

Department of Psychology
RESEARCH PERMISSION FORM

Project Title: Attention Training to Modify ERN and Risk for Anxiety in Adolescence.

Principal Investigator: Greg Hajcak, Ph.D.

Department: Psychology

You are being asked to allow your child to be a volunteer in a research study.

PURPOSE: The purpose of this study is to understand how your child's brain and body respond to thinking and feeling. Adolescence is a time when people begin to think and feel differently, and we are interested in understanding those changes. Around 660 adolescents (ages 11 to 14) will be included in this study.

PROCEDURES:

If you allow your child to be in this study, your child's participation will involve two lab visits, which will be separated by about two years. After your first visit, your child may be asked to complete some tasks at home on a computer or mobile device and return for another visit 8 weeks later. You can decide not to participate in the additional training or the second visit. At each lab visit, you will complete the following:

1. *Physiology Recording Session:* We will record your child's brain activity and muscle activity, while your child is making decisions about things we show them on a computer screen, playing some games on a computer, or just looking at pictures. We record brain activity using an EEG. To do this, we will use a specialized lycra cap that contains 32 recording disks (electrodes) that your child will wear on their head. In order to record the brain's activity, these disks need to be filled with a gel, which helps the sensors accurately record brain activity at the scalp. Therefore, your child's hair may need to be cleaned after the task. The gel washes off completely and easily. The EEG recording is completely painless, non-intrusive, and safe. It is similar to heart rate recordings (i.e., electrocardiogram or EKG) that are typical during routine physical exams—the only exception is that EEG records electrical activity generated by the brain rather than the heart.
2. *Guessing Game:* Your child may be invited to participate in a guessing task. In this task, your child will be shown a picture of two doors and will be asked to choose one. After picking a door, they will receive feedback on the screen indicating whether they won or lost on that trial. In this task, your child can make between \$0.00 and \$15.00, depending on how many correct guesses they make.
3. *Arrow Task:* Your child may perform a task that requires them to make rapid and accurate decisions about stimuli that are presented on the screen. The computer screen will display one of four stimuli on each trial: <<<<<, <<><<, >><>>, or >>>>>; your child's job is to respond to the direction of the central arrow and ignore the others.
4. *Picture Viewing Task:* Your child may be asked to participate in a picture-viewing task in which they will view age-appropriate emotional stimuli. Pictures used in this task are taken from the International Affective Picture System, which consists of hundreds of pictures of various contents, including neutral, pleasant and unpleasant pictures.
5. *Reaction Time Task:* Your child may play a reaction time task where they will press a mouse button in response to a white box appearing on the screen. Depending on how quickly they respond, they will receive feedback on whether or not they won or lost any money on that trial. There will also be a

- no money condition in which they will not win or lose any money no matter how they respond. In this task your child can make between \$0.00 and \$10.00, depending on how quickly they respond.
6. *Social Task*: Your child may also perform a task where they will see pictures of other kids and will vote on whether or not they like them. Also, your child will receive feedback from other kids.
 7. *Surveys*: Your child will be asked to fill out surveys or questions about his/her mood, personality, development, and relationships.
 8. *Interview*: You and your child will participate in an interview about his/her feelings, thoughts, activities, and relationships with others. We will also ask questions about the general well-being of your immediate family. With your permission and your child's assent, this interview will be audio-taped to allow us to monitor the reliability of our ratings. Once we have collected and checked the information, the original recording will be destroyed. You may choose to decline the audio recording and continue the interview without it. You will be given the option to complete some interviews over the phone prior to your initial visit in order to shorten the length of your visit to our lab. You may decline to participate in the phone interviews, and complete your interviews on the day of your visit instead.
 9. *fMRI*: Your child may be selected to complete the *Guessing Game* (described above) or other computer tasks in a functional magnetic resonance imaging (fMRI) scanner. This procedure involves separately recording your child's brain activity while laying down very still. It is noisy but completely painless. If your child is eligible, selected, and interested in this portion of the study, your child will visit our fake scanner to familiarize yourselves with the MRI environment (e.g., what the scanner looks and sounds like).
 10. *Additional Training*: Your child may be asked to complete additional tasks at home following the initial visit. This training is computerized (i.e., like playing a game) and designed to change the way your child responds to threat. Your child would be asked to complete two (2) sessions per week for eight (8) weeks. They could be randomized to either an active or control condition; the difference is that in the active condition, the computer trains your child's attention away from threat—which has been shown to reduce anxiety in previous studies. Your child will receive \$5 for each session they complete, for up to 16 training sessions in total. For every 100 levels they complete, they will receive 5 dollars. If your child completes all 16 training sessions, they will receive a bonus of \$20. If your child does this training, we would also ask that you come back for an additional lab visit afterwards. This visit will be much like the first—and you will get paid \$20 for each hour, plus a \$40 bonus for coming back.

