PROJECT TITLE:

Comparing psychosocial groups for reducing attention problems in adolescents with ADHD

PRINCIPAL INVESTIGATOR:
Margaret Sibley
Center for Child Health Behavior and Development
305 801 2472
Margaret.sibley@seattlechildrens.org

PARTICIPATING SITES[1]: University of Washington

Contents

1. Objectives

1.1. Purpose, specific aims, or objectives:

The Seattle Children's Behavior, Attention, Management (BAM) Clinic in the Department of Psychiary is adding a new group for adolescents with ADHD focused on mindfulness in the fall of 2025 (Mindfulness Awareness Practices for Adolescents (MAPA)). We wish to conduct a randomized controlled evaluation to compare it to the existing programming in the clinic for this population (Time Management, Organization, and Planning Skills; TOPS) to understand the different benefits these two groups may offer as a way to route future patients to the group that is likely to best meet their needs.

1.2. Hypotheses to be tested:

The two groups will lead to equal reductions in ADHD symptom severity as measured on the Conners 3 Rating Scale. However, the MAPA group will lead to greater improvements in self-regulation and trait mindfulness/mind wandering while the TOPS group will lead to greater improvements in executive functioning. Therefore, adolescents with ADHD who appear to have their greatest impairments in executive functioning might best be routed to the TOPS group while those who are struggling with emotion and attention regulation would best be routed to the MAPA group

2. Background

2.1. Relevant prior experience and gaps in current knowledge:

Mindfulness treatment (e.g., Mindfulness Based Interventions) for youth with ADHD has emerged as a novel empirically supported treatment for youth with ADHD, as evidence in a recent review published in the *Lancet Child and Adolescent Health* by PI Sibley (Sibley et al., 2023). TOPS is a well-established treatment for adolescents with ADHD (Evans et al., 2016; Sibley et al., 2024 for review). However, among diverse psychosocial approaches for treating ADHD in youth, little is known about what works for whom and why—important clinical information that can guide precision medicine (i.e., routing of patients to the group that might best meet their clinical needs).

2.2. Relevant preliminary data:[2]

Though several meta-analyses confirm the efficacy of TOPS for adolescents with ADHD, research on Mindfulness-Based Interventions (MBI) for adolescentt with ADHD has been more recent. Haydicky et al. used a pre-post design (N=20) and an adolescent sample (13-18 years), offering preliminary evidence that adolescents with ADHD will engage in an MBI and that there do not appear to be iatrogenic treatment effects. Session attendance was good (M =6.78 out of 8, SD = 1.11). Parents reported improved conduct symptoms and peer relations with medium to large effect sizes, as well as self-reported depression, anxiety, and internalizing symptoms at 6 week follow-up with medium to large effect sizes. Parent-reported inattention improved from pre- to post ($p = .07$) with a medium effect size. van de Weijer Bergsma et al. was a within group design (ages 11-15 years). Statistically significant pre-post improvements were reported for attention problems at 2-month follow-up (self and paternal report), externalizing problems at post-treatment and 2-month follow-up (paternal report), EF at 2-month follow-up (paternal report), visual sustained attention reaction speed, auditory sustain attention false alarm responses at post-treatment, and auditory sustained attention number of misses at 2-month follow-up. Outside the adolescent-specific age group, mixed-aged RCTs for individuals with ADHD have been conducted to further indicate the efficacy of MBIs: Valero et al. (9-14 year-olds with ADHD) reported significant improvements for MYmind vs. waitlist for inattention symptoms, EF, learning problems, aggression, and peer

relations at 6 month follow-up. Siebelink et al. included children and adolescents (ages 8-16 years) with larger pre-post treatment effects on self-control predicted by older age. These studies support the efficacy of adolescent ADHD MBIs.

2.3. Scientific or scholarly background:

Mindfulness-Based Interventions (MBIs) have garnered increasing support for ADHD (Sibley et al., 2023). MBIs yield medium to large effects for inattention (d=.91) and hyperactivity-impulsivity symptoms (d=.68) in adult ADHD samples with similar effect sizes in mixed child/adolescent samples (inattention d=.66, hyperactivity-impulsivity d=.47). In another meta-analysis, MBIs for ADHD had a large effect for inattention (Hedges' g = .83) and hyperactivity-impulsivity (Hedges' g = .68) compared to control conditions, though this was moderated by age with a lesser effect for younger age.

TOPS is a well-established treatment for adolescent ADHD that enacts improvement by remediating executive function skills specifically related to organization, time management, task management, and planning. For example, a 2017 meta-analysis (Bikic et al) found that twelve studies involving 1054 children (576 treatment, 478 control) produced a weighted mean effect sizes for teacher- and parent-rated outcome measures of organizational skills of g = 0.54 (95% CI 0.17 to 0.91) and g = 0.83 (95% CI 0.32 to 1.34), respectively. Weighted mean effect sizes of teacher- and parent-rated symptoms of inattention were g = 0.26 (95% CI 0.01 to 0.52) and g = 0.56 (95% CI 0.38 to 0.74), respectively.

2.4. Prior approvals:

NA

3. Study Endpoints[3]

3.1. Primary and secondary endpoints:

At baseline and study endpoint (after the final session of treatment), we will administer the Conners 3 (parent and self report), impairment rating scale (parent/self). BRIEF-2 (parent report), DERS emotion regulation measure (parent and self), and Trait Mindfulness Questionnaire (parent and self report). We also will administer the PROMIS (part a and b) to the youth (8 items). We also will administer the client credibility questionnaire and a satisfaction measure to the parent and the youth. We will also measure attendance at the intervention and treatment homework completion in both groups. A demographic form will also be administered to the parent about the teen to characterize the sample. Finally, at post-treatment we will administer youth and parent engagement questionnaires.

3.2. Primary or secondary safety endpoints:

NA

4. Drugs, Devices and Biologics[4]

4.1. Manufacturer and name of all drugs, devices and biologics:

NA

4.2. Description and purpose of all drugs, devices and biologics:

NA

4.3. Regulatory status of all drugs, devices and biologics:[5]

NA

4.3.1. Drugs or Biologics:
☐ IND Exempt. Explain:[6] Click here to enter text.
☐ IND.

4.3.2. Devices:
☐ IDE Exempt. Explain:[7] Click here to enter text.
☐ Abbreviated IDE / Non-Significant Risk. Explain:[8] Click here to enter text.
☐ IDE / Significant Risk.

4.4. Plans to store, handle, and administer any study drugs, devices and biologics so they will be used only on subjects and be used only by authorized investigators:
NA

5. Procedures Involved

5.1. Study design:[9]

This will be a randomized controlled trial in which incoming patients (N=36) who have been referred for ADHD psychosocial treatment at the Seattle Children's Behavior, Attention, Management clinic between ages 13-17 will be offered the opportunity to participate in this study. Currently, potential participants are referred to a single waitlist for the STAND intervention if they have ADHD and are in need of psychosocial treatment. STAND is a combined parent-teen group for adolescents with ADHD that focuses on building collaborative home plans to support the behavioral needs of youth. It runs for 10 weeks as a 90 minute group. During this group parents and teens learn a variety of strategies that they can collaboratively apply at home such as creating a structured homework plan, making a feasible daily routine, using active listening and I statement communication skills, and setting collaborative goals for task completion.

