Informed Consent

Neurobehavioral Targets of Mindfulness in Youth at Risk for Mood Disorders

NCT05345392

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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY
(Child Form)

Title: Brain, Emotions, and Mind-Wandering Study (BEaM)

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SOURCE OF SUPPORT: National Institutes of Mental Health (NIMH)

Key Information:

- You and your child are being asked to take part in a research study. The research team will explain the study to you and your child and will answer any questions that arise.
- The purpose of this research study is to better understand how well a mindfulness intervention works compared to an active control among children and adolescents at family risk for mood disorders.

- There will be no direct benefit to you and your child from participating in this research study. However, knowledge gained from the study may contribute to the scientific community, and our understanding of how to possibly prevent the onset of mood disorders in at-risk youth.
- Risks related to this research study may include possible emotional discomfort when discussing psychiatric symptoms, possible discomfort with being in a group setting, possible stress or boredom during the fMRI scan, and possible breach of confidentiality. All efforts will be made by the research team to minimize the occurrence of these risks.

We are conducting a research study to compare the effects of a mindfulness intervention versus a health and wellness intervention on emotions and mood in children and adolescents at family risk for mood disorders. Previous research has shown that adolescents with a family risk of major depressive disorder and/or bipolar disorder tend to have more difficulties regulating emotions and moods than those without family risk. Mood swings not only impact functioning and relationships, but also might put children and adolescents at increased risk for development of mood disorders themselves. We are interested in understanding how brain function is related to mind-wandering and mood swings. To do so, participants will be randomized (i.e., assigned by the flip of a coin) either to the Mindfulness-Based Intervention (MBI) group *or* to the Health and Wellness Intervention (HWI) group. Thus, neither the study investigators nor your child will choose which group they will participate in. Through this randomized controlled trial, we will better understand *how* and *for whom* mindfulness interventions work.

Who is being asked to take part in this research study? This study is recruiting 250 children (between the ages of 11 and 14 years old) who have a birth parent or full biological sibling (*i.e., sibling has the same biological mother and biological father as the participating child*) with major depressive disorder or bipolar I or II disorder. We are asking the parent or adult sibling with major depressive disorder or bipolar disorder to participate to confirm diagnosis and relevant family history. If the sibling with the mood disorder diagnosis is below the age of 18 years old, we will ask that the parent be present to confirm diagnosis and relevant family history.

What is a mindfulness intervention? Mindfulness is paying attention to the present moment, on purpose, and without judgement. Mindfulness interventions include exercises to increase this present-moment awareness. This idea has its roots in Buddhism, but over the past few decades, secular adaptations of mindfulness-based interventions have been used to treat disorders as diverse as pain, cancer, and depression. Mindfulness-based interventions have also been shown to be helpful in children and adolescents, particularly helping them to deal with stress. The mindfulness intervention in this study involves coming to a small group, between 2 and 7 other early adolescents, once a week for eight weeks. During this time, we will practice a number of exercises that help us to pay attention to the present moment: paying attention to our breath and different sensations (e.g., taste, touch, smell). In addition to these sessions, we will hold a parent orientation, to introduce mindfulness and answering any questions you may have about what your child will be experiencing. To help your child to integrate mindfulness into daily life, we will ask him or her to do a “home practice” throughout the intervention. Home practice consists of 15 minutes per day engaging in exercises that are meant to be relaxing and fun, that have been introduced that week in group.

What is the Health and Wellness Intervention (HWI)? The Health and Wellness Intervention (HWI) is inspired by the Health Enhancement Program (HEP) that has been used in prior research with adults. The HWI has been adapted for youth 11-14 years old, using brief, engaging, and age-appropriate activities. The HWI in this study involves coming to a small group, between 2 and 7 other early adolescents, once a week for eight weeks. This intervention will focus on stress management, social support, hobbies and interests, strengths and values, sleep health, nutrition, and exercise. You are highly encouraged to participate in the groups' weekly introductions and discussions. To help your child to integrate the stress management techniques into daily life, we will ask him or her to do a "home practice" throughout the intervention. Home practice consists of 15 minutes per day engaging in exercises that are meant to be relaxing and fun, that have been introduced that week in group.

