Brain Indices of Stimulant Treatment in Drug-Naive Youth at Risk for Substance Use Disorder
PI: Jeffrey Newcorn
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TITLE OF RESEARCH STUDY:

Title: Brain Indices of Stimulant Treatment in Drug-Naive Youth at Risk for Substance Use Disorder

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: Jeffrey Newcorn, MD and Iliyan Ivanov, MD

Physical Address: 19 East 98th Street, room 5E, NY, NY 10029

For fMRI scanning, the 1470 Madison Ave entrance will be used

Mailing Address: 1 Gustave L Levy Place Box 1230, NY, NY 10029

Phone: 212-659-8775 (Dr. Newcorn)

646-535-1618 (Dr. Krone)

WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to give permission for your child to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability, or your child's ability, to get medical care within the Mount Sinai Health System.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study which might make you change your mind about your child's participating will be given to you promptly.

Basic information about this study will appear on the website http://www.ClinicalTrials.gov. There are a few reasons for this: the National Institutes of Health (NIH) encourages all researchers to post their research; some medical journals only accept articles if the research was posted on the website; and, for research studies the U.S. Food and Drug Administration (FDA) calls "applicable clinical trials" a description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to examine the way Adderall influences brain functioning and learning

Your child may qualify to take part in this research study because he or she has ADHD and is willing to try Adderall, and play videogames in an fMRI scanner.

Funds for conducting this research are provided by the National Institute for Drug and Alcohol Abuse.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your child's participation in this research study is expected to last about a month.

The number of people expected to take part in this research study at Mount Sinai is 48.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to permit your child's participation in this research study, the following information describes what may be involved.

Many consent, screening, and follow-up procedures may be done via telehealth, meaning that a study team member may schedule you for a video-call and will speak to you while you and your child answer questions. If you are completing these procedures by telehealth, you will receive a link by email, and you can log in to sign consent and complete surveys on your computer, tablet, or cell phone.

The fMRI scan training (called Mock scanning) and the fMRI must take place face-to-face. For those procedures, you will arrive at the clinical entrance at the Hess building, at 1470 Madison Ave, before meeting a study doctor or coordinator in the lobby. At the clinical entrance, you and your child will be screened by hospital staff to make sure that you and your child are healthy enough to be allowed into the hospital's scanning area. At this time, that means you will be checked for fever, and asked questions about your health. Also, at this time, only one parent and no siblings are allowed to enter the hospital with your child. If you and your child are not wearing a face mask, you will be given a mask that you must wear for your entire visit. You and your child need to wear the mask over your nose and mouth at all times while in the hospital and when in the study offices. If you or your child are feeling unwell, have a cough, fever, or other symptoms of illness, you will not be allowed into the hospital and your appointment will be rescheduled. The study team will direct you to the patient elevator, and will meet you downstairs in the scanning suite.

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- SCREENING VISIT and BASELINE PROCEDURES:

Before any study procedures are done, we will discuss the study and, if you choose to have your family participate, you will sign the consent forms. We will video record the consent process. After signing consent, your family will complete a screening visit interview and questionnaires. We will NOT video record the screening interviews or questionnaires.

Screening procedures are usually completed over two separate days.

Screening over telehealth video call includes:

- Interviews, and you will complete forms discussing your child's symptoms, medical history, and other information necessary to confirm a diagnosis
- Your child will complete IQ testing and perform some other tasks that tell us about how he or she processes information, thinks, and responds to information.

Screening face-to-face includes:

- A physical exam and tests to make sure that he or she is healthy enough to participate in a trial of Adderall
- Your child will try out a mock fMRI machine to become familiar with the machine, and to make sure that he or she can complete a scan
- Finally, your child will complete an actual fMRI while playing a game in the scanner. The mock scan and the fMRI scan may happen on separate days.