The STAND program runs three times a year and the waitlist is much longer than the number of patients that this program can accommodate. Accordingly, we have sometimes offered TOPS (a lower resource and simpler program to deliver) to adolescents while they wait on the waitlist for STAND (so that they can get some form of care while they wait for STAND). Note, TOPS has not been offered in a few years. In this case we will specifically recruit from individuals who are on the STAND waitlist, waiting for care. We will not remove them from the STAND waitlist if they choose to participate in the study. They will still be eligible to receive STAND when it is their turn to be moved off the waitlist and into services. There will be no delay in receiving STAND created by participation in the study because only those who are not in the current round because they were not high enough on the waitilist will be offered the study.

If they wish to participate, they will be randomly assigned to receive the MAPA MBI or to receive TOPS at the clinic. Both groups will be 8-week, 90 groups that will run simultaneously via telehealth delivered by routine clinicians in the BAM clinic. Both groups will have one "pre-session" that parents join that explains the purpose of the group and what parents and teens can do to work together and support home practice of skills learned during the group. We will collect baseline and post-treatment ratings of outcome measures. There will be two cohorts (fall and winter and each cohort will enroll 18 youth for random assignment at a 1:1 ratio). Incoming patients who do not wish to participate in the study will still be eligible to enroll in standard

psychosocial treatment groups at the BAM clinic that they would otherwise be eligible for (i.e., declining to participate will not delay the treatment they otherwise would receive in the clinic).

Like TOPS, which has been an ad-hoc treatment offered at BAM for a number of years, but does not run on regular cycles, it is hoped that MAPA will become a fixture in BAM for years to come—of course this is contingent on a successful pilot of the program (i.e., that it is well-received by youth and caregivers and appears to be a program that has value to our clinic's specific patient population).

5.2. Research procedures:[10]

Parents of patients referred to SCH BAM program who are between the ages of 13-17 will be contacted by IRB-approved study team member and the study information will be shared. If interested in the study, the family will be contacted by a research assistant who will conduct a virtual information session over Zoom with the family to have a consent discussion and complete baseline measures over Redcap with an emailed link as described above. Measures will be completed during the zoom meeting so as to ensure that they can be reviewed by research assistants for completeness. Adolescents will be randomly assigned to receive TOPS or MAPA. They will receive the treatments as delivered naturalistically by the SCH clinicians. A trained observer will collect fidelity measures through live observation to assess the extent to which SCH clinicians implemented the treatments according to their standard elements. The fidelity forms will be submitted using a modification at a later date. They will not include any information about the clinicians individually but rather serves as documentation that the protocol was implemented in its entirety by the research team. Items will be worded such as "the adolescents participated in activity X." Attendance will also be taken by the trained observer and they will collect information on homework completion. These will not be participant facing records. Finalized materials for the intervention will be submitted to the IRB as a modification prior to beginning the group. At the end of the 8-weeks, adolescents and their parents will complete post-treatment rating scales as noted above. They will again receive a zoom link. The final 15 minutes of the last session of the treatment will be reserved for the completion of rating scales and parents will be invited to attend this portion of the final session. If the subject was not at the group meeting, we will schedule a separate zoom meeting with them to complete the rating scales.

Once the study is complete, individuals will have the opportunity to participate in the treatment group for which they were not randomized. This would occur for routine care and would not be part of the research.

5.3. Data sources that will be used to collect data about subjects:[11]

Parent and Self-report rating scales, direct observation of groups by a research assistant. The fidelity forms will be binary yes/no checklists (to be submitted in a modification) about whether adolescents who attended the group received each component of the treatment. The attendance records will be yes/no did the adolescent attend the session. The homework records will be yes/no did the adolescent complete the assigned homework. These will be collected in Redcap by the trained observer during the group. We will not collect any information on the participants from the EMR. With respect to contact information, IRB-approved study staff members will access contact information from the EMR to initially inform the families of the opportunity. However, the research team will collect contact information through redcap once the family has been referred to us and has indicated interest in learning more about the study/potentially participating.

5.4. Data to be collected, including long–term follow–up data:[12]

Please see attached redcap form for the variables that will be collected from parent and self-report.

Baseline: the **parent** and **adolescent** will each fill out the Conners-3, Impairment Rating Scale, BRIEF-2, DERS, and the FFMQ Trait Mindfulness Questionnaire.

Post-treatment: In addition to repeating the baseline measures, **parents** and **adolescents** will also complete the client credibility questionnaire and a satisfaction with treatment questionnaire.

6. Data and Biospecimen Banking[13]

6.1. Complete list of the data and/or biospecimens to be included in the bank:[14]
We will bank all measures collected in this study but it will be de-identified data.

6.2. Location of data and/or biospecimen storage:[15]
Redcap

6.3. List of those with direct access to data and/or biospecimens in the bank:
The PI and the research team members.

6.4. Length of time data and/or biospecimens will be stored in the bank:
Indefinitely

6.5. Procedures for protecting the confidentiality and privacy of the subjects from whom the data and/or biospecimens were collected:[16]
This will be completely de-identified, numerical data that will not be able to be linked back to any individual participants.

6.6. How the data and/or biospecimens will be made available for future use:
upon request by other research teams

6.6.1. Who can request data and/or biospecimens from the bank:
Qualified researchers who are covered by their institution's IRB, if required.

6.6.2. Format in which data and/or biospecimens will be provided:
Data file such as Excel or SPSS.

6.6.3. Process for investigators to request data and/or biospecimens:[17]
Email to the PI and provision of IRB approval, if required.

6.6.4. Restrictions on future use:[18]
NA

6.6.5. Plan for providing data results from banked data/biospecimens:
NA

7. Sharing of Results

7.1. Plan to share results with subjects/others:[19]

We will publish the results of this study in a peer review journal. No results from data will be provided directly to participants.

8. Study Timelines

8.1. Duration of an individual subject's participation in the study:
Individuals will participate in the study for approximately 12 weeks including baseline data collection, 8 weeks of treatment, and post-treatment data collection.

8.2. Duration anticipated to enroll all study subjects:
Two months.

8.3. Estimated date for the investigators to complete this study:
September 1, 2026

9. Study Population[20]

9.1. Inclusion criteria for each subject population (e.g., patients, parents, providers):
Incoming patient at Seattle Children's Psychiatry for ADHD adolescent services age 13-17.

Parents of an incoming patient at Seattle Children's Psychiatry for ADHD adolescent services

9.2. Exclusion criteria for each subject population:
For adolescent patients: Outside the study age range. Pursuing services for a presenting problem unrelated to ADHD. Unable to attend the scheduled group sessions.

For parents: they must be willing to fill out questionnaires about the adolescent.