What procedures will be performed for research purposes? There are four main components of participation in this study: baseline assessment, non-clinical laboratory visits (fMRI), mindfulness group ***or*** health and wellness intervention group (x8 weeks), and follow-up assessments. The next page outlines the interviews, questionnaires, and tasks you and your child will complete at different time points throughout the study and the type of information each involves.

Baseline Assessment: You and your child will be asked to take part in a baseline assessment appointment at our research office in Bellefield Towers or online via HIPAA-compliant Zoom or Microsoft Teams that will last 3-4 hours. During this visit, you and your child will be made aware of study information, including the study format and procedures. This assessment and may be audio and/or video recorded. In addition, you and your child will answer questions that will help the research staff to determine whether your child is eligible for the study. You and your child will be asked questions to determine whether your child will be able to undergo an fMRI scan. You and your child will also be asked questions about history of psychiatric symptoms and treatment. If information is revealed during the course of any study procedure that could potentially hurt him/her or others (i.e., suicidality), it may be necessary for study staff to notify you, the authorities, or other relevant individuals; in this case, appropriate intervention (e.g., referral to the emergency room) would be initiated. Additionally, if we find something clinically significant as part of this assessment, we will share our findings and recommendations with you and your child at the time of this assessment. We will not share results with any other providers.

If more than 4 months has passed between your child's baseline assessment and the start of their participation in 8-week group, we will ask you both to complete a check-in visit online or in-person so that we can obtain updated information about your child's symptoms.

If necessary, we will also confirm that your child has a family member with major depressive disorder or bipolar I or II disorder. This will be done by asking the family member with major depressive disorder or bipolar disorder about his/her symptoms (either in person or over the phone) and obtaining records that indicate the diagnosis. If the family member with major depressive disorder or bipolar disorder is not available for interview or under the age of 18 years old, we will ask you the relevant questions about his/her symptoms to evaluate for this diagnosis.

If you and your child attend all scheduled consent and baseline assessment visits on time (i.e., **within 15 minutes of the scheduled visit**) *and* **without any no-shows or sudden cancellations** (i.e., cancelling the day of the scheduled visit) then you will have a chance to win $100 through the University's payment system before the start of the 8-week group.

fMRI Visits: If you decide to have your child take part in this research study, your child will have an fMRI scan that lasts for 30 minutes; the total visit will last 2-3 hours. Participants will be met by a research assistant at the CMU-Pitt BRIDGE Center on Carnegie Mellon University's Campus in Oakland. Your child will be familiarized with the MR scanning environment and receive a tour of the facilities. If possible, your child will go in an MRI simulator (a plastic replica of the actual MRI scanner) so that he or she can be further familiarized with the scanner prior the scan. If your child also has a history of claustrophobia, weighs more than 300 pounds, or suspects that they may have a metallic object in their body, they may not participate in the study. There is a potential risk of the powerful magnetic field of the MRI scanner attracting ferromagnetic / metallic objects towards the center of the scanner. This includes aneurysm clips, non-removable body piercings, shrapnel, metal fragments in the eye, IUD that contains metal, and an implanted electronic medical device such as a cardiac pacemaker, deep brain stimulator, cochlear implant, neurostimulator, and insulin pump. You must tell the MRI operator if you know or suspect your child has any metal in their body.

The effects of MRI on the developing fetus are unknown. For this reason, participants in this research study should not become pregnant. Pregnancy testing may be performed before the research begins. The results of the pregnancy test are confidential and will be given to your child by one of the study nurses or doctors in private. We would not tell parent(s) or guardian(s) without your child's permission. However, under certain circumstances, we might be compelled to reveal this information. For example, if your child's life was at risk or if abuse was suspected, it may be necessary to inform you as parent(s) or guardian(s) or relevant authorities.

During research, if your child has a positive pregnancy test, we must withdraw your child from the research. This means that even if we do not reveal the results, parent(s) or guardian(s) may suspect that their child is pregnant despite our best efforts to maintain confidentiality. If your child becomes pregnant or if there is any chance that your child is pregnant (late menstrual period), please contact the research investigator immediately so that we may provide medical assistance and counseling.

