Has difficulty organizing tasks and activities	____	____	____	____
6. Avoids, dislikes, or reluctantly engages in tasks requiring sustained mental effort	____	____	____	____
7. Loses things necessary for activities (e.g., toys, school assignments, pencils, or books)	____	____	____	____
8. Is distracted by extraneous stimuli	____	____	____	____
9. Is forgetful in daily activities	____	____	____	____
10. Fidgets with hands or feet or squirms in seat	____	____	____	____
11. Leaves seat in classroom or in other situations in which remaining seated is expected	____	____	____	____
12. Runs about or climbs excessively in situations in which it is inappropriate	____	____	____	____
13. Has difficulty playing or engaging in leisure activities quietly	____	____	____	____
14. Is "on the go" or often acts as if "driven by a motor"	____	____	____	____
15. Talks excessively	____	____	____	____
16. Blurts out answers before questions have been completed	____	____	____	____
17. Has difficulty awaiting turn	____	____	____	____
18. Interrupts or intrudes on others (e.g., butts into conversations / games)	____	____	____	____
19. Loses temper	____	____	____	____
20. Argues with adults	____	____	____	____
21. Actively defies or refuses adult requests or rules	____	____	____	____
22. Deliberately does things that annoy other people	____	____	____	____
23. Blames others for his or her mistakes or misbehavior	____	____	____	____
24. Is touchy or easily annoyed by others	____	____	____	____
25. Is angry and resentful	____	____	____	____
26. Is spiteful or vindictive	____	____	____	____

Rater Initials: ___ ___ ___

10.7 **Simpson-Angus Rating Scale**

1. GAIT:
The patient is examined as he walks into the examining room, his gait, the swing of his arms, his general posture, all form the basis for an overall score for this item. This is rated as follows:

0 = Normal

1 = Diminution in swing while the patient is walking

2 = Marked diminution in swing with obvious rigidity in the arm

3 = Stiff gait with arms held rigidly before the abdomen

4 = Stopped shuffling gait with propulsion and retropulsion

2. ARM DROPPING:
The patient and the examiner both raise their arms to shoulder height and let them fall to their sides. In a normal subject, a stout slap is heard as the arms hit the sides. In the patient with extreme Parkinson's syndrome, the arms fall very slowly:

0 = Normal, free fall with loud slap and rebound

1 = Fall slowed slightly with less audible contact and little rebound

2 = Fall slowed, no rebound

3 = Marked slowing, no slap at all

4 = Arms fall as though against resistance; as though through glue

3. SHOULDER SHAKING:
The subject's arms are bent at a right angle at the elbow and are taken one at a time by the examiner who grasps one hand and also clasps the other around the patient's elbow. The subject's upper arm is pushed to and fro and the humerus is externally rotated. The degree of resistance from normal to extreme rigidity is scored as follows.

0 = Normal

1 = Slight stiffness and resistance

2 = Moderate stiffness and resistance

3 = Marked rigidity with difficulty in passive movement

4 = Extreme stiffness and rigidity with almost a frozen shoulder

4. ELBOW RIGIDITY:
The elbow joints are separately bent at right angles and passively extended and flexed, with the subject's biceps observed and simultaneously palpated. The resistance to this procedure is rated. (The presence of cogwheel rigidity is noted separately.)

0 = Normal

1 = Slight stiffness and resistance

2 = Moderate stiffness and resistance

3 = Marked rigidity with difficulty in passive movement

4 = Extreme stiffness and rigidity with almost a frozen shoulder

5. WRIST RIGIDITY or Fixation of position:
The wrist is held in one hand and the fingers held by the examiner's other hand, with the wrist n1oved to extension, flexion and ulner and radial deviation:

0 = Normal

1 = Slight stiffness and resistance

2 = Moderate stiffness and resistance

3 = Marked rigidity with difficulty in passive movement

4 = Extreme stiffness and rigidity with almost a frozen shoulder

6. LEG PENDULOUSNESS:
The patient sits on a table with his legs hanging down and swinging free. The ankle is grasped by the examiner and raised until the knee is partially extended. It is then allowed to fall. The resistance to falling and the Jack of swinging form the basis for the score on this item:

