UPMC HEALTH SYSTEM
Western Psychiatric Institute and Clinic
3811 O'Hara Street
Pittsburgh, PA 15213-2593

**CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY**

TITLE: Attention to Emotion in Adolescents

PRINCIPAL INVESTIGATOR:

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STUDY TEAM:

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SOURCE OF SUPPORT: National Institute of Mental Health (NIMH) and Brain & Behavior Research Foundation (BBRF)

***What is informed consent*?**

Federal regulations require that you are informed about research studies that you and your child have volunteered for before your child participates in them. The following information explains the aims, procedures, risks, benefits, restrictions, and requirements of this research study. Signing this form will indicate that this study has been explained to you and your child, and that you agree to participate in the study and allow your child to participate in the study.

***Why is this research being done?***

You and your child are being asked to participate in a research study examining how girls pay attention to emotional information in their environment and how this is associated with their risk for developing emotional disorders. Findings from this research study may help us to understand how adolescent girls navigate their emotions.

***Who is being asked to take part in this research study?***

Approximately 100 girls, ages 13-15 and their mothers will be asked to participate in the study. Mothers will vary in their experiences with depression. The study will take place at the Clinical Application of Neuroscience laboratory (CANlab) and the Clinical Neuroscience Research Laboratory (CNRL), both located in the Oxford Building, as well as the Families, Emotions, Neuroscience & Development (FEND) Laboratory, in the Sennott Square Building, and the Signal Processing Laboratory, in the Schenley Place Building. All of these laboratories are located on the University of Pittsburgh campus in Oakland.

***What procedures will be performed for research purposes?***

This study occurs over three time points across 12 months.

<u>Time 1 Lab Visit:</u>

This visit will last approximately 4-5 hours and may be split up across two separate laboratory visits, if desired.

During this visit, you and your child will be interviewed by an experienced clinician about your child's mood and any behavioral or emotional problems she may be experiencing or may have experienced in the past. At Time

1, you will also be interviewed about your moods and problems you may have experienced. The interviews will take about 1-1 ½ hours each and may also be videotaped and reviewed by research staff to ensure that the interviews are being conducted consistently. After this interview, parents and children who do not meet the inclusion criteria described will not be asked to take further part in study activities.

You and your child will also complete questionnaires about moods, behaviors, relationships with friends and family, and life events that may have happened to your family. You and your child will also fill out questionnaires about her physical development. We expect that it will take both you and your daughter about 30-60 minutes to complete these questionnaires. A member of our research staff will be available to answer any questions you or your child may have about these questionnaires.

Your daughter will also be asked to complete computerized tasks while we monitor her brain activity using EEG electrodes placed on her head and face. Tasks will involve viewing and responding to pictures of faces and geometric shapes as well as tasks that involve feedback on your daughter's performance.

You and your daughter will complete video-recorded interaction tasks. You and your daughter will rest quietly for a short period of time prior to beginning the tasks. Each task will include instructions from the research staff. There will be resting breaks in between tasks. Also during this time, your daughter will be asked to make a short speech. Research staff will provide the speech topic, and your daughter will be given time to prepare together. You will remain in the room while your daughter gives her speech. Two study staff members will also be present during the speech performance. Before and after the speech, you and your daughter will be asked to make ratings about the speech.

During the discussions and speech task, you will each be asked to wear special eyeglasses with a small camera attached to measure and record eye movements and pupil size. The eye-tracking glasses are designed to be lightweight and comfortable. Individuals who wear eyeglasses must either wear contact lenses on the day of the study or be comfortable with removing their glasses during the interaction tasks and for specific computerized tasks. You will each have three sensors placed on the chest. These sensors will be attached with a sticky pad for electrocardiogram readings to measure heart rate. A respiratory belt will be placed around the chest for measurement of respiratory rate. Two additional sensors attached with a sticky pad will be placed on the palm of the non-dominant hand for the measurement of skin conductance (i.e., sweat).

Your daughter will also be asked to complete computerized tasks while a camera tracks your child's eye movements. Eye tracking measurements will be collected using a small camera and computer software that will measure and record your child's eye movements and the size of her pupil. Tasks will involve viewing and responding to pictures of faces and tasks that test learning and memory about shapes and images.

You will also be asked to complete computerized tasks that test learning and memory about shapes and images.

<u>Time 2 Lab Visit:</u>

This visit will last approximately 2-3 hours.

Six months following the completion of the Lab Visit 1, you and your child will be scheduled to repeat the interviews, questionnaires, and some of the computerized tasks as described above.