Participants will complete questionnaires and tasks about his or her mood and behaviors. The online tasks will be completed on the day of your child's scan visit. Questionnaires may be completed on a laptop or other device, up to three days before or during the visit. Answers to questionnaires are not monitored in real time. This means that if your child endorses psychiatric symptoms, study staff will not be made aware until the next day, at the earliest. In the event that your child endorses suicidality, study staff would call to inform you on the next business day.

During the actual scan, your child will watch a movie. While your child is in the scanner, we

will record his or her heart rate, respiration and brain activity using a procedure called functional magnetic resonance imaging (fMRI). fMRI is a technique that locates where certain functions occur in the brain. The fMRI scanner is FDA approved. As with traditional MRI, the subject lies still on a table and enters into the scanner's imaging space so brain images can be recorded for study.

Because the noises produced by the scanner are loud and may be a source of discomfort, all subjects must wear earplugs during the MRI scan; disposable earplugs will be provided for your child. A staff member will be in constant contact with your child throughout the procedure, and the scan can be stopped at any time should your child be uncomfortable or is unable to tolerate the procedure.

There is a possibility that we could detect something unusual/different on your child's scan. MRI scans in this research study are performed to answer research questions and are not the type that reveals medical conditions. In the unlikely event that the individuals who review the scan detect a potential abnormality; the de-identified scan will be referred for further examination to a specialist (neuroradiologist) qualified to make a clinical interpretation and professional opinion. We will contact you as soon as possible and notify you that there may be some irregularity and that it is recommended you contact your child's physician. You will be responsible for following up with your physician. A copy of the scan can be made available to your child's physician upon request, should we receive a signed release. The consulting neuroradiologist will be available to answer any questions you or child's PCP might have about the findings on the scan.

At the investigator's discretion, you and your child may view their brain images and receive copies of them. However, you should be aware that brain structures within the normal population are highly variable, and that it is difficult to draw any conclusions from your child's images. You should also be aware there is a potential you and your child could experience some distress or discomfort from viewing their images.

Electronic Diary (ED): During the week after each scan visit, your child will be asked to answer brief, daily surveys in their ED regarding their mood and thoughts via text message on their phone for a total of 6 days. On weekdays, your child will receive one survey in the morning and two surveys in the afternoon/evening. On weekends, six surveys will be delivered throughout each day. We will be in touch with you if we receive any text messages indicating that your child may be in danger to themselves. If your child does not have a smartphone, we will provide them with a basic smartphone to use during the study. If your child completes an average of 75% or more of the ED surveys in each week, they will earn a $20 bonus at each timepoint and have a chance to win a free iPad mini when the study's enrollment is closed.

Optional Hair Sample: We will obtain hair from the upper part of the back of your child's head. We will measure the levels of a stress hormone, cortisol, from your child's hair. We will collect the hair samples two times during the study. The hair samples are optional. The amount of hair obtained is not likely to be noticeable.

Mindfulness Group or Health and Wellness Intervention Group

After the successful completion of the first brain scan visit, your chill be randomly selected to participate in ***either*** the Mindfulness-Based Intervention (MBI) group ***or*** the Health and Wellness Intervention (HWI) group. The group will begin approximately within 3 weeks after the first scan visit. The groups will be held at either Webster Hall or Sterling Plaza in Oakland, or at the UPMC Center for Integrative Medicine in Shadyside depending on which group your child is randomly selected to participate in. These sessions will be audio- and/or videotaped in order to be sure that study instructors are administering the programs correctly.