0 = The legs swing freely

1 = Slight diminution in the swing of the legs

2 = Moderate resistance to swing

3 = Marked resistance and damping of swing

4 = Complete absence of swing

7. HEAD DROPPING:
The patient lies on a well-padded examining table and his head is raised by the examiner's hand. The hand is then withdrawn and the head allowed to drop. In the normal subject the head will fall upon the table. The movement is delayed in extrapyramidal system disorder and in extreme parkinsonism it is absent. The neck muscles are rigid and the head docs not reach the examining table. Scoring is as follows:

0 = The head falls completely with a good thump as it hits the table

1 = Slight slowing in fall, mainly noted by lack of slap as head meets the table

2 = Moderate slowing in the fall quite noticeable to the eye

3 = Head falls stiffly and slowly

4 = Head does not reach the examining table

8. GLABELLA TAP:
Subject is told to open eyes wide and not to blink. The glabella region is tapped at a steady, rapid speed. The number of times patient blinks in succession is noted:

0 = 0 - 5 blinks

1 = 6 – 10 blinks

2 = 11 – 15 blinks

3 = 16 - 20 blinks

4 = 21 and more blinks

9. TREMOR:
Patient is observed walking into examining room and is then reexamined for this item:

0 = Normal

1 = Mild finger tremor, obvious to sight and touch

2 = Tremor of hand or arm occurring spasmodically

3 = Persistent tremor of one or more limbs

4 = Whole body tremor

10. SALIVATION:
Patient is observed while talking and then asked to open his mouth and elevate his tongue. The following ratings are given:

0 = Normal

1 = Excess salivation to the extent that pooling takes place if the mouth is open and the tongue raised.

2 = When excess salivation is present and might occasionally result in difficulty in speaking

3 = Speaking with difficulty because of excess salivation

4 = Frank drooling

10.8 **Barnes Akathisia Rating Scale (BARS)**

Name:_____ **Date:**_____

Barnes Akathisia Rating Scale (BARS)

Instructions: Patient should be observed while they are seated, and then standing while engaged in neutral conversation (for a minimum of two minutes in each position). Symptoms observed in other situations, for example while engaged in activity on the ward, may also be rated. Subsequently, the subjective phenomena should be elicited by direct questioning.

Objective

0 Normal, occasional fidgety movements of the limbs
1 Presence of characteristic restless movements: shuffling or tramping movements of the legs/feet, or swinging of one leg while sitting, *and/or* rocking from foot to foot or "walking on the spot" when standing, but movements present for less than half the time observed
2 Observed phenomena, as described in (1) above, which are present for at least half the observation period
3 Patient is constantly engaged in characteristic restless movements, *and/or* has the inability to remain seated or standing without walking or pacing, during the time observed

Subjective

Awareness of restlessness
0 Absence of inner restlessness
1 Non-specific sense of inner restlessness
2 The patient is aware of an inability to keep the legs still, or a desire to move the legs, *and/or* complains of inner restlessness aggravated specifically by being required to stand still
3 Awareness of intense compulsion to move most of the time *and/or* reports strong desire to walk or pace most of the time

Distress related to restlessness
0 No distress
1 Mild
2 Moderate
3 Severe

Global Clinical Assessment of Akathisia

0 *Absent.* No evidence of awareness of restlessness. Observation of characteristic movements of akathisia in the absence of a subjective report of inner restlessness or compulsive desire to move the legs should be classified as pseudoakathisia
1 *Questionable.* Non-specific inner tension and fidgety movements
2 *Mild akathisia.* Awareness of restlessness in the legs *and/or* inner restlessness worse when required to stand still. Fidgety movements present, but characteristic restless movements of akathisia not necessarily observed. Condition causes little or no distress.
3 *Moderate akathisia.* Awareness of restlessness as described for mild akathisia above, combined with characteristic restless movements such as rocking from foot to foot when standing. Patient finds the condition distressing
4 *Marked akathisia.* Subjective experience of restlessness includes a compulsive desire to walk or pace. However, the patient is able to remain seated for at least five minutes. The condition is obviously distressing.
5 *Severe akathisia.* The patient reports a strong compulsion to pace up and down most of the time. Unable to sit or lie down for more than a few minutes. Constant restlessness which is associated with intense distress and insomnia.