9.2.1. If individuals will be excluded from the research based on language, socioeconomic status, physical characteristics (e.g., gender identity, age, ethnicity), sexual orientation, religion, or access to technology provide a justification for each exclusion criterion:[21]
N/A

9.3. Plan to ensure that subject selection is equitable:[22]
The BAM clinic offers openings to clinical care on a first come first serve basis. As such, we will offer the opportunity to participate in the study to all incoming adolescents during the trial period on a first come first serve basis. This includes patients that are already on the waitlist as well as those that are joining the waitlist for the first time. We will call patients on the waitlist in the order that they joined it before we start offering the study opportunity to new patients.

9.4. Populations with special considerations, involved in the study:[23]
☒ Children/Teenagers[24]
Risk assessment specific to this vulnerable population and additional safeguards:[25]
This is a minimal risk study as it focuses on studying routine care programming for ADHD. Students with acute psychiatric needs are not triaged to these programs by BAM. There is a risk of breach of confidentiality due to the group nature of treatment, however, as is standard clinic procedure we will reiterate the importance of confidentiality at the beginning of every group. All research team members will also be trained in the conduct of research, confidentiality procedures. Data will be stored securely in REDCap with access limited to IRB-approved study team members.

☐ Children who are Wards of the State[26]
Risk assessment specific to this vulnerable population and additional safeguards:
✍Click here to enter text.

☐ Adults Unable to Consent [27]
Risk assessment specific to this vulnerable population and additional safeguards:
✍Click here to enter text.

☒ Individuals who use a language other than English[28]
Anticipated language(s) for subjects and their parent(s)/LAR:
We do not anticipate adolescents who speak a language other than English in this study because they rarely present at the clinic. However, if there are potential adolescent participants or parents/LARs who use a language other than English, they will be permitted to participate and we will submit an amendment at that time for a translated consent form/assent form and will use a translator from the hospital for the consent documents, assessments, and treatment (as is BAM policy anyway). Spanish and Creole versions of the forms are validated and have been used previously by the research team.

Process to ensure study information is available throughout the research to individuals who use a language other than English:[29]
We will use hospital interpreters if we find that a parent/child who is eligible for the study does not speak English. We will translate the consent forms and all participant-facing materials into the language of the individual and interpreters would be present at all interactions with the study team, starting with recruitment, and the treatment groups.

☐ Neonates of Uncertain Viability or Non–Viable Neonates[30]
Risk assessment specific to this vulnerable population and additional safeguards:
✍Click here to enter text.

☐ Pregnant Women[31]
Additional safeguards:
✍Click here to enter text.

☐ Prisoners[32]
Additional safeguards:
✍Click here to enter text.

☐ Economically or educationally disadvantaged persons[33]
Additional safeguards:
✍Click here to enter text.

10. Number of Subjects

10.1. Total number of subjects to be enrolled locally:[34]
36

10.2. Total number of subjects to be enrolled across all participating sites:[35]
36

10.3. Number of screened subjects versus the actual number enrolled in the research:[36]
The waitlist for ADHD adolescent psychosocial groups is currently upwards of 70 adolescents in our age range; anyone who is on the waitlist will be eligible. We anticipate we will be able to identify 18 families who are interested for our first cohort.

10.4. Power analysis:
A power analysis was conducted to determine the appropriate number of participants needed to detect large effects (*d*=.8; power=.80; α=.05), as this is the average between-group effect size across studies of behavioral treatment for ADHD (*d*=.83; Fabiano et al., 2009). Results suggested that at least 32 individuals are needed to obtain sufficient power to detect the expected effects in a basic t-test.

11. Withdrawal of Subjects

11.1. Anticipated circumstances under which subjects will be withdrawn from the research without their consent:
If they attend zero sessions of the treatment we will withdraw them from the research study. If they attend at least one session of the treatment we will retain them in the research study.

11.2. Procedures for orderly termination:
We will inform the family that they have been removed from the research study if they attend zero of the eight sessions of the treatment.

11.3. Procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection and withdrawal from data/biospecimen banking:
We will destroy all baseline data from participants who withdraw.

12. Risks to Subjects

12.1. Reasonably foreseeable risks to subjects (include each study population, each arm, and optional procedures):
The main risk associated with this study is the time it takes to complete extra pre-post rating scales, which is not a part of standard clinical care. In addition, there is a risk of emotional discomfort filling out personal questions about one's behavior or problems the youth is having at home or school. There is always a chance of loss of confidentiality, although we will make all efforts to prevent this. The specific MAPA curriculum that we will use in this study is being adapted from existing MBI programs. Though effect sizes for MBIs and youth-only TOPS interventions are similar in the research, we do not know whether TOPS or MBI is more effective and so patients could be randomized to a group that is less effective than the other. However, both groups are expected to be more effective than the alternative (sitting on the waitlist for care). The group will start on the standard fall and winter schedules for all BAM groups which will be in October and January. There will be enough time to recruit all participants in the windows between when the group opens and when it begins. This follows standard clinic operating procedures. If we do not have 18 participants by the group's start date, we will start with fewer participants and submit a modification to run the groups a 3rd time to ascertain the recruitment goal. For questions about serious misbehavior (i.e., threatening or hurting others) we will conduct a risk assessment if these items are endorsed. If an imminent risk to others is detected, we will break confidentiality to keep the recipient of the harm safe.

For parents: Parent participation includes filling out some survey questions about what their impressions are of the program their child received. For questions about serious misbehavior (i.e., threatening or hurting others) we will conduct a risk assessment if these items are endorsed. If an imminent risk to others is detected, we will break confidentiality to keep the recipient of the harm safe.

For TOPS group: There is no known risk that is associated specifically with the TOPS group versus the MAPA group.

For MAPA group: There is no known risk that is associated specifically with the MAPA group versus the TOPS group.

12.2. Procedures with unforeseeable risks:
NA

12.3. Procedures with risks to an embryo or fetus should the subject be or become pregnant:
NA

12.4. Risks to others who are not subjects:
NA

12.5. Procedures performed to lessen the probability or magnitude of risks:
All data will be stored in seattle children's redcap. We will keep all data coded with a study id number and all identifying data (required for follow-up of participants) will be stored separately in a sharepoint list on a secure Seattle children's server. Consent forms with identities will be stored separate from participant data in redcap.

When using Zoom, the follow actions will be taken to protect confidentiality and privacy:
- Use the latest version of Zoom available.
- Make the meeting private.
- Require a password for meeting entry.
- Disable private chat.

13. Potential Benefits to Subjects

13.1. Potential benefits that individual subjects may experience from taking part in the research:[37]
The benefit to participating in this study is that youth may receive extra care for their ADHD while they are waiting for standard services at the BAM clinic.

14. Data Analysis/Management

14.1. Data analysis plan, including statistical procedures:

Using the General Linear Model (GLM), we will conduct a series of mixed design analyses in SPSS with each outcome variable as the dependent variable and group (MAPA vs. TOPS) as the between-subjects predictor. Time (baseline, post-treatment) will be the within-subjects predictor. Cohen's *d* effect size will be calculated as a measure of change over time for each group. Using standard

interpretation guidelines, .2 = small effect, .5 = medium effect, and .8 = large effect (Cohen, 1988). In considering relative change between the groups, we will calculated an effect size based on the mean baseline to post-treatment change in the MAPA group minus the mean baseline to post-treatment change in the OST group, divided by the pooled baseline standard deviation (Morris, 2008). Prior to analyses, all assumptions of the GLM will be tested.