- TREATMENT VISIT PROCEDURES (may be done by telehealth):

Baseline to Week 1) After the fMRI, if your child is eligible to participate, he or she will be assigned to a low dose of Adderall. Your child will take the medication for a week and then, at the end of the week, our doctors will ask you:

- questions about your child's symptoms and side effects
- Your child's weight
- to count the number of pills your child has taken during the week

The doctor may adjust your child's medication dose, if necessary; and you will be told how to adjust the medication you give to your child.

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Week 1 to Week 2) Our doctors will ask you the same questions and complete the same procedures that you completed the week before. If medication changes need to be made, the doctor will discuss them with you. Your child will continue to take medication as directed.

Week 2 to Week 3)

Your child will take the medication for a week and then will return to the offices to see our doctors at the end of this week. By then, your child will have been on medication for three (3) weeks, and will be ending the study with another fMRI scan.

- END OF TREATMENT fMRI VISIT

  Before you come into the office for the final visit, you will complete some of the study procedures over telehealth video call, and by filling out forms online.

  - We will ask you questions about symptoms and side effects
  - We will count the number of pills your child has taken during the week
  - You and your child will be asked to complete interviews and answer questions from scales that you had completed during the screening
  - You will be asked questions about your health and your child's health to make sure you are healthy enough to come into the hospital.

  When you arrive at the Hess building, at 1470 Madison Ave, you will pass through the clinical entry point just like you were at your visit for the first scan and training.

  - Your child will have blood pressure and weight checked
  - Your child will complete an actual fMRI while playing a game in the scanner and perform some other tasks that tell us about how he or she processes information, thinks, and responds to information.
  - This is the end of the study

  After the end of the study, your study team will discuss your plans for continuing care and help you with referrals to treatment.

<u>Optional Sharing of Information.</u>

Your child may be eligible for participation in more than one study conducted by the researchers in our program. The researchers in our program often use the same assessments across studies. This means that you and your child will only need to perform some assessments once, but you can participate in more than one study at the same time. Each study that asks for identifying information will still ask for your consent to participate before we will release the information.

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(1) Will you allow the researchers to transfer your child's information to use in other research studies in which you want to participate?

*Yes*_____ *No*_____

The researchers would like to ask your permission to keep the data collected from your child during this study to use them in future research studies. Please tell us how we may use this material in future research studies.

(1) Will you allow the researchers to store your child's information to use in future research studies?

Yes_____ No_____ If no, please stop here. If yes, please continue to the next question.

(2) The researchers can keep your child's information stored in one of two different ways: one way will store your child's information in a way that it is linked to his/her identity (through the use of a code that can indicate the information came from him/her personally) and the other way will store your child's information anonymously (no one will know who the information is from). It will not be stored both ways, so you must choose one of these two options. Please note that if you choose to have your child's information stored anonymously, you will not be able to change your mind to ask for your child's information to be destroyed at a future date. How would you like your child's information stored? Please initial **ONE** choice:

I would like my child's information stored with a link to my identity_____
I would like my child's information stored anonymously _____

Do you give permission to have assessment information (including the screening and outcome measures) **given to other researchers** at Mount Sinai or other institutions for use in research that is either related or not related to the purpose of this study? Please initial your choice:

*Yes*_____ *No*_____

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RESPONSIBILITIES FOR PARTICIPATING IN THIS RESEARCH:

If you decide to permit your child to take part in this research study, you would be responsible for the following things: supervising your child's use of the medication, providing accurate information about your child's response to the medication, and attending appointments as scheduled.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

Taking part in this research study may lead to added costs for your child, such as travel expenses, or for time off of work

If you agree to permit your child to take part in this research study, we will pay your family $50 for each of two fMRIs, and $10 for travel expenses for each of 3 visits. Your child can also win up to $15 for playing the game in the fMRI scanner. Payments are provided in the form of checks. Checks require some time to be prepared and will be given as available.