Scoring the Barnes Akathisia Rating Scale (BARS)

The Barnes Akathisia Rating Scale is scored as follows:

Objective Akathisia, Subjective Awareness of Restlessness and Subjective Distress Related to Restlessness are rated on a 4-point scale from 0 – 3 and are summed yielding a total score ranging from 0 to 9.

The Global Clinical Assessment of Akathisia uses a 5-point scale ranging from 0 – 4.

Citation: Barnes TR: A Rating Scale for Drug-Induced Akathisia. British Journal of Psychiatry 154:672-676, 1989.

10.9 **Abnormal Involuntary Movement Scale (AIMS)**

Abnormal Involuntary Movement Scale

(AIMS)

Abnormal Involuntary Movement Scale (AIMS)

Examination Procedure

Either before or after completing the examination procedure, observe the patient unobtrusively at rest (e.g., in the waiting room).
The chair to be used in this examination should be a hard, firm one without arms.

1. Ask the patient whether there is anything in his or her mouth (such as gum or candy) and, if so, to remove it.
2. Ask about the *current* condition of the patient's teeth. Ask if he or she wears dentures. Ask whether teeth or dentures bother the patient *now*.
3. Ask whether the patient notices any movements in his or her mouth, face, hands, or feet. If yes, ask the patient to describe them and to indicate to what extent they *currently* bother the patient or interfere with activities.
4. Have the patient sit in chair with hands on knees, legs slightly apart, and feet flat on floor. (Look at the entire body for movements while the patient is in this position.)
5. Ask the patient to sit with hands hanging unsupported -- if male, between his legs, if female and wearing a dress, hanging over her knees. (Observe hands and other body areas).
6. Ask the patient to open his or her mouth. (Observe the tongue at rest within the mouth.) Do this twice.
7. Ask the patient to protrude his or her tongue. (Observe abnormalities of tongue movement.) Do this twice.
8. Ask the patient to tap his or her thumb with each finger as rapidly as possible for 10 to 15 seconds, first with right hand, then with left hand. (Observe facial and leg movements.)
9. Flex and extend the patient's left and right arms, one at a time.
10. Ask the patient to stand up. (Observe the patient in profile. Observe all body areas again, hips included.)
11. Ask the patient to extend both arms out in front, palms down. (Observe trunk, legs, and mouth.)
12. Have the patient walk a few paces, turn, and walk back to the chair. (Observe hands and gait.) Do this twice.

Abnormal Involuntary Movement Scale (AIMS)

Patient Information								
Patient		Date	Day	Mth.	Year	Time	Hour	Min
Personal notes								

Scoring Procedure

Complete the examination procedure before making ratings.
For the movement ratings (the first three categories below), rate the highest severity observed.
0 = none, 1 = minimal (may be extreme normal), 2 = mild, 3 = moderate, 4 = severe.
According to the original AIMS instructions, one point is subtracted if movements are seen **only on activation**, but not all investigators follow that convention.

Facial and Oral Movements	
1. Muscles of facial expression, e.g., movements of forehead, eyebrows, periorbital area, cheeks. Include frowning, blinking, grimacing of upper face.	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
2. Lips and perioral area, e.g., puckering, pouting, smacking.	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
3. Jaw, e.g., biting, clenching, chewing, mouth opening, lateral movement.	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
4. Tongue. Rate only increase in movement both in and out of mouth, not inability to sustain movement.	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

Abnormal Involuntary Movement Scale (AIMS)