14.2. Quality control procedures for collected data:[38]
We will have a research assistant review all data collected in redcap immediately after participants complete the forms to identify questions that were not answered and to request that the participant answers the questions if they were missed accidentally.

15. Confidentiality and Privacy[39]

15.1. Procedures to secure research records[40], data, and/or biospecimens during storage, use, and transmission:
We will store all data from the study in secure REDCap Research Servers at Seattle Childrens. No data or research records will be stored at UW.

15.2. Steps that will be taken to protect the privacy interests throughout the study:[41]
We will hold all study assessments over secure Zoom room and we will request that participants take Zoom meetings in a private location. Links to redcap will be sent directly to participants (by text message/direct message/email depending on the preference of the participant). When conducting asessments we will use the latest version of zoom available, make the meeting private, require a password for meeting entry, disable private chat. We will not audio or video record. We will only share the screen if requested by the participant during a discussion of the consent form. However, no screen sharing will occur for the assessment portion of the meeting.

When Seattle Children's clinicians are delivering the treatment over zoom, screen sharing will be used during the Zoom meetings to show powerpoint slides related to the treatment (which will be uploaded through a modification prior to the start of the group). The clinicians delivering the treatment will follow the standard procedures at Seattle Children's for running telehealth groups—which includes using the latest version of zoom, the meeting link is only accessible through direct link in the patient's secure mychart portal, private chat is always disabled, there is a waiting room that the clinician decides who can enter. There will be no audio or video recording.

15.3. Location where the data and/or biospecimens will be stored:
Seattle Children's Redcap

15.4. Length of time data and/or biospecimens will be stored:
Indefinitely.

15.5. Individuals with access to data and/or biospecimens:

IRB-approved study team members and those who later request data as described in banking section.

15.6. Process for the transmission of data and/or biospecimens outside Seattle Children's:
15.6.1. List of data and/or biospecimens that will be transmitted:
If we share data with an external collaborator, we will do so by giving them access to a seattle children's redcap/one drive server. A modification will be submitted to provide more information about external collaborators if they become involved in the research.

15.6.2. Individual(s) who will transmit data:
N/A

16. Provisions to Monitor Data to Ensure the Safety of Subjects[42]

16.1. Plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe:[43]
NA no more than minimal risk

16.2. Data reviewed to ensure safety of subjects:
NA

16.3. Safety information collection procedures:
NA

16.4. Frequency of cumulative data review:
NA

16.5. Conditions that trigger an immediate suspension of the research:
NA

17. Use of Social Media

17.1. Types of social media to be used and how:
NA

17.2. Measures in place to protect the privacy or confidentiality of subjects:[44]
NA

17.3. Types of communications that will be submitted to the IRB for review:[45]
NA

17.4. If user-generated content will be active, how it will be monitored and what actions will be taken to ensure subject safety and study integrity:
NA

18. Research Related Injury[46]

18.1. Available compensation in the event of research related injury:
NA

19. Recruitment Methods[47]

19.1. When, where, and how potential subjects will be recruited[48]:
A clinic staff member in the Psychiatry Clinic, who is also a member of the research team, will call families who are on the STAND waitlist to share the opportunity to participate in this study. We will call patients on the waitlist in the order that they joined it before we start offering the study opportunity to new patients. If interested in the study, the family will give verbal consent to share their first name and contact information with a research team member so that they can be contacted by the research assistant to conduct a virtual information session over Zoom with the family to have a consent discussion and complete baseline measures over Redcap with an emailed link.

19.2. Steps that will be taken to protect privacy during the recruitment process:[49]
Private zoom/phone calls will be made when engaging with families. The study team will ask if families are in a private space when they speak to them.

19.3. Sources of subjects:[50]
BAM clinic incoming patients.

19.4. Methods that will be used to identify potential subjects:
We will call patients on the STAND waitlist for adolescent ADHD psychosocial services in BAM and offer it to them on a first come first serve basis.

19.5. Materials that will be used to recruit subjects:[51]
Phone script in Click

19.6. Recruitment methods not controlled by Seattle Children's:
N/A

20. Consent/Assent/Permission[52]

20.1. Consent/assent/permission process:[53]
Prior to the group starting, each adolescent and their parent will schedule a zoom call together with a study staff member who will go through the consent form (which will be signed digitally). The parent will be the point of contact for scheduling the zoom call. Parent consent and youth assent will be obtained and after they have gone through the consent form in its entirety, the study staff member will summarize the main points on the consent form and offer an opportunity to discuss questions and concerns. The family members will sign digitally a consent form using an e-signature (in redcap). Given the age range of this study, all participants are expected to be in 8th grade or higher, thus conducting a consent conversation at an 8th grade language level should be appropriate for both the parent and the youth together. The electronic process of an e-signature is used because we will not be in person with the family, but we will still be meeting face to face over zoom for an otherwise comprehensive consent discussion that emphasizes the autonomy of the parent and youth in deciding whether to participate in the study. We will not record the meeting. The consent materials will be on one page in redcap and they will review them while on the zoom call with the research team. They will be able to scroll up and down. If preferred by the family, the research team can share the screen to go over the consent form section by section together. Otherwise the family members can indepdnetntly review the redcap consent forms and sign them .If a participant has trouble navigating the consent form, which is available by a web=link, we will explore alternatives to reduce technology barriers such as sending the link to their smartphone or putting it in the zoom chat (as well as screen sharing demonstration as

mentioned above).They will be able to move backwards and forwards through the redcap forms (consent and surveys). We will be in the zoom with them to provide technology support as needed. They will be able to stop and continue at a later time through a link that allows them to restart the survey where they left off. They can stop participating at any time in the process. The forms are expected to take approximately 15 minutes to complete. We will estimate 30 minutes for the visit including both the consent process and the survey completion.

20.1.1. Alternative way of obtaining consent/assent/permission information for individuals who are not able to receive/access/use the electronic consent system being used or explanation as to why an alternative process is unnecessary:[54]
If a patient cannot access a redcap link, we will mail them a physical copy of the consent. If a patient does not have access to zoom technology at the moment of the meeting, we will perform the consent conversation over the phone.

20.1.2. Where the consent/assent/permission process will take place:
Over Zoom will be standard practice but a phone call will be used if the individual cannot access zoom.

20.1.3. Steps that will be taken to protect privacy during the consent/assent/permission process:[55]
We will ask families to take the Zoom call in a private location. The research staff member will also be in a private location.

20.2. Plan for documenting consent/assent/permission:[56]
Digitally in Redcap using an e-signature.

20.2.1. Plan to confirm that the individual who provides the electronic signature[57] is the subject (or their parent/LAR), when the signature is not personally witnessed by a member of the study team or explanation as to why such a plan is unnecessary:[58]
N/A the research team member will be on zoom with the families and will be able to confirm that they digitally signed the consent forms.