MBI Groups: There will be between 3 and 8 early adolescents (between the ages of 11 and 14 years old) in each group. Groups will focus on age-appropriate exercises to promote present-moment, non-judgmental awareness. During the first group, we will do a mindfulness exercise with the children and their parents and introduce everyone to the materials that will be covered; after this, the groups will not include parents. Exercises will be chosen to promote attention to present moment sensations and thoughts, with the intention of observing without judgement. These exercises include but are not limited to: mindful attention to breath, body scan (mentally "scanning" the body from toes to head), mindful eating, and mindful movements. These activities have been used in children and adolescents in this age range previously and have been shown to improve response to stress. Parental engagement in these activities and encouragement is strongly encouraged. To help your child to integrate mindfulness into daily life, we will ask him or her to do a "home practice" throughout the intervention. Home practice consists of 15 minutes per day engaging in exercises that are meant to be relaxing and fun, that have been introduced that week in group. Throughout the study, the study investigators will be available to answer questions or discuss any concerns that you might have.

HWI Groups: There will be between 3 and 8 early adolescents (between the ages of 11 and 14 years old) in each group. Groups will focus on age-appropriate exercises to promote stress management skills which will include topics such as using social supports, strengths, and values as well as discussing healthy sleep habits, exercising, and nutrition. All groups will take place in-person at either Webster Hall or Sterling Plaza in Oakland which is very close to our research offices. During the first group, we will discuss different aspects of stress (e.g., positive versus negative stress, positive coping mechanisms), play a game with the children and their parents, and introduce everyone to the materials that will be covered; after this, the groups will not include parents. These types of activities have been used in children and adolescents in this age range previously and have been shown to improve response to stress. Parental engagement in these activities and encouragement in these activities are strongly encouraged. To help your child to integrate the stress management techniques into daily life, we will ask him or her to do a "home practice" throughout the intervention. Home practice consists of 15 minutes per day engaging in exercises that are meant to be relaxing and fun, that have been introduced that week in group. Throughout the study, the study investigators will be available to answer questions or discuss any concerns that you might have.

Post-Intervention Follow-Ups: You and your child will be invited approximately 6 months following the last scheduled group for a brief online visit (15-30 minutes) via Microsoft Teams or Zoom where we will gather additional feedback about the intervention and suggestions for further development. About 9 months after the last group, further evaluation and follow-up will

be conducted both in-person and online. During the in-person visit, your child will be asked to complete an online task. Then, a separate online visit will be scheduled which will include administering several scales to you and your child to assess mood, anxiety, and other symptoms.

Additional Procedures & Information: We may contact you at a future date to ask if you and your child might be interested in participating in additional/optional procedures.

If you have concerns about being able to travel for an in-person intake visit, scan visits, or groups you may be offered/scheduled for a Lyft ride.

If you are traveling greater distances for study visits (i.e., ~40 miles or more) then you will receive mileage reimbursement.

What are the possible risks, side effects, and discomforts of this research study?

Below is a table summarizing the risks associated with this study:

Procedure	**Expected Frequency – Adverse Event**	**Measures taken**
Self-Report Questionnaires and Electronic Diary Surveys	Infrequent – Some individuals experience emotional discomfort (e.g., embarrassment, stress, anxiety, etc.) when discussing their mental health, symptoms, or psychiatric history, yet the information being requested is standard in clinical settings. Detecting a previously unrecognized psychiatric problem.	Your child does not have to answer any questions that he/she/they are not comfortable with; Interviews are conducted by professional and experienced staff members; If participation is too burdensome, your child may discontinue his/her participation in the study, either temporarily or permanently; referral to physician or clinician if necessary.
MBI Group	Rare – Mindfulness exercise can lead to uncomfortable emotions, re-experiencing of traumatic events, an individual feeling like he or she is not really in his body (depersonalization) Rare – Breach of confidentiality Infrequent – Some individuals may experience discomfort with being in a group setting	Your child will be reminded that he, she, or they can take breaks whenever necessary. Two bachelor's or master's levels instructors with extensive experience with child and adolescents will be running this group; At the beginning of the group, the instructors and participants will establish group agreements that will enforce being respectful to each other, etc. so that the participants feel as comfortable as possible in the group. If participation is too burdensome, your child may discontinue his/her participation in the study, either temporarily or permanently; referral to physician or clinician if necessary. We will avoid discussion of diagnoses and other sensitive information during group; and participants will be referred to by their first names, without disclosure of additional identifying information.
HWI Group	Infrequent – Some individuals may experience discomfort with being in a	At the beginning of the group, the instructors and participants will establish group