Extremity Movements	
5. Upper (arms, wrists, hands, fingers). Include movements that are choreic (rapid, objectively purposeless, irregular, spontaneous) or athetoid (slow, irregular, complex, serpentine). Do not include tremor (repetitive, regular, rhythmic movements).	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
6. Lower (legs, knees, ankles, toes), e.g., lateral knee movement, foot tapping, heel dropping, foot squirming, inversion and eversion of foot.	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

Trunk Movements	
7. Neck, shoulders, hips, e.g., rocking, twisting, squirming, pelvic gyrations. Include diaphragmatic movements.	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

Global Judgements	
8. Severity of abnormal movements. Based on the highest single score on the above items.	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
9. Incapacitation due to abnormal movements.	☐ none, normal ☐ minimal ☐ mild ☐ moderate ☐ severe
10. Patient's awareness of abnormal movements.	☐ no awareness ☐ aware, no distress ☐ aware, mild distress ☐ aware, moderate distress ☐ aware, severe distress

Abnormal Involuntary Movement Scale (AIMS)

Dental status	
11. Current problems with teeth and/or dentures.	☐ no ☐ yes
12. Does patient usually wear dentures?	☐ no ☐ yes

10.10 **Child Health Questionnaire Parent Form 28-item (CHQ-PF28)**

CHILD HEALTH QUESTIONNAIRE (CHQ-PF28)

PARENT FORM – 28 ENGLISH (U.S.)

ID NUMBER

TODAY'S DATE

MONTH / DAY / YEAR

INSTRUCTIONS: This form asks about your child's health and well-being. Your responses will be treated confidentially. There are no right or wrong responses. If you are unsure how to respond to a question, give the best response you can. It is important that you fill in each question. Please use blue or black ink.

Correct Marks: ■ ☒ ☑

SECTION 1: YOUR CHILD'S GLOBAL HEALTH

	Excellent	Very good	Good	Fair	Poor
1.1. In general, would you say your child's health is:	☐	☐	☐	☐	☐

SECTION 2: YOUR CHILD'S PHYSICAL ACTIVITIES

The following questions ask about physical activities your child might do during a day.

2.1. During the past 4 weeks, has your child been limited in any of the following activities due to health problems?	Yes, limited a lot	Yes, limited some	Yes, limited a little	No, not limited
a. Doing things that take a lot of energy, such as playing soccer, or running?	☐	☐	☐	☐
b. Doing things that take some energy such as riding a bike or skating?	☐	☐	☐	☐
c. Bending, lifting or stooping?	☐	☐	☐	☐

SECTION 3: YOUR CHILD'S EVERYDAY ACTIVITIES

3.1. During the past 4 weeks, has your child been limited in the AMOUNT of time he/she could spend on schoolwork or activities with friends due to EMOTIONAL difficulties or problems with his/her BEHAVIOR?

Yes, limited a lot	Yes, limited some	Yes, limited a little	No, not limited
☐	☐	☐	☐

3.2. During the past 4 weeks, has your child been limited in the KIND of schoolwork or activities he/she could do with friends due to problems with his/her PHYSICAL health?

Yes, limited a lot	Yes, limited some	Yes, limited a little	No, not limited
☐	☐	☐	☐

SECTION 4: PAIN

4.1. During the past 4 weeks, how often has your child had bodily pain or discomfort?

None of the time	Once or twice	A few times	Fairly often	Very often	Every/almost every day
☐	☐	☐	☐	☐	☐

SECTION 5: BEHAVIOR
Below is a list of items that describe children's behavior or problems they sometimes have.

5.1. How often during the past 4 weeks did each of the following statements describe your child?

	Very often	Fairly often	Some-times	Almost never	Never
a. Argued a lot?	☐	☐	☐	☐	☐
b. Had difficulty concentrating or paying attention?	☐	☐	☐	☐	☐
c. Lied or cheated?	☐	☐	☐	☐	☐

5.2. Compared to other children your child's age, in general would you say his/her behavior is:

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

SECTION 6: WELL-BEING
The following phrases are about children's moods.

