CONSENT TO PARTICIPATE IN BIOMEDICAL RESEARCH

Understanding the Neural Bases of Emotion Dysregulation in Adult ADHD

You are asked to participate in a research study conducted by John Gabrieli, Ph.D., from the Department of Brain and Cognitive Sciences at the Massachusetts Institute of Technology (M.I.T.) and researchers at Massachusetts General Hospital (MGH). You were selected as a possible participant in this study because you meet the age requirements and the study's target populations. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

- **PARTICIPATION AND WITHDRAWAL**

Your participation in this study is completely voluntary. If you choose to participate you may subsequently withdraw from the study at any time without penalty or consequences of any kind. If you choose not to participate, that will not affect your relationship with MIT or your right to health care or other services to which you are otherwise entitled.

- **PURPOSE OF THE STUDY**

We are doing this research to learn about the brain areas involved in the ability to regulate emotions in adults with Attention Deficit Hyperactivity Disorder (ADHD) compared with healthy adults using Magnetic Resonance Imaging (MRI). We are asking you to take part in this research study because you are in our targeted study groups (healthy control or ADHD). The results of this study will help health professionals to potentially more sensitively assess and treat adults with ADHD and improve the quality of life for many people living with ADHD.

- **PROCEDURES**

The MRI scanner is a large machine shaped like a tube. You will lie comfortably on a table that slides into a tunnel slightly wider than your body. The space within the large magnet in which you lie is somewhat confined. We can stop the scan at any time, if needed. You will be asked to keep your head still during the whole testing procedure, although you can move your hands a little to press a button box. The MRI makes loud banging noises as it takes pictures. We will give you earplugs or headphones that you will be required to wear to reduce the noise. You will be able to hear and speak to the research staff at all times during the scan. You will also hear repetitive tapping sound that arise from the MR scanner. During the scan you will not be exposed to x-rays or any other form of ionizing radiation, but rather a magnetic field and radiofrequency magnetic fields that have no harm on human body. You will not feel these fields. During the time you are lying in the scanner, you will be asked to pay attention to a series of neutral and emotionally charged pictures, and be given instructions on how to respond to the pictures.

Some of the pictures may be emotionally arousing, which some participants may find uncomfortable. Before the scan, you will be introduced to the imaging machine and to familiarize yourself with how the machine works and what the experience will be like. The total scanning time will be about 50-60 minutes.

After you complete the scan, we will give you the option to participate in a 10-minute motor task experiment. This would involve performing simple motor tasks such as walking on the sides of your feet or tapping your hand as fast as possible during 5 seconds. Your decision to perform this extra 10-minute task will not affect your participation in this study.

- **POTENTIAL RISKS AND DISCOMFORTS**

Functional Magnetic Resonance Imaging

Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in your body, it is *very* important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed. In addition, watches and credit cards should also be removed as these items could be damaged. You will be provided a way to secure them, when in the scanner. If you have any history of head or eye injury involving metal fragments, or if you have ever worked in a metal shop, or wear braces, you should notify the operator/investigator, as this may mean that you should not participate.

There is possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not an unexpected occurrence and should not be painful. Some of the radiofrequency imaging coils, imaging software and devices being use in your scan are not approved by the FDA but are similar counterparts that have been previously approved by the FDA. There is a small risk of heating from the cables associated with these devices. Please report any heating sensation immediately. Dizziness of nausea may occur if you move your head rapidly while within the magnet.

IF YOU FEEL DISCOMFORT AT ANY TIME, YOU SHOULD NOTIFY THE OPERATOR AND THE EXAM CAN BE DISCONTINUED AT ANYTIME.

Most studies of MR during pregnancy show no evidence of risk to the fetus. However, given the limited data and the vulnerability of the fetus, women who are pregnant should not participate in MR studies. You have stated that you are not pregnant, however women are frequently not aware that they are pregnant in the first trimester of pregnancy. If you do not know if you are pregnant and would like to check, free pregnancy tests are available from the researcher. You can withdraw from the study at any time, without penalty.