	group setting Rare – Breach of confidentiality	agreements that will enforce being respectful to each other, etc. so that the participants feel as comfortable as possible in the group. We will avoid discussion of diagnoses and other sensitive information during group; and participants will be referred to by their first names, without disclosure of additional identifying information.
fMRI testing	Likely – Stress, fatigue, or boredom.	Breaks between tests; If participation is too burdensome, your child may discontinue his/her participation in the study, either temporarily or permanently.
fMRI scan	Rare – Discomfort from radio frequency-induced heating and loud noises the MRI machine makes when it is turned on. Anxiousness or claustrophobia while inside the MRI machine. Injury due to implanted metallic objects. Potential risk to unborn fetuses. Lightheadedness when your child first sits up after lying in the MRI machine.	Earplugs and headphones to reduce hearing discomfort; time in a mock scanner to become familiar with the scan space; careful screening to make sure metallic objects are not in room; if discomfort due to the MRI is too much for your child to bear, he/she will have the ability to stop the scan at any time.
Optional Hair Sample	Rare – There is a risk of injury while collecting hair samples using fine scissors.	Hair sampling will be conducted by a trained staff member to minimize this risk. If your child is uncomfortable, hair sampling will be conducted at a later time. The results from hair samples will only be used for research purposes and you cannot obtain a report of the results. Hair samples will be coded by your child's study identification number with no identifiers.
Confidentiality	Rare – Breach of confidentiality: Individuals outside of the study may learn of an individual's participation and data collected for the study about that individual. We may also offer you a Lyft ride if transportation is a barrier for your participation. With any electronic or outside services, there is a risk for breach of confidentiality due to information these services need to provide successful support and/or transportation.	All data will be coded exclusively with study ID number. Only the people who need to know your child's name for research purposes will know your child's name. Identifiable data will only be available to study investigators and their staff. Study materials will be stored in a locked cabinet in a locked office, and computer files will be password protected.
Text Messaging & Email	Rare - Breach of confidentiality: Text messages or emails may not be encrypted or secure during their transmission or storage and it is	Only research staff will have access to study cellphones to communicate with participants which will help to eliminate confidentiality risks. Additionally, only study staff will have

	possible they could be intercepted and used by others not associated with this study.	access to participant email addresses.
Internet Communication	Rare – Although every reasonable effort has been taken, confidentiality during internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.	Secure videoconferencing platforms and a secure online database will be respectively used for online assessments and collecting questionnaires/tasks.

If necessary, we may ask your child to repeat some of these procedures. This would happen if our collection of some of the data (such as heart rate, or the fMRI itself) is incomplete due to technical failure, late arrival, or unforeseen problems. In the event that we need to repeat procedures, we will only do so if you and your child are willing, and we will pay your child for the time that is involved an amount that is consistent with what he/she earned for that part of the study the first time.

What are possible benefits from taking part in this study? There may be no direct benefit to your participation in this study. However, we are testing whether these 8-week group interventions may help children with mood swings. Knowledge gained from the study may contribute to the scientific community, and our understanding of how to possibly prevent the onset of mood disorders in at-risk youth. Thus, individuals with a family history of bipolar disorder or major depressive disorder, and society at large may benefit from the information gathered. Additionally, your child may benefit from learning about mindfulness *or* healthy coping strategies as part of participating in the groups.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study? You will be promptly notified if any new information, either good or bad, develops during the course of this study and which may cause you to change your mind about your child's continuing participation.

Will I or my insurance provider be charged for the costs of any procedures performed as part of this research study? None of the services and/or procedures your child will receive during this research study as described above will be billed to you or your health insurance. If you receive a bill or believe that your child's health insurance has been billed for something that is part of the research study, notify a member of the research team or UPMC Patient Billing Services.

