Informed Consent, Assent, and Parental Permission form for Research

6816

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KEY INFORMATION

(If you are a parent reviewing this form, "you" and "your" refer to your child.)

You have been asked to participate in the research study, "Behavioral and Neural Target Engagement for ADHD Executive Working Memory Training – Phase II." You have been asked to participate because you have a diagnosis of ADHD, or because you volunteered to be in a comparison group of people who do not have ADHD. This page gives you key information to help you make your decision about participating. There is more information in a Detailed Consent after this page. This research is funded by the National Institute of Mental Health (NIMH). NIMH is paying Hartford Hospital and Dr. Stevens to conduct this research.

What is the study about and how long will it last?

By doing this study, we hope to learn how a memory training intervention can help reduce symptoms of ADHD. For the participants in the ADHD group, the main parts of the study include two MRI scans to measure brain function, 5 weeks of computerized tasks, some questionnaires, and an interview. This is completed in two study visits and 20 brief training sessions completed at home. You will also be contacted for a follow-up visit 3 months later, which includes completing questionnaires remotely. For the non-ADHD group, the main parts of the study include two MRI scans to measure brain function, some questionnaires, and an interview. This research study will include 130 people. This includes 90 ADHD diagnosed participants and 40 non-ADHD participants. This study is expected to last 3 years.

What are the key reasons you might choose to volunteer for this study?

The research offers no direct benefit to you. But the study will help researchers learn more about ADHD. We hope this information will help us learn how to treat ADHD better in the future. For a complete description of benefits, see the Detailed Consent.

What are the key reasons you might choose not to volunteer for this study?

Although this study is considered to be minimal risk, you might not want to volunteer because of inconvenience, boredom, risks to privacy, or discomfort talking about your thoughts and feelings. For a complete description of risks, refer to the Detailed Consent.

Do you have to take part in the study?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

What if you have questions, suggestions or concerns?

If you have questions, suggestions, or concerns regarding this study or want to withdraw from the study contact Dr. Michael Stevens of the Olin Neuropsychiatry Research Center, at (860) 545-7552. Other contacts who might answer different types of questions for you are listed later in the Detailed Consent.

DETAILED CONSENT

A. The Purpose and procedures of this research

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

The purpose of this study is to understand how the brain's working memory system functions in teenagers with Attention-Deficit / Hyperactivity Disorder (ADHD). We hope that what we learn helps us understand what types of memory training can help decrease symptoms of ADHD. It also could lead us to new treatments.

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, 5 weeks of training (for participants in the ADHD group), and two magnetic resonance imaging (MRI) brain scans. Participants in the ADHD group will also be contacted for a follow-up visit three months later that involves completing questionnaires remotely. 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. If you are currently taking any stimulant, short half-life medications for ADHD, you will not take your medication on the day of your visit. The reason for this is that there must be a 24 hour "wash-out" period when no medications are present in your body during the MRI scan. You will be able to start taking your ADHD medication again immediately after your study visit.

In accordance with pandemic guidelines, Hartford HealthCare has established procedures that will allow some study activities to be completed remotely, including informed consent. With your permission, you have the option of completing this document and other procedures via the following electronic platforms: correspondence by email, questionnaires by secured website link (RedCap), consent by secured website link (RedCap) and video platform (Zoom), clinical interviews by video platform (Zoom), and training sessions by video platform (Zoom). Questions about these procedures can be addressed by research staff or any of the contacts listed on page 6 of this consent form.

1. You will meet with study staff for an interview without your parent(s). Also, one of your parents will be interviewed about you. The interview will ask about your mental health, sometimes including questions about drug use and sexual history for a complete history of mental health. Please know if you feel uncomfortable during the interview you are free to stop at any time. This interview will be videotaped, if you agree. We videotape so that staff can review information they may have missed or so other staff can reach the same results. Only staff who work directly 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. Your parent/guardian will also be asked to complete several questionnaires about you as well. 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 or remotely, and your answers will not be visible to anyone.

3. We will ask you to complete some tests, done by paper-and-pencil and computer. These tests assess attention, memory, reaction time, reward and punishment, etc. We will be tracking your eye position and gaze with a device that is attached to the monitor while you complete the computer tests. We will be tracking your movement with a device that is attached to your wrist like a watch.