Depending on how many of the tasks (listed above) your child is selected for and decides to participate in, the study will take approximately 4 hours on average. Your family will receive \$20 per hour for your participation, and will get frequent breaks.

During each visit, you (the parent) will be asked to fill out surveys about your child's mood, personality, development, and relationships while you are in the lab with your child. Participation in these tasks is voluntary. In addition, you will participate in an interview about your child's temperament, behavior, and adjustment. You will also answer some questions about yourself and your child's immediate family. As well, you will also answer questions about your mood, behavior, use of medications, and menstrual cycle. With your permission, these interviews will be audio-taped to allow us to monitor the reliability of our ratings.

RISKS/ DISCOMFORTS: Potential risks include getting tired or uncomfortable from completing the questionnaires, performing the tasks, and thinking about sad memories. You and your child are welcomed to take short breaks between the various tasks. During the EEG recording, there is a small possibility of mild skin irritation (redness) where the electrode contacts the skin. However, this is rare and temporary.

There is a small chance that you or your child may feel uncomfortable answering questions about some aspects of your personal life. If you or your child prefer not to answer certain questions, you are both free not to do so.

In the MRI portion of the study, your child may feel anxious about the tight space within the MRI machine, or about the loud noises that it makes. Before completing the task, you will both be taken to a fake scanner to ensure that your child will be comfortable in the MRI machine. During the task, your child will have a device in their hand during the scans that will allow them to alert us if they need attention immediately. They will be able to communicate with us and may terminate the scan anytime they want by squeezing a device that we will provide. Additionally, the MRI itself produces a loud banging noise throughout the MRI session that some people find uncomfortable. We will minimize perception of this noise by using earphones to decrease outside noise. There are no known risks of having an **MRI during pregnancy, but to be safe pregnant women are not eligible to participate in that portion of the study.**

Your child will not be allowed to participate in the fMRI portion of the study if they have metal objects or certain devices in their body (e.g., pacemaker), and they will be required to remove all metallic objects from their body before entering the scanner (e.g., jewelry). To be eligible for the fMRI portion, your child may not have braces.

As metallic objects may experience a strong attraction to the magnet, it is very important that you notify the researcher of any metal objects, devices, or implants that are in or on your child's body before entering the magnet room. This includes braces, as well as biomedical devices such as pacemakers and aneurysm clips, prostheses, and other metallic objects embedded in the body such as bullets, buckshot, shrapnel, and any metal fragments from working around metal. Individuals with pacemakers or metal implants such as aneurysm clips should not undergo an fMRI procedure and will be excluded from the fMRI portion. All other metallic objects must also be removed from your child's person prior to entering the magnet room or approaching the magnet to prevent them from becoming a projectile or getting pulled by the magnet. In addition, objects such as watches, credit cards, and hearing aids could be damaged in the presence of the magnetic field. Although the long-term risk of exposure to the MRI environment is not known, the risk is thought to be very low.

INCIDENTAL FINDINGS:

The procedures in this study are being done, and results reviewed, only for research reasons, as explained in the beginning of this consent form. In other words, **this study is neither designed nor intended to detect health problems and the scans that are done in this study are not the same as those done by a doctor for medical reasons.** Nonetheless, it is possible that during review of your child's scan, we may uncover something that may (potentially) have health importance. Such findings are called 'incidental findings'. Most incidental findings represent common minor abnormalities that pose no clinical risk and require no medical referral: for example, one study found that 61 out of 151 participants (40%) had such incidental findings that required no referral. Incidental findings that require medical referral are much rarer: for example, a study of children and young adults found that only 1 out of 225 participants required urgent medical referral, and another study found that only 2 out of 2000 people needed a medical referral for an aneurysm and 1 out of 2000 people needed medical referral for a potentially malignant brain tumor. **If we notice an incidental finding, the principal investigator will contact you to discuss what the finding possibly means, if you agree to be told this information.** You will then be referred to your medical doctor for follow-up.

The researchers of this study are not medical doctors and are not trained to assess these possible findings. Therefore, your consent your child to be in this study also includes permitting the Director of the *fMRI* Center and/or principal investigator to share your child's data in a confidential manner with experts outside of the study team so that more information regarding the importance of any uncovered incidental findings can be determined. If no experts outside the study team are available, your consent for your child to be in this study also includes permitting the researchers to submit scan data directly to your primary care physician for further consultation. If you do not have one, assistance will be provided in securing one.