6.1. During the past 4 weeks, how much of the time do you think your child:

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Felt lonely?	☐	☐	☐	☐	☐
b. Acted nervous?	☐	☐	☐	☐	☐
c. Acted bothered or upset?	☐	☐	☐	☐	☐

SECTION 7: SELF-ESTEEM
The following ask about your child's satisfaction with self, school, and others. It may be helpful if you keep in mind how other children your child's age might feel about these areas.

7.1. During the past 4 weeks, how satisfied do you think your child has felt about:	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied
a. His/her school ability?	☐	☐	☐	☐	☐
b. His/her friendships?	☐	☐	☐	☐	☐
c. His/her life overall?	☐	☐	☐	☐	☐

SECTION 8: YOUR CHILD'S HEALTH
The following statements are about health in general.

8.1. How true or false is the statement for your child?	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. My child seems to be less healthy than other children I know.	☐	☐	☐	☐	☐
b. My child has never been seriously ill.	☐	☐	☐	☐	☐
c. I worry more about my child's health than other people worry about their children's health.	☐	☐	☐	☐	☐

8.2. Compared to one year ago, how would you rate your child's health now:

Much better now than 1 year ago	Somewhat better now than 1 year ago	About the same now as 1 year ago	Somewhat worse now than 1 year ago	Much worse now than 1 year ago
☐	☐	☐	☐	☐

SECTION 9: YOU AND YOUR FAMILY

		None at all	A little bit	Some	Quite a bit	A lot
9.1.	During the past 4 weeks, how MUCH emotional worry or concern did each of the following cause YOU?					
	a. Your child's physical health	☐	☐	☐	☐	☐
	b. Your child's emotional well-being or behavior	☐	☐	☐	☐	☐

		Yes, limited a lot	Yes, limited some	Yes, limited a little	No, not limited
9.2.	During the past 4 weeks, were you LIMITED in the amount of time YOU had for your own needs because of:				
	a. Your child's physical health	☐	☐	☐	☐
	b. Your child's emotional well-being or behavior?	☐	☐	☐	☐

		Very often	Fairly often	Sometimes	Almost never	Never
9.3.	During the past 4 weeks, how often has your child's health or behavior:					
	a. limited the types of activities you could do as a family?	☐	☐	☐	☐	☐
	b. interrupted various everyday family activities (eating meals, watching tv)?	☐	☐	☐	☐	☐

9.4. Sometimes families may have difficulty getting along with one another. They do not always agree and they may get angry. In general, how would you rate your family's ability to get along with one another?

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

10.11 **Parenting Stress Index-Short Form (PSI-4-SF)**

PSI-4 SHORT FORM

Record/Profile Form

Richard R. Abidin, EdD

Instructions:

On the inside of this form, write your name, gender, date of birth, ethnic group, and marital status; today's date; and your child's name, gender, and date of birth. This questionnaire contains 36 statements.

Read each statement carefully. For each statement, please focus on the child you are most concerned about and circle the response that best represents your opinion. **Answer all questions about the same child.**

Circle SA if you strongly agree with the statement.
Circle A if you agree with the statement.
Circle NS if you are not sure.
Circle D if you disagree with the statement.
Circle SD if you strongly disagree with the statement.

For example, if you sometimes enjoy going to the movies, you would circle A in response to the following statement:

I enjoy going to the movies. SA (A) NS D SD

While you may not find a response that exactly states your feelings, please circle the response that comes closest to describing how you feel. **Your first reaction to each question should be your answer.**

Circle only one response for each statement, and respond to all statements. **Do not erase!** If you need to change an answer, mark an "X" through the incorrect answer and circle the correct response. For example:

I enjoy going to the movies. SA A NS (D) (SD)

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PSI-4 SHORT FORM

Answer Sheet

Name _____ Gender _____ Date of birth ___/___/___

Ethnic group _____ Marital status _____ Today's date ___/___/___

Child's name _____ Child's gender _____ Child's date of birth ___/___/___

SA = Strongly Agree **A = Agree** **NS = Not Sure** **D = Disagree** **SD = Strongly Disagree**

