Hartford HealthCare

Informed Consent for Research

6816

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You have been asked to participate in the research study, "Changes in Brain Function through Repeated Emotion Regulation Training." This research study is expected to last 2 years. You have been asked to participate in this study either because you have a diagnosis of depression or anxiety or because you volunteered to participate as a healthy control.

A. The Purpose and procedures of this research

A.1. What is the purpose of this research?

This study will examine brain activity by taking pictures of your brain with magnetic resonance imaging (MRI) scanner during various computer-based tasks. This will help us to better understand how brain function changes during intervention-like training designed to teach emotion regulation techniques. This research will lead to a better understanding of how emotion regulation based therapies influence brain function in individuals with anxiety or depression. It will provide the basis for future, externally-funded grant proposals.

A.2. What procedures are involved with participation in this research study?

All of the procedures in this study are for the purposes of experimental research. Participation will involve an interview with a staff member, some questionnaires and testing, 6 sessions of guided practice or training and two MRI brain scans. We also will collect a urine sample for reasons described below. Typically, the interview is conducted first, followed by the other procedures, but this might vary from person to person.

1. We will ask you to meet with study staff for an interview. This interview will ask about your mental health, sometimes including questions, if involved, about drug use and sexual history for the purpose of a complete history of mental health. Please know that if you feel uncomfortable during the interview you are free to stop at any time or to not answer any questions that make you uncomfortable. This interview will be videotaped if you agree so that other research staff associated with this study can independently review your answers. We videotape so staff can review information they may have missed. Only staff that work on this study can watch the videos. The recorded interviews will be labeled with a random ID number. Recordings will be encrypted in a secure, password-protected database. Only study staff can access this information. The videotaping is optional but preferred.
2. We will ask you to fill out several questionnaires that measure your personality, attitudes, and current thoughts and feelings. Some questionnaires will be done by paper-and-pencil, and some will be done on a computer. All the questionnaires (paper and computer) will be completed in a private room, and your answers will not be visible to anyone.

We will ask you to complete some tests of cognitive ability

3. Before any MRI, you will be asked to give us a small urine sample. We will use this sample to test for recent drug use. Recent drug use may change brain function in ways that would interfere with the study. These results will not be shared with anyone outside of the research team.. However, the

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principal investigator may delay MRI scanning or decide you should not participate based on the results of the drug test.

4. If you are female, we will test the urine sample for pregnancy. There are no proven health risks to pregnant women or unborn children from MR scanning. However, if we discover you are pregnant, we will not allow you to participate in the MRI. We do not share the results of this test with anyone else outside of the research team.
5. You will get two brain scans using a magnetic resonance imaging (MRI) machine. The MRI requires between 1-1.5 hours. This includes time to prepare, perform the scan, and answer questions when the MRI is done. Functional magnetic resonance imaging (MRI) is a method that measures brain activity as you do simple tasks. For MRI, you will change into hospital clothes in a private room. Before you enter the MRI machine, research staff might connect painless sensors to your fingers. These sensors will keep track of things like your heart rate, breathing, sweat or the level of oxygen in your blood. None of these things are painful. It can take several minutes to properly connect and test the monitors. You will then lie on your back on a table that slides into the MR machine. Your head will be placed securely into a comfortable frame. This will help you to keep your head still during the scan. During the scan, a camera several feet behind the MRI scanner will track the position of your eyes using a mirror that rests on the frame. You will have to remain still for about 1 hour. During the scan, you can talk with the research staff in the control room. If you become uncomfortable, you can ask to stop at any time without penalty. Trained MRI technicians, research assistants, and physicians will perform the MRI scans.
6. This experiment is about seeing how your brain works while you see pictures that usually make people feel strong emotions. In the MRI, when you see various images on a computer monitor, you will sometimes be asked to maintain or deliberately try to decrease the intensity of the emotion you are feeling. You also will tell us how intense your feelings are using buttons located under your fingers. Instructions for the tasks will be explained to you when you are in the MRI.
7. You will receive 6 sessions of guided practice or training that will take place over the course of three weeks. These sessions will take place at the Olin Center, Institute of Living, or can be completed at home with a laptop that we provide. These at-home sessions will be monitored by a Research Assistant who will supervise the training sessions through Skype or similar web-based video communication system.