Will I be paid if I take part in this research study? Your child will receive $25 for the initial baseline visit, up to $55 for Scan 1/Questionnaires/Tasks/Optional hair sample, $75 for Scan 2/Questionnaires/Tasks, $100 for Scan 3/Questionnaires/Tasks, up to $130 for Scan 4/Questionnaires/Tasks/Optional hair sample, up to $280 for completing the daily online surveys, $10 for the 6 month follow-up and $50 for the 9 month follow-up visits. Additionally, you will be paid $25 for the initial baseline visit, $10 for the 6 month follow-up visit, $50 for the 9 month follow-up visit, and receive a $15 transportation stipend for bringing your child to

each mindfulness or HWI group. Additionally, if it's necessary for you and your child to complete the check-in visit due to the 4 month gap between their initial baseline visit and the start of group, you will each be paid $20. Therefore, your child can earn up to $725 for participating in this research study. (If the check-in visit would be necessary to complete, then your child can earn up to $745 for participating in this research study.) You will earn up to $205 for participating in this research study. (If the check-in visit would be necessary to complete, then you can earn up to $225 for participating in this research study.)

Since you and your child are being compensated for your participation in this study, both of your names, address(es), and social security numbers will be released to the Accounting Office. If the total reimbursement for your participation in research is greater than $2000 in a year, this will be reported to the Internal Revenue Service (IRS) as income.

Who will pay if I am injured as a result of taking part in this study? University of Pittsburgh investigators and their associates who provide services at UPMC recognize the importance of your voluntary participation to their research studies. These individuals and their staff will make reasonable efforts to minimize, control, and treat any injuries that may arise because of this research. There is no compensation available if you are injured. You do not waive any rights by signing this form.

Who will know about my participation in this research study? The research staff will keep all information obtained from this research as confidential (private) as possible. All paper records and audio/videotapes related to your involvement in this research study will be stored in either a locked file cabinet or a secure, electronic database. Your identity on these records will be indicated by a case number rather than by name, and the information linking these case numbers with your identity will be kept separate from the research records. The information obtained in this study may be published in medical journals, but your identity will not be revealed. Data from this study will be shared with The National Data Archive in accordance with the NIMH data sharing policy. This data will not contain your child's name or any personal identifying information and will be coded with Global Unique Identifier (GUID) number only. This will be kept in a secure electronic database to which only the investigators and the research staff will have access.

Will this research study involve the use or disclosure of my identifiable medical information? If your child is receiving, or has previously received, mental health treatment at UPMC, this research study may involve the recording of identifiable medical information from your child's hospital and/or outpatient clinic records at UPMC. If your child is currently receiving mental health treatment outside of UPMC, we may obtain a copy of the child's identifiable medical record information. You may need to sign an additional authorization form to release this information. The information collected, from either UPMC or a non-UPMC entity, will be limited to information concerning your child's psychiatric symptoms, mood, and behavior, and will be used to help determine diagnoses. This authorization is valid for an indefinite period of time. However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing.

Who will have access to my identifiable information related to my participation in this research study? In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study:

• Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study.

• Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders made by the investigators for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

• Audio/video recordings and associated ratings may be shared with other research studies for training and reliability purposes.

• The fact that you are participating in a research study may also be known to individuals involved in administrative activities associated with the conduct of the study.

• The National Institutes of Health (NIH) will have access to information related to your participation in this study.

- De-identified data might be shared with other investigators for additional analyses or other collaborations. Identifiers will be removed any may be used for future research.

*This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the research team cannot release or use your child's information, documents, or samples that may identify them in any action or suit unless you say it is okay. The research team also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

The research team may release information about your child when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does

not stop you from willingly releasing information about your child's involvement in this research. It also does not prevent you from having access to your child's information.

Is my child's participation in this research study voluntary? Your child's participation in this research study, to include the use and disclosure of their identifiable medical information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide consent for the use of your child's identifiable medical information for the purposes described above, your child will not be allowed, in general, to participate in the research study). Whether or not you provide your consent for participation in this research study will have no effect on your child's current or future relationship with the University of Pittsburgh, or your child's current or future medical care at a UPMC Health System hospital or affiliated health care provider or your child's current or future relationship with a health insurance provider.

For how long will the investigators be permitted to use and disclose identifiable information related to my child's participation in this research study? The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your child's participation in this research study for a minimum of seven years following the completion and final reporting of this research study, or for five years past the age of majority (23 years old) after study participation ends. Audio/video recordings and research records will be kept for a period not exceeding seven years from the end of the study. After seven years, all audio/video recordings will be erased. Audio/video recordings will be erased earlier at your request or your child's request.