Tax law may require the Mount Sinai Finance Department to report the amount of payment received from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if payments received equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

It is important to know that your child may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be improvement in ADHD symptoms. After study participation has ended, the study team will also be able to refer you to continuing care elsewhere.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Although Adderall is FDA approved for treatment of ADHD in children and is generally considered to be safe, some common side effects of Adderall include: insomnia, loss of appetite, irritability, headache, occasional moodiness, or increased tics. Other more serious adverse effects such as palpitations and increased heart rate have been documented.

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There are no known risks associated with MRI, although some children do not like to be in enclosed spaces, and some children do not like the noise associated with the machines. We provide time in the mock scanners to let the children become accustomed to the scanners, and this helps to reduce any psychological discomfort associated with the scanning.
There is always risk of loss of private information, but there are procedures in place to minimize the risk. Your information is held in locked cabinets, and the Mount Sinai computer system uses firewalls, passwords and encryption systems to protect your privacy. This risk is expected to occur rarely

In addition to these risks are there are general risks:

- Psychological risks your child may feel discomfort while talking to the clinician about adverse life events and traumatic experiences. The assessments are being conducted by licensed, trained mental health professionals who use best standards of care and assessment when working with your child, so this risk is considered minimal.
- Legal risks (for example, in case of newly uncovered information about child abuse the team may need to report to the child protective services). These occasions are expected to occur rarely.
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to permit your child to take part in this research study without any penalty. The choice is totally up to you.

Instead of being in this research study, the choices may include trying Adderall or another FDA approved medication with a clinical team, such as your pediatrician, or through your child's clinic.

The important risks and possible benefits of these alternatives are listed below:

- All medications have potential of side effects
- There is always potential of loss of information, psychological discomfort, or other risks of being evaluated, whether in a clinical setting or in a research setting.
- Your clinical treatment team can provide you with more treatment options, such as other FDA approved medications (e.g., Ritalin, Strattera, Intuniv, etc), or other preparations of medication that do not need to be taken in pill form (e.g., patches).

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- Your clinical treatment team may also provide treatment for a longer period of time, as this study is a short-term trial.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If your child is injured or made sick from taking part in this research study, medical care will be provided. Generally, this medical care will be billed to you and/or your child's health care insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your child's insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may decide to stop your child's participation in this research study at any time without any penalty. This will not affect your or your child's ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you, or your child, are otherwise entitled.

If you decide to stop your child's participation in the research study, please contact the Principal Investigator or the research staff. At that point, we will ask you to complete some safety assessments in order to make certain that your child is not experiencing any side effects.

If you decide to stop your child's participation in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the investigator can collect information from your child's routine medical care. If you agree, this data will be handled the same as research data.

You may also withdraw your permission for the use and disclosure of any of your child's protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your authorization, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your child's health information may still be used or shared after you withdraw your authorization if your child has an adverse event (a bad effect) from participating in the research study.

Withdrawal without your permission: The study doctor, the sponsor or the institution may stop your child's involvement in this research study at any time without your permission. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your child's best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your permission.

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CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt your child, please contact the office of the research team and/or the Principal Investigator at phone number 212-659-8775

If your child experiences an emergency during participation in this research, contact 911 or go to the emergency room. You may also call*, in an emergency,* **917-748-8695**

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for the Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about rights of research subjects.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

In the past, Dr. Jeffrey Newcorn (the Principal Investigator in this study) received financial compensation as an advisory board member for Shire Pharmaceuticals (manufacturer of Adderall, the drug whose effects on the brain are being evaluated in this study).

Currently, Dr. Newcorn receives financial compensation as a consultant or advisory board member from other companies that either develop or assess treatments for ADHD.

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If you have questions regarding paid relationships that your physician/researcher may have with industry, we encourage you to talk with him or her, or check for industry relationships posted on individual faculty pages on our website at http://icahn.mssm.edu/.

As you take part in this research project it will be necessary for the research team and others to use and share some of your child's private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be disclosed (shared) with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your child's: name, address, telephone/fax numbers, dates of birth, admission, discharge, social security number, medical records number, other unique codes.

The researchers will also get information from your child's medical record including your electronic medical record, your hospital or clinic, and/or your private doctor.