1.	I often have the feeling that I cannot handle things very well.	SA	A	NS	D	SD
2.	I find myself giving up more of my life to meet my children's needs than I ever expected.	SA	A	NS	D	SD
3.	I feel trapped by my responsibilities as a parent.	SA	A	NS	D	SD
4.	Since having this child, I have been unable to do new and different things.	SA	A	NS	D	SD
5.	Since having a child, I feel that I am almost never able to do things that I like to do.	SA	A	NS	D	SD
6.	I am unhappy with the last purchase of clothing I made for myself.	SA	A	NS	D	SD
7.	There are quite a few things that bother me about my life.	SA	A	NS	D	SD
8.	Having a child has caused more problems than I expected in my relationship with my spouse/parenting partner.	SA	A	NS	D	SD
9.	I feel alone and without friends.	SA	A	NS	D	SD
10.	When I go to a party, I usually expect not to enjoy myself.	SA	A	NS	D	SD
11.	I am not as interested in people as I used to be.	SA	A	NS	D	SD
12.	I don't enjoy things as I used to.	SA	A	NS	D	SD
13.	My child rarely does things for me that make me feel good.	SA	A	NS	D	SD
14.	When I do things for my child, I get the feeling that my efforts are not appreciated very much.	SA	A	NS	D	SD
15.	My child smiles at me much less than I expected.	SA	A	NS	D	SD
16.	Sometimes I feel my child doesn't like me and doesn't want to be close to me.	SA	A	NS	D	SD
17.	My child is very emotional and gets upset easily.	SA	A	NS	D	SD
18.	My child doesn't seem to learn as quickly as most children.	SA	A	NS	D	SD
19.	My child doesn't seem to smile as much as most children.	SA	A	NS	D	SD
20.	My child is not able to do as much as I expected.	SA	A	NS	D	SD
21.	It takes a long time and it is very hard for my child to get used to new things.	SA	A	NS	D	SD
22.	I feel that I am: (Choose a response from the choices below.)	1	2	3	4	5
23.	I expected to have closer and warmer feelings for my child than I do, and this bothers me.	SA	A	NS	D	SD
24.	Sometimes my child does things that bother me just to be mean.	SA	A	NS	D	SD

1. a very good parent.
2. a better-than-average parent.
3. an average parent.
4. a person who has some trouble being a parent.
5. not very good at being a parent.

SA = Strongly Agree	A = Agree	NS = Not Sure	D = Disagree	SD = Strongly Disagree

25.	My child seems to cry or fuss more often than most children.	SA	A	NS	D	SD
26.	My child generally wakes up in a bad mood.	SA	A	NS	D	SD
27.	I feel that my child is very moody and easily upset.	SA	A	NS	D	SD
28.	Compared to the average child, my child has a great deal of difficulty in getting used to changes in schedules or changes around the house.	SA	A	NS	D	SD
29.	My child reacts very strongly when something happens that my child doesn't like.	SA	A	NS	D	SD
30.	When playing, my child doesn't often giggle or laugh.	SA	A	NS	D	SD
31.	My child's sleeping or eating schedule was much harder to establish than I expected.	SA	A	NS	D	SD
32.	I have found that getting my child to do something or stop doing something is: (Choose a response from the choices below.)	1	2	3	4	5

1. much harder than I expected.
2. somewhat harder than I expected.
3. about as hard as I expected.
4. somewhat easier than I expected.
5. much easier than I expected.

33.	Think carefully and count the number of things which your child does that bothers you. For example, dawdles, refuses to listen, overactive, cries, interrupts, fights, whines, etc. (Choose a response from the choices below.)	1	2	3	4	5

1. 1-3
2. 4-5
3. 6-7
4. 8-
5. 10

34.	There are some things my child does that really bother me a lot.	SA	A	NS	D	SD
35.	My child's behavior is more of a problem than I expected.	SA	A	NS	D	SD
36.	My child makes more demands on me than most children.	SA	A	NS	D	SD

Please do not write in this area.

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