The discovery of an incidental finding may cause you to feel anxious. If you have further tests done by your medical doctor, those results will then become part of your child's medical record, which may affect current and future health or life insurance. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

Do you agree to be informed of any incidental findings discovered during the course of this research study? Choose, and sign below one option:

YES, I want to be informed of incidental findings discovered during the course of this research study

NO, I do not want to be informed of incidental findings discovered during the course of this research study

BENEFITS: There is no direct benefit as a result of being in this study. Potential benefits include contributing to research that will help us understand the nature of late childhood and early adolescent mood and personality

PAYMENT: Your family will receive \$20 an hour for participation in the study, for each visit. In addition, your child will receive between \$0.00 and \$15.00 as a bonus based on your performance in the EEG guessing task. If your child is selected to complete additional tasks at home, they will receive up to \$80, with a bonus of \$20 for completing all sessions. You will then be asked to return for the post-assessment, for which your family will receive a bonus of \$40 in addition to \$20/hour and money earned during the guessing task. For each visit that you make to Florida State University to participate in our study, you will be compensated for gas if the miles you travel in both directions combined is equal to or higher than 30 miles. You will be compensated at a rate of .25 cents per mile traveled. If you participate in the second lab visit two years later, we will also give you a bonus of \$40, in addition to \$20/hour and money earned during the guessing task. For every eligible participant you refer to the project, your family will receive \$10 in cash or Amazon gift cards.

CONFIDENTIALITY: Protecting You and Your Child's Privacy in this Study:

All the information we get from you and your child will be kept private and confidential to the extent permitted by law. We will take steps to help make sure that all the information we get about your child from your child and you is kept private. We will do this by not writing down your child's name, your name, or anything else that could link your child in any way to the information you or your child gives us for our study. Instead, we will use a code (i.e., your child's data and your data will be assigned a subject number). The list of code numbers and corresponding names will be kept in the study computer and will be encrypted. If any papers and talks are given about this research, your child's name and your name will not be used.

We want to make sure that this study is being done correctly and that your child's rights and welfare are being protected. For this reason, we will share the data we get from him/her and you in this study with the study team, Florida State University's Committee on Research Involving Human Subjects, applicable Institutional officials, and certain federal offices. However, if your child tells us they are going to hurt him/herself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this.

This study requires that we collect very private information about you and your child. While you and your child are in this study we will get data about you and your child's health from some of the tests each of you will have done in this study. You have a right to privacy but the data we get about you and your child's health in this study can be shared with the people referenced above (the study team, the sponsor of this study, those who work for the sponsor, Florida State University's Committee on Research Involving Human Subjects, applicable institutional officials, and certain federal offices).

You and your child's health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure you and your child's rights and safety are protected. Not all of these people are required by law to protect your health data. They might share it with others without your permission. For example, the sponsor of this study, the National Institutes of Health, does not have to make the same promise under the law to protect your health data. However, they follow other policies that require all government officials to respect the privacy of research subjects.

You have the right to stop allowing us to use or give out you or your child's health data. You can do this at any time by writing to Dr. Greg Hajcak. If you do this, we will stop collecting any new health data from you and your child. We will use any data we collected before you wrote your letter. When you sign the consent form at the end, it means:

- That you have read this section.
- That you will allow the use and reporting of you and your child's health data as described above.

In a lawsuit, a judge can make us give him the information we collected about your child.

If your child is paid \$600 or more a year as a research subject, your child's social security number will be reported to those in charge of taxes. You may have to pay taxes on this money.

COSTS TO YOU: There is no cost for participating in this study.

ALTERNATIVE: Your alternative is to not allow your child to participate in this study and to choose not to participate yourself.

SUBJECT RIGHTS:

- Your child's participation in this study is voluntary. You do not have to give your permission for your child to be in this study if you don't want them to do it.
- You have the right to change your mind and have your child leave the study at any time without giving any reason, and without penalty.
- Any new information that may make you change your mind about allowing your child to be in this study will be given to you.
- You will get a copy of this permission form to keep.
- You do not lose any of your or your child's legal rights by signing this permission form.

QUESTIONS ABOUT THE STUDY OR YOUR RIGHTS AS A RESEARCH SUBJECT:

- If you have any questions, concerns or complaints about the study, you may contact Dr. Greg Hajcak at greg.hajcak@med.fsu.edu. Dr. Hajcak's office is located in the Psychology B building, room 439; 850-645-9268
- If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), you are encouraged to contact the FSU IRB at 2010 Levy Street, Research Building B, Suite 276, Tallahassee, FL 32306-2742, or 850-644-8633, or by email at humansubjects@fsu.edu

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to allow your child to be a volunteer in this study.

Child's Name (Printed)

Printed Name of Parent/Legal Guardian

Signature of Parent/Legal Guardian

Date

Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