20.2.2. If using electronic consent, plan to manage consent documentation over the life of the study in a way that maintains integrity and accessibility:[59]
The Redcap functionality allows you export the consents as pdfs-so we can export them as pdfs and keep them in a specific folder on a secure Seattle children's server to have back-up documentation.

20.2.3. If consent/permission will be documented in writing (check one):
☒ "SOP: Written Documentation of Consent (HRP-091)" will be followed.
☐ "SOP: Written Documentation of Consent (HRP-091)" will not be followed.
Process of documenting consent:[60]

20.2.4. If consent/permission will not be documented in writing (check all that apply, *complete Section 21.11 to request a Waiver of Documentation of Consent*)[61]
☐ A written statement/information sheet describing the research will be provided to subjects.[62]
☐ A written statement/information sheet describing the research will not be provided to subjects. Explain: Click here to enter text.
☐ A consent script will be used.[63]

20.3. Waiting period available between approach and obtaining consent/assent/permission:

Up until the start date of the group.

20.4. Process to ensure ongoing consent/assent/permission:
We will inform families that they can inform the study staff at any time if they no longer want to participate in the research. Families will be informed that they can inform the study staff at any time if they no longer wish to participate in the study and this will not impact the treatment in which they are entitled to.

20.5. If this box is checked, "SOP: Informed Consent Process for Research (HRP-090)" will be followed: ☒

20.6. If "SOP: Informed Consent Process for Research (HRP-090)" will not be followed, address the following:[64]

20.6.1. Role of the individuals listed in the application as being involved in the consent process:
✍Click here to enter text.

20.6.2. Time that will be devoted to the consent discussion:
✍Click here to enter text.

20.6.3. Steps that will be taken to minimize the possibility of coercion or undue influence:
✍Click here to enter text.

20.6.4. Steps that will be taken to ensure the subject's understanding:
✍Click here to enter text.

20.7. **Individuals who use a language other than English**

20.7.1. Presentation of Research Information and Documentation:
☒ Appendix A-10 of the Investigator Manual will be followed[65]
☐ Short form procedures may be used per HRP-091. If so, choose applicable box(es):
☐ Per section 5.5.1
☐ Per section 5.5.2
☐ Appendix A-10 of the Investigator Manual will not be followed. Explanation of procedures not following Appendix A-10:
✍Click here to enter text.

20.8. **Subjects Who Are Not Yet Adults (Infants, Children, Teenagers)**

20.8.1. Process used to determine whether an individual has not attained the legal age of consent under the applicable law of the jurisdiction in which the research will be conducted (e.g., individuals under the age of 18 years):[66]

Clinic staff have access to adolescent dates of birth in Epic and will verify patient age in Epic. They will be asked to only refer to the research team families that are within the 13-17 year old age range.

20.8.2. Permission will be obtained from:[67]

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, or LAR.
☒ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child, or LAR.
☐ Permission will not be obtained.[68]

20.8.3. Waiver of permission designed for conditions or for a subject population for which parent/LAR permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children).[69]

20.8.3.1. The research involves no more than minimal risk to the subjects because:
N/A

20.8.3.2. Parent/LAR permission is not a reasonable requirement to protect subjects because:
N/A

20.8.3.3. Description of the mechanism in place that substitutes the parent/LAR for protecting the children who will participate:
N/A

20.8.4. Process used to ensure permission is obtained from an individual or individuals (when two parent permission is required) with legal authority to provide such permission::[70]
We will verify in the EMR who the adolescent's legal guardian is and confirm the individual's identity over Zoom prior to obtaining consent.

20.8.5. Assent will be obtained from:[71]
☒ All children.
☐ Some children. Specify: ✍Click here to enter text.
☐ None of the children. Explain: ✍Click here to enter text.

20.8.6. Procedures for obtaining and documenting assent:

Adolescents will also be in the consent discussion with their parents and will be given a separate redcap link to confirm their assent.

20.8.7. Plan for re-approaching children who have reached the age of majority to obtain consent:[72]
We will call the adolescent on the phone and set up a separate zoom meeting to obtain consent if they reach the age of majority while actively participating in the study. They would not be re-approached if the only procedures left are data analysis.

20.9. **Cognitively Impaired Adults/Adults Unable to Consent**[73]

20.9.1. Process used to determine whether an individual is capable of consent:
N/A

20.9.2. Individuals from whom permission will be obtained in order of priority:[74]
N/A

20.9.3. Assent will be obtained from:
☐ All of these subjects.
☐ Some of these subjects. Specify: ✍Click here to enter text.
☐ None of these subjects. Explain: ✍Click here to enter text.

20.9.4. Process for obtaining and documenting assent:[75]
N/A

20.10. **Waiver or Alteration of Consent/Assent/Permission**[76]

20.10.1. Reasons for requesting a waiver or alteration of informed consent/assent/permission:[77]
NA

20.10.2. Consent/Assent Waiver/Alteration Criteria justifications:[78]

20.10.2.1. The research involves no more than minimal risk to the subjects because:
NA

20.10.2.2. The waiver or alteration will not adversely affect the rights or welfare of the subjects because:[79]
NA

20.10.2.3. The research could not practicably be carried out without the waiver or alteration because:[80]
NA

20.10.2.4. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format because:[81]
NA

20.10.2.5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation:
NA

20.10.3. If the research involves a waiver of the consent process for emergency research, provide sufficient information for the IRB to make it determinations:[82]
NA

20.11. **Waiver of Written Documentation of Consent/Permission (address one option):**

20.11.1. Option 1:

- The research involves no more than minimal risk to the subjects because:
- The research involves no procedures for which written consent is normally required outside of the research context because:

20.11.2. Option 2:
- The principle risk of a signed consent document would be the potential harm resulting from a breach of confidentiality because:
  ✍Click here to enter text.
- Both are true:
  ☐ The only record linking the subject and the research would be the consent document
  ☐ The subject or LAR will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

20.11.3. Option 3:
- The research involves no more than minimal risk to the subjects because:
  ✍Click here to enter text.
- The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm. Explain:
  ✍Click here to enter text.
- There is an appropriate alternative mechanism for documenting that informed consent was obtained. Explain:
  ✍Click here to enter text.

21. HIPAA Authorization and RCW Criteria

21.1. HIPAA Authorization (check all boxes that apply):
- ☐ The study does not involve the receipt, creation, use and/or disclosure of protected health information (PHI).[83]
- ☒ HIPAA authorization will be obtained as part of a signed consent form.
- ☒ The study will access PHI without prior authorization from subjects (including for recruitment purposes – e.g., reviewing the medical record to determine eligibility). *Complete Section 21.2 to request Waiver of HIPAA Authorization*.
- ☐ Subjects will review a written statement/information sheet with the appropriate HIPAA language but will not provide a written signature. *Complete Section 21.2 below to request an Alteration of HIPAA Authorization*.[84]
- ☐ Other. Explain:[85]
  ✍Click here to enter text.