<u>Time 3 Lab Visit:</u>

This visit will last approximately 3-4 hours and may be split up across two separate laboratory visits, if desired.

Twelve months following the completion of the Lab Visit 1, you and your child will be scheduled to repeat the interviews, questionnaires, and some of the computerized tasks as described above. Some of the repeated EEG tasks will now provide feedback to your daughter on her performance during the task, based on activity from her brain waves.

Additional Lab Visit:

This visit will last approximately 2-3 hours.

For newly enrolled families, this visit will typically occur within 1 month of Lab Visit 1. However, families who were already enrolled or completed the study before the introduction of this additional lab visit are eligible to participate at their earliest convenience.

During this visit, you and/or your daughter will be scheduled to repeat some of the interviews, questionnaires, and computerized EEG and behavioral tasks described above. In addition, you and your daughter will be interviewed by an experienced clinician about life experiences that you may have had that have to do with discrimination and bias and how these experiences may have affected your health and well-being. You and your daughter will also complete questionnaires about such experiences. A member of our research staff will be available to answer any questions you or your daughter may have about these interviews and questionnaires.

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

While completing the questionnaires and interviews, you or your child may become aware of feelings of happiness, sadness, or other mood states that you had not considered before. It is also possible that the questions may make you or your child uncomfortable or embarrassed. You or your child may also become tired or bored during the questionnaires, interviews, interactions, or computerized tasks. You and your child will be offered breaks, and questionnaires may be completed at your convenience in your home should you or your child become too bored or tired during the study visit. If your child shows undue distress or discomfort at any time, the procedures will be stopped. You and your child will be encouraged to express any concerns and ask questions throughout the study. Further, if you have any questions, concerns, or discomfort arising from these procedures, you are encouraged to contact the Principal Investigator, Dr. Woody, at the phone number listed on the first page of this document.

Because your information is being used in this research study, there is a rare risk that that information could become accessible to people other than members of this research team. Breaches in confidentiality are rare. To minimize these risks, your information (assessments, interviews, and video recordings) will be given an identification number; your names will not be used. All information recorded will be kept in secure files. Only the Co-Investigators listed on this consent form and their research staff will have access to these data.

There are minimal risks involving routine EEG assessments collected during computerized tasks. The main EEG-related risks include: The cap holding the electrodes on your head may feel tight and thus, may be associated with headaches upon prolonged use, which go away upon its removal. If you report a headache, we will remove the cap. Some of the adhesives we use with electrodes could cause skin irritation in people with skin allergies. We will ask if your child has skin allergies before using these products with her. Finally, some of the images during the computerized tasks will be “flickered” quickly on the screen, which, in rare cases, can induce a seizure in individuals with a history of seizures. We will ask if your child has a personal history of seizures and/or a family history of hereditary epilepsy to determine if it is safe for her to complete these tasks.

***What are possible benefits from taking part in this study?***

Neither you nor your child will benefit directly from participating in this research. However, many children who have participated in studies have indicated that they find the sense of accomplishment of completing the study as well as the individualized attention received to be a rewarding experience. Also, knowledge gained from the study may also contribute to a better understanding of adolescent psychological functioning.

***Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?***

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study. You, or your insurance provider will be billed for routine care services, or

services **not connected** with the study, and will be responsible for any associated co-pays, co-insurances, and deductibles.

***Will I be paid if I take place in this research study?***

You and your child will be paid a total of $350 for completing all parts of this study. If your child completes only part of the study, for any reason, you will be paid as follows:

You and your child will be paid $100 for completing Time 1 Lab Visit procedures. If you choose to break Time 1 procedures into two separate lab visits, you and your child will be paid $50 at each visit. You and your child will be paid $75 for completing Time 2 Lab Visit procedures and $100 for completing Time 3 Lab Visit procedures. If you choose to break Time 3 procedures into two separate lab visits, you and your child will be paid $50 at each visit. You and your child will be paid $75 for completing the Additional Lab Visit procedures.

If after completing the Time 1 Lab Visit procedures, which include essential in-person activities, you and your daughter are not able to attend in-person Time 2 or 3 Lab Visits due to COVID-19-related concerns, then you and your daughter will be provided with the option to participate in follow-up activities that can be conducted remotely (diagnostic interviews and questionnaires). If you choose to complete follow-up visits remotely, you will be compensated $25 for these reduced, remote activities. If you choose to complete a remote Time 2 visit, you will still be eligible to complete an in-person Time 3 Lab Visit, if you so choose.