During the study the researchers will gather information by:

- taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- completing the tests, procedures, questionnaires and interviews explained in the description section of this consent
- reviewing HIV-related information, which includes any information indicating that your child has had an HIV related test, or have HIV infection, HIV related illness or AIDS, or any information which could indicate that your child has been potentially exposed to HIV
- reviewing mental health records
- reviewing alcohol and/or substance abuse records
- reviewing psychotherapy notes

Why is your child's protected health information being used?

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Your personal contact information, and that of your child, is important to be able to contact you during the study. Your child's health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who your child is, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat your child in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your child's information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your child's information. If any payments for taking part in this study, the Mount Sinai Finance Department may need names, addresses, social security numbers, payment amounts, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your child's protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your child's protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project: James Blair, PhD at the Child and Adolescent Mental Health Centre, Mental Health Services, Capital Region of Denmark, Copenhagen, Denmark or the Boys Town National Children's Hospital.
- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: National Institute of Health
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Food and Drug Administration (FDA)

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- The United States Department of Health and Human Services and the Office of Human Research Protection.

In almost all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, the Office for Human Research Protections (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your child's medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your child's protected health information?
Your authorization for use of your child's protected health information for this specific study does not expire.

Will you be able to access your child's records?

During participation in this study, you will have access to your child's medical record and any study information that is part of that record. The investigator is not required to release research information that is not part of your child's medical record to you.

Do you need to give us permission to obtain, use or share to you or your child health information?

NO! If you decide not to let us obtain, use or share your child's health information you should not sign this form, and your child will not be allowed to volunteer in the research study. If you do not sign, it will not affect treatment, payment or enrollment in any health plans or affect eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your child's protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study

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may still use your child's protected information that was already collected if that information is necessary to complete the study. Your child's health information may still be used or shared after you withdraw your authorization should your child have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your child's protected health information for research that means your child will also be withdrawn from the research study, but standard medical care and any other benefits to which your child is entitled will not be affected. You can also tell us you want to withdraw your child from the research study at any time without canceling the Authorization to use your child's data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive the information to continue to protect confidentiality.

If as part of this research project your child's medical records are being reviewed, or your child's medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your child's medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your child's HIV-related information without authorization. If you or your child experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

Certificate of Confidentiality: To further protect your child's privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This Certificate does not mean that the Department of Health and Human Services approves of this research. Rather, it is

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intended to ensure that your child's identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above. The research staff will not share any of your child's research information with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that your child or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect your child or others. A Certificate of Confidentiality does not prevent you, your child, or a member of your family from voluntarily releasing information about your child or his/her involvement in this research. This means that you. Your child and your family must also actively protect your child's privacy. If an insurer or employer learns about your child's research participation, and you agree that they can have your child's research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

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Signature Block for Research Involving Children

Your signature documents your permission for the child named below to take part in this research and to the use and disclosure of this child's protected health information. A signed and dated copy will be given to you.

Printed name of child	Date
Signature of parent or guardian	Time
Printed name of parent or guardian	❑ Parent ❑ Guardian (May provide permission only if legally authorized to consent to the child's general medical care.)
Signature of second parent	Date
Printed name of second parent	Time

Note on Second Parent: *If the IRB determined both parents must give permission unless an exception below applies, and if documented permission of the second parent of this child is not obtained, indicate the reason: (select one)*

- ❑ *Second parent is deceased*
- ❑ *Second parent is not reasonably available*
- ❑ *Second parent is unknown*
- ❑ *Only one parent has legal responsibility for the care and custody of the child*
- ❑ *Second parent is incompetent*

Person Explaining Study and Obtaining Consent

Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

If a witness is required to observe the consent process , document below:

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the parent(s)/guardian, and that permission was freely given.

Signature of witness to consent process	*Date*
Printed name of person witnessing consent process	*Time*

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

----------FOR IRB USE ONLY----------

Rev 6.22.16

Effective Date: 11/8/2022
End Date:11/7/2023