21.2. HIPAA Waiver/Alteration Criteria: [86]

21.2.1. Reasons for requesting a waiver or alteration of HIPAA Authorization:
we will request a HIPAA waiver because in order to call families to let them know they are eligible for the study, we will need to access their PHI.

21.2.2. The use or disclosure of PHI involves no more than a minimal risk to privacy of individuals, based on, at least the presence of the following elements:

21.2.2.1. An adequate plan to protect the identifiers from improper use and disclosure: We will not extract any identifiers from the EPIC record that

they came from during this process. The study team members, who are also clinic staff, will view the names and contact information of the waitlisted potential participants in EPIC and will contact them using this information. We will not need to access any additional information besides their contact information. Since we will not extract any information, there will not be information to destroy. We will not share information viewed in EPIC with anyone outside the research or clinical team.

21.2.2.2. An adequate plan to destroy identifiers at earliest opportunity consistent with conduct of research:

Refer to Section 15.

21.2.2.3. Assurances that PHI will not be reused or disclosed to any other party or entity, except as required by law or for authorized oversight of the research:

PHI will be used as described in the protocol.

21.2.3. The research could not practicably be conducted without the waiver or alteration of authorization:

We could not know the contact information or identity of eligible participants without looking this information up in EPIC. Therefore we cannot ask them for authorization since we wouldn't know who they are until we access it.

21.2.4. The research could not practicably be conducted without access to and use of the PHI:[87]

There is no way to know who is on the waitlist and how to contact them without accessing their PHI.

22. Payments/Costs to Subjects[88]

22.1. Amount, method, and timing of payments to subjects:[89]

None

22.2. Reimbursement provided to subjects:[90]

None

22.3. Additional costs that subjects may be responsible for because of participation in the research:[91]

None. Patients will pay for clinical services as they normally would in the SCH Psychiatry clinic..All of the interventions described in this study will be billed to insurance as group psychotherapy- 90 minutes. The same billing code will be used for both groups.

23. Community-Based Settings[92]

23.1. Site(s) or location(s) in the community where the research team will conduct the research:

N/A

23.2. Composition and involvement of any community advisory board:

N/A

23.3. For research conducted outside of the organization and its affiliates:[93]
23.3.1. Site-specific regulations or customs affecting the research:
N/A

23.3.2. Local scientific and ethical review structure:
N/A

24. Resources Available

24.1. Qualifications (e.g., training, education, experience, oversight) of investigator(s) to conduct and supervise the research:[94]
The PI has a long history of conducting clinical research, including treatment evaluation studies like this one, with adolescents with ADHD across a wide range of settings. This includes seven federally or foundation funded clinical trials of organization skills training for adolescents with ADHD. The PI has over 130 publications on ADHD across the lifespan and has conducted treatment research in a variety of settings including schools, university clinics, community mental health centers, and recreational programs.

24.2. Other resources available to conduct the research:[95]
N/A

25. Coordinating Center Procedures

25.1. Coordinating center institution:
Seattle Children's Research Institute

25.2. If Seattle Children's is the coordinating center:
25.2.1. Process to ensure communication among sites:[96]
N/A there is only one site.

25.2.2. Process to ensure all site investigators conduct the study according to the IRB approved protocol and report all non-compliance:
N/A

25.2.3. Process to ensure all required approvals are obtained at each site:
N/A

25.2.4. Process to ensure all sites are informed of any problems and/or interim results:
N/A

26. International Center for Harmonization of Good Clinical Practice (ICH-GCP)

26.1. If you have committed to conducting the described study per ICH-GCP, check this box: ☐[97]

- This is generally applicable for contracts with industry-sponsored studies or sponsor protocols. See your contract/agreement or Sponsor Documentation if you are unsure.
- Note that completing GCP training is a separate activity and does not automatically mean that you have committed to conducting the study per ICH-GCP.
  If you check the box, upload a current curriculum vitae (CV) for the PI to the "Other Attachments" section of the "Local Site Documents" SmartForm.

[1] Provide a list of the participating sites (pSITEs). pSITEs are those sites outside Seattle Children's that will rely on the Seattle Children's IRB as their IRB of record. All pSITEs should be listed even if no study procedures will occur at the site. Remove the heading if this is not a study where Seattle Children's IRB will serve as the IRB of record for other institutions.

[2] Include information if this protocol is associated with other IRB-approved studies (e.g. is this application the next part/phase of a previously approved application.

[3] In clinical trials, an endpoint is an event or outcome that can be measured objectively to determine whether the intervention being studied is beneficial. Some examples of endpoints are survival, improvements in quality of life, relief of symptoms, and disappearance of the tumor.

[4] Include information on a drug or biologic in this section if: (1) the study specifies the use of an approved drug or biologic; (2) the study uses an unapproved drug or biologic; (3) the study uses a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition; or (4) data regarding subjects will be submitted to or held for inspection by the Food and Drug Administration (FDA). Only include information on a device in this section if: (1) the study evaluates the safety or effectiveness of a device; (2) the study uses a humanitarian use device (HUD) for research purposes; or (3) data regarding subjects will be submitted to or held for inspection by the FDA. Please note that certain software functions, mobile medical applications, and general wellness products may meet the definition of a device. As of October 2024, the IRB no longer applies enforcement discretion to device studies because the FDA has clarified that enforcement discretion only applies to manufacturer requirements.

[5] See the Investigator Manual HRP-103 for sponsor requirements for FDA-regulated research.

[6] Explain what IND exemption category applies to the drug and why. Note that a drug is not exempt from an IND unless all criteria for one category are met. See "HRP-306: Drugs" for more information.

[7] Explain what IDE exemption category applies to the device and why. Note that a device is not exempt from an IDE unless all criteria for one category are met. See "HRP-307: Devices" for more information.

[8] Explain why the device is NOT a significant risk device. A significant risk device means an investigational device that: (a) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a

subject; (b) is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; (c) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (d) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

[9] Be sure to indicate if controls will be included and include information about why control arms are ethically acceptable.

[10] Describe all of the research procedures being performed. Be sure to make it clear which procedures apply to each subject population. When applicable, describe how research procedures differ from standard of care and/or affect standard of care. Describe any audio/video recording that will be involved.

[11] Attach all surveys, scripts, and data collection forms to the "Supporting Documents" page.

[12] Include information about the frequency of data collection.

[13] See HRP-001 - SOP – Definitions for definition of banking. Type N/A if not applicable. If the data is subject to NIH Genomic Data Sharing Policies or other data sharing policies (e.g. you will submit data to dbGaP, NDAR, FITBIR), indicate here. Note that sharing with federal policies requires information to be included the consent forms. See HRP-502 F Language Resource Text for sample language.

[14] If applicable, include a list of identifiers that will be banked.

[15] Be general (e.g., researchers' lab, clinic, etc.)

[16] Generally, data and/or biospecimens should be released in a coded, non – identifiable manner.

[17] Include a description of the process used to verify and document that any required approvals have been obtained prior to release of data/biospecimens from the bank.

[18] You can allow for use for broad purposes

[19] This includes putting results and/or data in the subject medical records.