Additionally, any parking or public transportation fees related to the study will be paid for by the study ($5 per study visit).

Finally, a subset of girls will have the opportunity to complete an EEG task that involves winning money. For girls that complete this task, they can earn $5. This subset of girls will be chosen solely based on time constraints (i.e. girls who have time remaining in the EEG time slot after completing other primary study tasks).

***Who will know about my participation in this research study?***

Any information about your child obtained from this research will be kept as confidential (private) as possible. All records related to your child's involvement in this research study will be stored in a locked file cabinet. All database records related to your child's involvement in this research study will be stored with password protection. Your child's identity on these records will be indicated by a case number rather than by her name, and the information linking these case numbers with your identity will be kept separate from the research records. Your child will not be identified by name in any publication of the research results unless you and your child sign a separate consent form giving you and your child's permission (release).

An exception to confidentiality is information on child abuse and neglect that is obtained during research. The investigator will report such information to the appropriate local (i.e., Children, Youth and Families [CYF]) or state agency as required by Commonwealth of Pennsylvania law. If information about abuse comes up that must be reported, or if a court order to release reports is received, an attempt will be made to inform you before CYF or any other agency is consulted. Within these bounds of confidentiality permitted by law, no information about you will be shared with any individual or agency without your prior consent.

De-identified data may also be shared with other researchers who are conducting similar research, or uploaded to a secure online research data repository for the purpose of promoting faster progress toward the publication of scientific findings. De-identified study research records may be shared with others for research and training purposes only, including the study sponsor (National Institutes of Health).

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

***Who will have access to identifiable information related to my participation in this research study?***

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information related to you or your child's participation in this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your child's identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information related to your child's participation in this research study in response to an order from a court of law. If the investigators learn that you, your child, or someone with whom you or your child are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

***For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?***

The investigators may continue to use, for the purposes described above, identifiable information related to your child's participation in this research study for a at least 7 years following final reporting or publication for a project or for 5 years past age of your child's majority (23 according to PA State Law after study participation ends and for as long (indefinite) as it may take to complete this research study). No identifiable research data will be disclosed to those who are not members of this research team.

***Is my/my child's participation in this research study voluntary?***

You and your child's participation in this study is completely voluntary. You may decide not to participate, not to permit your child to participate, or your child may stop participating at any time, even after you sign this form. Your decision will not affect the care your child receives from WPIC or the University of Pittsburgh Medical Center, and will not affect yours or your child's current and future relationship with those facilities or with the University of Pittsburgh.

***May I withdraw, at a future date, my consent for participation in this research study?***

Yes. To do so, you must contact the Principal Investigator who is listed on the first page of this consent form. If you withdraw your child from this study, any research information that was collected prior to your withdrawal will continue to be used. The Principal Investigator may withdraw you and your daughter from the study, for example, if you or your daughter no longer fit the inclusion criteria, your daughter is unable to perform the EEG tasks, or if you or your daughter are unable to follow instructions by the study team.

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**CONSENT TO PARTICIPATE**

All of the above has been explained to me and all of my current 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 the researchers listed on the first page of this form.

Any questions which I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212- 2668).

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____ _____

Participant's (Parent's) Signature Date

_____

Participant's (Parent's) Printed Name

**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 aspect 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

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INTEREST IN PARTICIPATING IN FUTURE RESEARCH

Participant's Initials:

_____I agree to be contacted about other research studies involving childhood/adolescent behavioral and emotional health.

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**AUTHORIZATION FOR USE OF VIDEO RECORDINGS**

I give permission to the investigators listed on the front page of this consent document and their research staff to use any audio and/or video recordings of my participation in this research with outside health professionals for the purposes indicated below. **The investigators will not release any additional identifiers (i.e., your name, contact information, etc.) with the recordings and the recordings will be marked with a case number instead of your name.** Please review the following options for your recordings and your daughter's recordings then initial next to each case for which you are willing to give consent.

1. Recordings can be shown to subjects in **other experiments**. For example, we may use segments of your video to show examples of different mood states.

   Participant Initials:_____

2. My recordings can be used for **scientific publications**. For example, screen shots from your video may be used in scientific journals or publications to describe study procedures and outcomes.

   Participant Initials:_____

3. My recordings can be shown at **meetings of scientists**. For example, video segments may be shown at meetings or conferences to describe study procedures and outcomes.

   Participant Initials:_____

4. My recordings can be shown in **teaching**. For example, segments may be used in describing the study procedures, or students may be asked to rate emotional state based on facial expressions.

   Participant Initials:_____