A.3. Which of these procedures is experimental?

All the procedures in this study are for the purpose of experimental research. These procedures are not provided for your treatment.

A.4. Where will participation take place?

All parts of this study will take place in the Whitehall Building at the Institute of Living (the Olin Neuropsychiatry Research Center), 200 Retreat Avenue, Hartford, CT 06106.

A.5. How long will participation last?

Your participation in the study will require about 6-7 hours in total, over the course of 8 visits. This includes filling out some questionnaires, an interview, cognitive tests, six training sessions two MRI sessions, and some questions about your MRI experience.

B. The possible risks, discomforts and side effects of the procedures are described below, including safeguards to be used for your protection.

A. Urine Test: There are no physical risks associated with giving the urine specimen. Test results are confidential. They will be used only for research purposes

B. Cognitive Tests: The tests we use to measure cognitive abilities are standard tests employed in any psychologist's office. They are often challenging and new. Although these tests will be fairly short, a brief break will be offered mid-way through the tests to make sure you don't become tired.

C. Interview Questions: While there are minimal risks associated with the interview, you may find questions asked in the interview to be very personal. Some people find the questions make them uncomfortable or even anxious. Please let the research staff know at any point if you feel this way. What you say in the interview will remain confidential unless you express a desire to cause harm to yourself or someone else. In this case, we would need to discuss this issue with a treatment provider. If you are not currently receiving treatment for those issues, study staff under direction of the Principal Investigator will recommend treatment options to you.

D. Videotaping: Some people feel uncomfortable being videotaped when answering questions about their feelings and attitudes. Our staff are trained to make you feel comfortable answering questions. You can take breaks or stop at any time. These recordings will not be seen by anyone other than research staff. They will be stored electronically in password protected files indefinitely. Your name or other identifying information will not be stored with the file.

E. MRI: Magnetic resonance imaging is thought to be completely safe. It is approved by the United States Food and Drug Administration (FDA). Research has not found any negative effects of MRI. No x-rays or radioactivity are involved. However, some people get uncomfortable (feeling anxious or shut in). These feelings are usually strongest when first entering the MRI. These feelings generally go away as they get used to it.

Being inside the MRI scanner can also be noisy. You will wear special noise-cancelling headphones that reduce the noise. We will talk with you at times during the MRI. We will answer any questions you have. If you become too uncomfortable, inform the staff and we will take you out of the MRI. You cannot have the MRI scan if you are pregnant, or if you have any metal object (such as a heart pacemaker or artificial joint) inside your body. We will make sure we collect enough information about possible metal objects prior to beginning the study. The machine that tracks your eye position uses infrared (IR) radiation. Very high IR levels can be harmful. However, this machine uses very low IR.

The level of IR involved is less than what is found in normal sunlight. There are no known risks in using this machine.

The MRI is not intended or designed to be a diagnostic or therapeutic examination. However, a radiologist will read your MRI results. There is no guarantee that the radiologist will detect any and all abnormalities. However, if any findings of concern are noted, one of the physicians supervising the study will contact you by telephone to let you know. If you give permission, the physician supervising the study can speak with your designated healthcare professional to relate these incidental findings. Upon request, we will provide a hard copy of the scan and/or radiology study report.

C. There are possible benefits to you or others to be expected from your participation in this research.

A. This study will be of no direct benefit to you.

B. By participating, your information will add to our knowledge of the relationship of brain activity involved with emotion regulation.

D. There are alternatives to participation in this study that you should consider.

This is not a treatment study. You may choose not to participate in this study without any penalty to you.

E. Who can you call if you have questions about this study?

You do not have to sign this consent form until all the questions you have at this time are answered. The investigator is willing to answer any questions you may have about the study procedures. Below is a list of contacts if you should have any questions about the study.