[20] If your population will differ from the representative population where the study will take place (e.g., race, ethnic group, or gender), provide a rationale for the differences.

[21] Seattle Children's IRB prohibits the exclusion of populations based on language, socioeconomic status, physical characteristics (e.g., gender identity, age, ethnicity), sexual orientation, religion, or access to technology unless there is sufficient justification for the exclusion. Specifically for language, the cost of translation and/or interpreter services will not be considered sufficient justification for the exclusion of participants who use a language other than English in accordance with NIH guidelines, in most circumstances. ("Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources." 59 FR 11146, March 28, 1994). See Investigator Manual HRP-103 for additional information.

[22] The plan must take into consideration the purpose of the research and the setting in which the research will be conducted. The plan must ensure that no group of people is either unfairly over-represented or unfairly excluded from participating in research. Your response should include how the recruitment process and other aspects of the study (as appropriate) are designed to facilitate equitable selection.

[23] If you check a box below, be sure to include the additional considerations associated with the population.

[24] Refer to HRP-416 CHECKLIST: Children.

[25] If the study is minimal risk, explain why. For studies that present greater that minimal risk include, as applicable: (1) why direct benefits are anticipated, (2) why risks are justified by anticipated benefit and/or the relationship between risk and prospective benefit compared to available alternatives, (3) why risk represents only minor increase over minimal risk, (4) how study procedures are reasonably commensurate with those inherent to the child's actual or expected conditions, (5) whether the interventions/procedures are likely to yield generalizable knowledge about the participant's condition and why it is of "vital importance" to understanding or amelioration of the participant's underlying disorder or condition, and (6) an explanation of what alternative methods/approaches were considered to make the above assessments (as applicable). As applicable, provide evidence-based information to support your assessment.

[26] This population may be wards of the state or any other agency, institution, or entity. For studies that present greater than minimal risk, refer to HRP-416 CHECKLIST: Children, Section 6, for additional guidance on required considerations for this population.

[27] This refers to both cognitive impairments and adults who are incapacitated for any other reason. As applicable, refer to HRP-417 CHECKLIST: Cognitively Impaired Adults.

[28] This includes subjects and their parent(s)/LAR.

[29] Applicable to information conveyed in writing and verbally. For example, your plan could include translating all study documents and having a study team member or interpreter available who can speak the language to answer questions.

[30] Refer to HRP-413 CHECKLIST: Neonates and HRP-414 CHECKLIST: Neonates of Uncertain Viability.

[31] This box does not need to be checked if pregnant women are not a target population and pregnancy is irrelevant to risk considerations. Refer to HRP-412 CHECKLIST: Pregnant Women.

[32] Refer to HRP-415 CHECKLIST: Prisoners

[33] Indicate how you will ensure that there is no coercion or undue influence

[34] A subject is considered "enrolled" when they consent to be in the study.

[35] Only applicable for multisite studies.

[36] i.e., numbers of subjects excluding screen failures.

[37] Payment for participation is not considered a benefit.

[38] For example, data will be double entered, data will be reviewed by another study team member to ensure accuracy, etc.

[39] If your study is multisite and there are differences in how confidentiality will be maintained by the coordination center and our local site, this should be explained in this section (e.g. local site will have samples that are linked to a person's name, but the coordination center will only receive coded samples without any links). Confidentiality regarding use of Social Media will be explained in a protocol section below.

[40] Including the signed consent/assent/permission forms and any information/documentation collected during the consent process.

[41] Privacy refers to persons and their interests in controlling the access of others to themselves. For example, based on privacy interests, people want to control the time and place where they give information, the nature of the information they give and who receives and can use the information.

When providing a response, consider the subject population and nature of the study. For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy counseling center that is clearly identified as such by signs on the building.

[42] Applicable for studies that present more than minimal risk.

[43] Include information about who (describe in terms of role or group) will review the data.

[44] This should be specific to the social media you are using for the research.

[45] All communications that are directed towards subjects and specific to a particular study will require prior IRB review and approval. All non-IRB reviewable communications can be described in general terms by category – news stories, relevant publications – and representative examples of each can be provided.

[46] Applicable if the research involves more than minimal risk to subjects. If minimal risk, this section is N/A.

[47] If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) those methods should also be described here.

[48] If the study will enroll or seek permission from individuals who speak a language other than English and recruitment methods will differ for these individuals (e.g., they will be approached by a bi-lingual person outside the study team), be sure your description covers these methods as well.
[49] For example, subjects will be initially approached in a private room or a letter rather than a postcard will be sent when the study name may disclose health information about the potential subject.

[50] For example, medical records, CIS, clinical databases, other study records. If the study will access PHI for recruitment purposes without prior authorization from subjects, please address this in the HIPAA Authorization section below.

[51] Attach copies of these documents to the Recruitment Materials section of the study SmartForm. For printed advertisements, attach the final copy. For online advertisements, attach the final screen shots (including any images). When advertisements are taped for broadcast, send the final audio/video tape to IRB@seattlechildrens.org. You may attach the wording of the advertisement to the SmartForm prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.

[52] "Permission" refers to consent obtained from a parent or LAR.

[53]Address the following in the response, as applicable:

1. How you will ensure that subjects and/or their parent/LAR have sufficient opportunity to discuss and consider whether or not to participate in the research.
2. Speak to the suitability of the intended consent process for the intended audience, taking into consideration the subject's and/or parent/LAR's age, language, comprehension level, and familiarity with technology tools (if applicable).
3. If using an electronic process to send consent information or obtain documentation of consent (e.g., e-signature), identify the process to be used to send the consent information (e.g., e-mail).
4. If using an electronic process (e.g., e-mail), describe the procedures that ensure the electronic process allows subjects/parents/LARs to ask questions they may have before signing (e.g., by in-person discussions, telephone calls, videoconferencing). If conducting a consent conference, describe the method to be used for the conference (e.g., telephone call, video conference), specifying any programs (e.g., Zoom) to be used. If applicable, indicate that the consent discussion will be audio or video recorded and whether recording will occur within any programs being used (e.g., Zoom).
5. If using an electronic process, describe how the subject and/or parent/LAR will navigate the consent materials, including whether the subject/parent/LAR will have the ability to move backwards and forwards within the electronic system and to stop and continue at a later time. Also indicate how long it will take.
6. The availability of study personnel to assist subjects and/or their parent/LAR in using the electronic process, if applicable.

[54] Some study teams are currently considering creative solutions for such individuals; these potential solutions include snail mail, drive through paperwork for consent, and loaner device/hotspots for e-consenting. If no alternative will be made available (meaning these individuals cannot be enrolled), the IRB will look for a sufficient rationale for this exclusion.

[55] For example, the consent discussion will take place in a private room.

[56] Address the following in the response, as applicable:
1. Identify the means of documenting consent/assent/permission (e.g., in writing, verbally, etc.). If obtaining an electronic signature, identify the specific software/application to be used.
2. Include a description of how the consent/assent form(s) will be delivered, including any programs (e.g. REDCap) to be used.
3. Include a list of any information about the individual that will be collected during the assent/consent/permission process.
4. If the research is conducted outside of Washington State, provide confirmation that the electronic documentation of consent is legally effective in that jurisdiction. Note, the study team's location while

conducting the study dictates the jurisdiction. For single IRB studies, the participating site's study team location while conducting the study dictates the jurisdiction.