4. For participants in the ADHD group, training sessions will be done at home on a PC tablet computer you will borrow from us for 5 weeks. You will return the tablet at the second in-person visit. You are responsible for maintaining the condition of the tablet during the 5-week training period. In case of mechanical failure or malfunction, a replacement tablet will be provided to ensure that you are able to complete all 20 sessions. All training sessions will be remotely supervised by Olin research staff using video-teleconferencing. Each session will last about 45-50 minutes. All 20 sessions will be scheduled in advance at a time you can reliably keep. You will be assigned at random ("by chance") into one of two groups. Both groups will perform cognitive training exercises. But for one group, those training exercises are believed to have specific effects on the brain. For the other group, their training exercises are not expected to change brain function in the way we predict. You will not learn which group you were in until the study is over.

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

6. 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, including parents, if you are at least 13 years old.

7. You will have two brain scans, 6-8 weeks apart, using a magnetic resonance imaging (MRI) machine. The MRI scans will last about 1.5 - 2 hours. This includes time to prepare, perform the scan, and answer questions when the MRI is done. Functional magnetic resonance imaging (fMRI) 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 MRI machine. Your head will be placed securely into a comfortable frame. This will help you to keep your head still during the scan. 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 and research assistants will perform the MRI scans.

8. This experiment is about seeing how your brain works while you perform several tasks. In the MRI, you will be using buttons located under your fingers. Instructions for the tasks will be explained to you when you are in the MRI.

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 and Huntington Buildings at the Institute of Living (the Olin Neuropsychiatry Research Center). The buildings are located at 200 Retreat Avenue, Hartford, CT 06106.

A.5. How long will participation last?

Participation requires 14-16 hours in total for those in the non-ADHD group. This includes an interview (1-2 hours), virtual surveys (1 hour total), and two in-office visits (5-7 hours each) – which includes an MRI (1-2 hours), computer testing (2 hours), questionnaires (30 min), and cognitive testing (1-2 hours). Participation in the ADHD requires 30-32 hours in total. This includes all of the activities listed for the non-ADHD group, as well as training sessions and virtual visits. The training sessions requires an additional 12 hours (35 minute sessions occurring 4 times a week for 5 weeks). A virtual testing session will also occur before and after the training sessions are completed (1-1.5 hours each), and a 3-month follow up virtual visit requires an additional 30 minutes.

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

B1. 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. Pregnancy test results are only reported to the Department of Children and Families when positive for a female under age 13, as required under Connecticut mandated reporting laws. Otherwise, test results are not released to anyone outside the research team, including parents.

B2. 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 short, a brief break will be offered mid-way through the tests to make sure you don't become tired.

B3. Interview Questions

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 member 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 and/or parent. If you are not currently receiving treatment for those issues, study staff under direction of the Principal Investigator will recommend treatment options to you.

B4. Videotaping

Some people feel uncomfortable being videotaped when answering questions about their feelings and attitudes. Our staff members 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. Your name or other identifying information will not be stored with the file. The video recordings will be destroyed after 6 years following completion of the study.

B5. Eye Tracking

The eye tracking device uses near-infrared light. This is found in our natural environment and there are no known risks using this machine.

B6. Questionnaires

There are no risks to answering questions about your personality, health, and behaviors. Some of the questions ask about private information. Safeguards are in place to ensure all your personal information is kept private.

B7. Working Memory Training Sessions (ADHD group only)

There are no known risks to completing the training sessions. You may become tired or bored during the training sessions. A Research Assistant will be monitoring your progress during the sessions and available to answer any questions you may have during the sessions.

B8. 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 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 before we begin the study. 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.

B9. ADHD Medication 24 hour "wash-out"

If you are taking any ADHD medications, there are no physical risks associated with stopping your ADHD medication for 24 hours. There are no reports that have shown any "rebound" effect on behavior, cognition or brain function in the hours or days after discontinuing a psychostimulant drug, Some studies have reported that there might be an increased risk for ADHD-diagnosed persons while driving an automobile when not taking their prescribed medications. However, this research is not entirely consistent and there are no clear medical guidelines. If you have a driver's license and are currently taking ADHD medications, your parents will be encouraged to provide transportation to the study appointments. If transportation cannot be provided and parents have concerns, you will not be included in the study if practical constraints cannot be overcome. However, you may be eligible to receive taxi or Uber rides if needed, whenever this is geographically feasible (e.g., live within 20-30 minutes of the Olin NRC).