Will participation in this study affect ongoing treatment in any way? The study will not impact *ongoing* treatment. However, we do request that your child *not* engage in new treatment or change medications during or 4 weeks prior to the start of the 8-week group, unless clinically necessary. If we do uncover additional concerning symptoms during assessment, we will inform you and provide a referral to an appropriate provider or other resource.

May I withdraw, at a future date, my consent to participate in this research study? You and your child are free to refuse to participate in this study or to withdraw at any time, your consent for participation in this research study, including the use and disclosure of your identifiable medical information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable medical information for the purposes described above, you may also be withdrawn, in general, from further participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.) Audio and/or video recordings will continue to be stored for research purposes by identification number only, unless you or another family member request that it be destroyed. To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

If I agree to take part in this research study, can I be removed from the study without my consent? Your child may be removed from this study by the investigators if you or your

child does not follow the instructions given by the investigator and the research team. If your child drops out or is withdrawn from the protocol, your child's treatment with his/her psychiatrist (if applicable) will not be affected. Any identifiable research information recorded for, or resulting from, your child's participation in this research study prior to the date that your child was removed from the study may continue to be used and disclosed by the investigators for the purposes described above.

May I be contacted about possible participation in future research studies? You may be contacted in the future about possible research studies for which you might be eligible. You are under no obligation to participate in any future study. There is also a possibility that you may be eligible for other research studies conducted by our associates. You may be contacted via phone or email by members of our research team or their associates to determine your interest in those other studies, but you are never under any obligation to participate in those. Any future contact and any participation in the future studies are completely optional and not a requirement of this study.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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VOLUNTARY CONSENT

All of the above has been explained to me and all of my questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigators listed on the first page of this form at the telephone numbers given. Any questions I have pertaining to the research have been and will be answered by Dr. Danella Hafeman (246-5820).

Any questions I have concerning my child's rights as a research participant will be answered by the Human Subjects Protection Advocate at the University of Pittsburgh HRPO Office (1-866-212-2668).

_____
Child Participant's Name (Print)

I understand that as a minor (age less than 18 years) the above –named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study and provide my authorization to share my child's medical records with the research team. A copy of this consent form will be given to me.

_____ _____
Parent's Name (Print) Relationship to Participant (Child)

_____ _____
Parent's Signature Date

Hair Samples
_____ YES, I AGREE FOR MY CHILD TO COMPLETE THE HAIR SAMPLES.

_____ NO, I DO NOT AGREE FOR MY CHILD TO COMPLETE THE HAIR SAMPLES.

ASSENT:

This research has been explained to me, and I agree to participate. Because participation in this research study could result in harm to a fetus, you cannot be pregnant while you are in the study. To be a part of the research, you must not have sex or you must use birth control. Before you start this research, you may be tested for pregnancy. If so, one of the research nurses or doctors will meet privately with you to tell you your pregnancy test results. We will not tell your parent(s)/guardian(s) your results without your permission, except under certain circumstances, for example, if your life was at risk, or if the pregnancy was the result of suspected abuse. In these instances, we may need to tell your parent(s)/guardian(s) or relevant authorities.

Even if we do not tell your parent(s)/guardian(s) about the positive results, they may guess that you are pregnant because we may need to tell them you cannot participate in the research. During the research, if you become pregnant, or if there is a chance that you are pregnant, you or your parent(s)/guardian(s) should contact the research personnel immediately so that we may provide assistance and counseling. If you become pregnant during the research, we must remove you from the research.

_____ _____
Signature of Child/Adolescent Subject Date

_____
Printed Name of Child/Adolescent Subject

VERIFICATION OF EXPLANATION:
I certify that I have carefully explained the nature and purpose of this research to the above-named subject, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no

research component of this protocol was begun until after this consent form was signed.

_____	_____
Signature of Person Obtaining Assent	Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study

_____	_____
Signature of Person Obtaining Consent	Date