[57] Electronic signature in this context refers to a legally effective electronic signature (e.g., a signature obtained via DocuSign) and does not apply to procedures where a waiver of documentation of consent is requested.

[58] Indicate "N/A" if not obtaining an electronic signature. Researchers are encouraged to consider the risks and benefits of the research when determining whether it is necessary to verify the subject/parent/LAR identity. For example, consider how likely it is that someone other than the subject would provide the consent. Social behavioral minimal risk research will not typically warrant identity verification.

[59] For example, consent forms will be downloaded as soon as they are full executed and saved electronically in a location accessible to the study team.

[60] This section describes the ways in which the procedures will not follow Seattle Children's SOP.

[61] See "HRP-411: Waiver or Written Documentation of Informed Consent" for further information.

[62] An information sheet template (HRP-502D) can be found in the Click IRB Library and should be attached to the consent form of the study SmartForm. For internet research, the information sheet can be translated to an on-line format, if desired.

[63] The IRB sometimes requires a script if you are having the consent conversation over the phone rather than in person. Templates for a consent script are available on the IRB website on the Participant Recruitment page and should be attached to the study SmartForm.

[64] This section describes the way(s) in which the processes for this study will not follow Seattle Children's SOP.

[65] Note the Short Form Consent may only be used when certain conditions are met. See HRP-091 for requirements for Short Form consent form use.

[66] For research conducted in the state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children." The age of majority in Washington is 18; however, sometimes younger children have ability to consent for certain types of care (e.g. sexual reproduction/health; mental health; drug/alcohol treatment). For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." If the sites in other states in the study are conducting their own IRB review, you do not need to worry about this--type N/A. If you are conducting research and are actively recruiting participants outside of Washington who are NOT coming to SCH to give consent and who will be covered under SCH IRB approval, this section should be addressed in your protocol.

[67] For minimal risk studies and greater than minimal risk studies that offer a prospect of benefit, the IRB generally requires one parent to provide permission for the child to participate.

[68] If permission will not be obtained, please address this in the Waiver or Alteration of Consent Process below.

[69] A waiver under this category is not available for FDA regulated studies. If you are requesting a waiver of parent/LAR permission under this category, you do not need to complete Section 20.10 for the same population.

[70] See HRP-013 for more information.

[71] The IRB generally follows the following guidelines for written assent: children 7-12 should provide written assent on the "simple" assent form (HRP-502G); children 13-17 should provide written assent by co-signing the parental permission form (HRP-502A). The IRB will consider other assent scenarios (e.g. verbal assent for some or all children; not requiring assent for some or all children; or waiving assent): please provide details about the plan for your study. See HRP-090 and HRP-416 for more information on waiving assent and when assent is not necessary.

[72] See Appendix A-13 of the Investigator Manual HRP-103 for requirements for re-consent at age 18. If you think you meet the conditions for a waiver at 18, please address this in the Waiver or Alteration of Consent Process below.

[73] See "HRP-417 Cognitively Impaired Adults" for further information.

[74] For example: durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child. If you are following HRP-013 in order to make this determination, simply state that in this section. For research conducted in the state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "legally authorized representative." For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." If the sites in other states in the study are conducting their own IRB review, you do not need to worry about this--type N/A. If you are conducting research and are actively recruiting participants outside of Washington who are NOT coming to Washington to give consent and who will be covered under SCH IRB approval, this section should be addressed in your protocol.

[75] The IRB may allow the person obtaining assent to document assent on the consent document.

[76] Provide justifications/explanations for each subject population for which a waiver/alteration is being requested.

[77] For example: consent/parental permission will not be obtained, required information will not be disclosed, the research involves deception, waiver for participants who turn 18, waiver for information collected about a non-present parent, or other waivers as necessary.

[78] The IRB needs to make all the waiver findings and key to this determination is that the IRB understand why it is not practicable to do the research without a waiver of consent. You need to provide a rationale in order for the IRB to consider whether the waiver criteria are met. See "HRP-410: Waiver or Alteration of the Consent Process" for further information.

[79] Possible reasons might include: a) you are not collecting information that could put subjects or their families at harm, e.g., affect eligibility for insurance, employability, stigmatization; b) you are not collecting information that would alter or affect the subject's care; c) any publication or presentation of research results would be done in a manner that would never reveal an individual's identity either directly or indirectly.

[80] Possible reasons could be: a) inability to locate families because of the lengthy time period over which the records/samples were created; b) many of the subjects whose records, data, or biospecimens will be used may have died and contacting the families about the research could cause harm and anguish to families; c) all eligible patients must be included in the study for the results to be meaningful.

[81] For example, identifiers are necessary, so that researchers can perform quality checks or identifiers are necessary to link data from multiple sources.

[82] See "HRP 419: Waiver of Consent for Emergency Research" for further information.

[83] PHI is health information that is also identifiable because it includes one or more of the 18 HIPAA identifiers. See Investigator Manual HRP-103 for the list of HIPAA identifiers.

[84] If your study involves using or creating PHI and your only contact with participants is online, you can request an alteration of HIPAA authorization to remove the signature requirement. As an alternative to a waiver of documentation of consent and an alteration of HIPAA authorization, you must demonstrate that the electronic consent signatures are compliant with applicable state/international law (in Washington, see RCW 19.34.300).

[85] For example: altering HIPAA elements for international research.

[86] Provide justifications/explanations for each subject population for which a waiver/alteration is being requested.

[87] Possible reason could be: the nature of the research is specific to individuals' health and requires access to individuals' health records.

[88] See "HRP-316: Payments" for further information.

[89] Methods of payment include check, ClinCard, gift cards, etc. Provide details on who will be the recipient of the payment (parent or child).

[90] Reimbursement is used when the subject is paid back for travel expenses such as transportation, food, childcare, or lodging. Reimbursement is generally distributed to person who incurred cost (usually parent) and requires receipts to be submitted.

[91] This could include things like fuel/transportation costs, parking, and/or childcare.

[92] Community-based settings may include community clinics, schools, non-profit organizations, etc.

[93] Type N/A if this section does not apply.

[94] Provide enough information to convince the IRB that the principal and/or co-investigator(s) are appropriately qualified to conduct and supervise the proposed research. When applicable, describe their prior clinical experience with the test article or study-related procedures, or describe their knowledge of the local study sites, culture, and society.

[95] For example, as appropriate: (1) Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit? (2) Describe the time that you will devote to conducting and completing the research. (3) Describe the facilities in which the research will be conducted. (4) Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research. (5) Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

[96] Including communication between sites of current study document versions and modifications.

[97] If you check the box, you are required to conduct your study according to the principles outlined at https://www.ich.org/products/guidelines/efficacy/efficacy-single/article/integrated-addendum-good-clinical-practice.html.