Questions about:	Contact	Phone #
the research, research-related treatments, or a research related injury	Dr. Michael Stevens, Ph.D.	(860) 545-7552
your rights as a research participant	An IRB Representative	(860) 972-2893
the research in general	Vice President, Research	(860) 972-2893
a confidential issue that you would like to discuss with someone not associated with research	Patient Advocates	(860) 972-1100

F. Your participation in the research is voluntary.

You may refuse to participate, withdraw your consent, and discontinue participation in the research at any time. You may do so without penalty, or loss of benefits to which you are otherwise entitled. Your decision whether to participate will not affect your future medical care at Hartford Hospital.

G. You will receive financial compensation for your participation in this research.

For participating in this study, you will be compensated a total of $120-$140 after completing all 8 visits. This money will be provided to you on a cash "debit card" after you complete your appointment(s). If you complete only part of the study, you will be compensated for your time, but will not receive compensation for portions not completed.

A note about the Internal Revenue Service (IRS): Hartford Hospital is required to report payments of $600 or more to the IRS. This means that if you receive $600 or more from Hartford Hospital during the calendar year, your compensation will be reported to the IRS and you will receive an IRS 1099 Form.

H. Your confidentiality will be guarded to the greatest extent possible.

Hartford Hospital will protect all the information about you and your part in this study, just as is done for all patients at Hartford Hospital. Your records will be maintained in accordance with applicable state and federal laws. However, private identifiable information about you may be used or disclosed for purposes of this research project as described in the study's authorization form.

A. Safeguards: There are several safeguards in place to ensure the confidentiality of the data collected in this experiment. Hartford Hospital will protect all the information about you and your part in this study, just as is done for all patients at Hartford Hospital. Your records will be maintained in accordance with applicable state and federal laws. However, private identifiable information about you may be used or disclosed for purposes of this research project as described in the study's authorization form. To help protect your confidentiality, all data collected about you will only be identified by a code number and not your name. The link that identifies which code belongs to you will be kept in a secured database that only the researchers on this study will have access to. Your name or identifiable information will not appear in any publications or presentations resulting from this study.

B. Research Disclosures: You should know that data we collect in this project will likely be used for comparison to data from other studies conducted in our center or in cooperation with other researchers. Any data used in this manner will be stripped of information that would identify whom it came from.

By signing this consent, you are agreeing to the use or disclosure of protected health information as described above. If you do not agree to the use or disclosure of the information as described and therefore do not sign this consent, you may not be in the study. Because research studies often take years to complete data collection and to analyze and interpret the results, by signing this consent, you agree to these uses indefinitely. If, after signing the consent, you change your mind, you have the right to revoke your consent, in writing. However, you may be withdrawn from the study.

Once your private information has been disclosed, it can no longer be considered protected, as the recipient(s) could possibly disclose it to others.

You may obtain a copy of the Hartford Hospital Privacy Notice for a complete description of the hospital's privacy practices for protected health information. You have the right to review the Notice before signing this consent.

I. What happens if you are injured as a direct result of your participation in this research project?

In the event that you are injured as a direct result of taking part in this research, you will receive help in the following way:

If you have medical insurance, Hartford Hospital will collect fees for medical treatment at Hartford Hospital from your insurance company. If you are not fully covered by insurance or uninsured, the research sponsor of the study or Hartford Hospital will cover these expenses.

There is no plan for Hartford Hospital to pay for your medical expenses at other hospitals or for pain and suffering, travel, lost wages, or other indirect costs of taking part in this research. You do not waive any of your legal rights by signing this informed consent document.

J. Signatures

You will be given a copy of this informed consent document to keep. By signing below, it means that you have read it, that you voluntarily agree to participate in this research, , "Changes in Brain Function through Repeated Emotion Regulation Training." ," and that you consent to the performance of the procedures listed above.

Participant's Signature	Printed Name	Date

Legally Authorized Healthcare Representative	*Printed Name*	*Date*

Person Obtaining Participant's Signature	Printed Name	Date