In addition, some people find viewing emotionally arousing photographs uncomfortable. While they may briefly feel uncomfortable this feeling should subside. If you feel particularly uncomfortable you can tell the experimenter that you would like to stop.

The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform medical diagnosis. The investigators and MIT are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the finding merits further investigation, in which case the investigator will contact you and your primary care physician and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting physician, and MIT are not responsible for any examination or treatment that you undertake based on these findings. Because the images collected in this study may not comprise a proper clinical MRI scan, these images will not be made available for diagnostic purposes.

- **POTENTIAL BENEFITS**

The data we collect from your participation in this research can be used to advance scientific knowledge; however, you will not directly benefit from participating in this study. This study could provide society with valuable information about the brain bases during emotion regulation in adults suffering from ADHD compared to healthy adults. The results of this study may help health professionals to more sensitively assess and effectively treat adults with ADHD, and significantly improve the quality of life for many families living with ADHD. Given the lack of forseeable risks and the potential benefits, we believe the cost/benefit ratio is favorable.

- **ALTERNATIVES TO PARTICIPATION**

The alternative to participating in this study is not to participate. What this means is that you can decide not to participate, at any time, in the experiment.

- **PAYMENT FOR PARTICIPATION**

<u>Functional Magnetic Resonance Imaging</u>
You will be compensated $30 per hour for the study. Should you decide to withdraw from the study or should the investigator withdraw you from the study before its completion, you will be compensated a proportional amount.

- **CONFIDENTIALITY**

Your identity will be kept as confidential as possible, as is required by law. Except where required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of MIT, but in this case, you will be identified only by a unique code

number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, you identity will not be disclosed. Patient information may be provided to Federal and other regulatory agencies as required.

Any information that is obtained in connection with the study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If you become ill during research, you may have to drop out, even if you would like to continue. The investigator will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If you must drop out because the investigator asks you to or because you have decided on your own to withdraw, you will be paid for the amount of the study completed.

- **IDENTIFICATION OF INVESTIGATORS**

If you have any questions or concerns about the research, please feel free to contact John Gabrieli, Ph.D., at the Department of Brain and Cognitive Sciences, 43 Vassar St., 46-4033, Cambridge, MA 02139, phone: 617-253-8946, email: gabrieli@mit.edu

- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

If you feel you have suffered an injury, which may include emotional trauma, as a result of participating in this study, please contact the person in charge of the study as soon as possible.

In the event you suffer such an injury, M.I.T. may provide itself, or arrange for the provision of, emergency transport or medical treatment, including emergency treatment and follow-up care, as needed, or reimbursement for such medical services. M.I.T. does not provide any other form of compensation for injury. In any case, neither the offer to provide medical assistance, nor the actual provision of medical services shall be considered an admission of fault or acceptance of liability. Questions regarding this policy may be directed to MIT's Insurance Office, (617) 253-2823. Your insurance carrier may be billed for the cost of emergency transport or medical treatment, if such services are determined not to be directly related to your participation in this study.

- **RIGHTS OF RESEARCH SUBJECTS**

You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you feel you have been treated unfairly, or you have questions regarding your rights as a research subject, you may contact the Chairman of the Committee on the Use of Humans as Experimental Subjects, M.I.T., Room E25-143B, 77 Massachusetts Ave, Cambridge, MA 02139, phone 1-617-253 6787

SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

_____
Name of Subject

_____
Name of Legal Representative (if applicable)

_____ _____
Signature of Subject or Legal Representative Date

☐ I wish to be contacted for follow-up studies.

SIGNATURE OF INVESTIGATOR

In my judgment the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____ _____
Signature of Investigator Date

CONSENT TO RECONTACT

We may run a follow-up to this study, for which we might want to include you as a participant. Do you agree to being recontacted and invited to participate in such a follow-up study? This does not constitute consent to participate, only to be contacted.

Yes_____ No_____

We may in the future run other, unrelated studies for which we would want to include you as a participant. Do you agree to being recontacted at a future date to participate in such a study? This does not constitute consent to participate, only to be contacted.

Yes_____ No_____