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

This study will be of no direct benefit to you. By participating, your information may add to our knowledge of how the brain's working memory system works.

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

Although we are testing the potential for these working memory training exercises to form the basis of a new treatment, this study is not a treatment study. There are no other specific types of treatment for ADHD that you should consider if you choose to not participate in this trial. 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	Michael Stevens, PhD Godfrey Pearlson, MD	(860) 545-7552 (860) 545-7757
your rights as a research participant	An IRB Representative	(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 any hospital in the Hartford HealthCare network.

To withdraw or revoke your consent t any time, you must submit a written request to Dr. Michael Stevens here at the Olin Neuropsychiatry Research Center, 200 Retreat Ave., Hartford, CT 06106. Your data will be anonymized (all identifiers removed) or destroyed according to your wishes.

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

For participating in this study, you will be compensated a standard rate of $20 per hour (not including time spent on the training sessions). If you complete only part of the study, you will be compensated for your time, but will not receive compensation for portions not completed. This money will be provided to you on a cash "debit card" after you complete your appointment(s). To show our appreciation for completing all aspects of the study, you will receive a $50 bonus payment at the end of the study if all study procedures, including the parent questionnaires and training sessions, are completed. You will be compensated $300-$370 for completing all parts of the study, which includes the bonus payment.

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.

H1. 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.

H2. 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.

H3. NDA: Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a computer system run by the National Institute of Health that allows researchers to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things more quickly than before. Data from all participants will be shared with NDA. During and after the study, the researchers will send information about your health and behavior (collected during your interview, cognitive testing and questionnaires as well as your parents interview) and in some cases, your MRI data, to NDA. However, before they send it to NDA, they will remove information such as name, address and phone number, and replace that information with a code number. Other researchers nationwide can then file an application with the National Institutes of Health to obtain access to your study data for research purposes. Experts at the National Institutes of Health who know how to protect health and science information will look at every request carefully to minimize risks to your privacy. You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA might help researchers around the world treat future children and adults with psychiatric disorders so that they have better outcomes. NDA will report to Congress and on its website about the different studies that researchers are conducting using NDA data; however, NDA will not be able to contact you individually about specific studies. You may decide now or later that you do not want to share your information using NDA. If you know now you do not want us to share your information please indicate that at the appropriate checkbox at the end of this document. If you decide that later, please contact Dr. Stevens in writing, and he will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://nda.nih.gov.

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. Authorization to Use and Disclose Information for Research Purposes

Federal regulations (HIPAA Privacy Rule) give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What information may be used and given to others?

If you choose to be in this study, the study Research Assistant will get personal information about you. This may include information that might identify you. The Research Assistant may also get information about your health including:

- Research records
- Information from interviews and questionnaires conducted as part of Research Study, including medical history

• All medical records or reports created in connection with Research Study, such as any radiology reports, lab results, psychological test results, consultation reports, results of physical examinations, summary notes and treatment records
• Records about your study visits and the results of testing your past study participation. This information will include information about brain structure and function and about performance on the experiment collected during MRI.

Who may use and give out information about you?
Information about your health may be used and given to others by the study doctor and study staff. They might see the research information during and after the study.

Authorized Uses/Disclosures:

This form authorizes the following persons or entities to obtain, use or disclose my Protected Health Information in connection with the Research Study:

• Hartford Hospital
• The principal investigator, Michael C. Stevens, Ph.D., Hartford Hospital/Institute of Living
• The co-investigators, Godfrey Pearlson, M.D., Hartford Hospital/Institute of Living, Yale University; Jimmy Choi, Psy.D., Hartford Hospital/Institute of Living
• Any researchers or Hartford Hospital staff working under the principal investigator's or any co-investigator's direct supervision

Who might get this information?

The Protected Health Information may be disclosed to the following:

- Hartford HealthCare Research Institute Administrative staff or Institutional Review Board members
- Any government agency overseeing this research at HH for which authorization would be required by law;
- The research sponsor, The National Institute of Mental Health;
- Other researchers for data comparison purposes, provided data used for this purpose is stripped of personally identifying information;
- Other: Vince Calhoun PhD and data programmers working under his direct supervision at the COINS research network at the University of Georgia. Dr. Calhoun is a "Business Associate" who manages and maintains the Olin Neuropsychiatry Research Center's Database.
- Governmental agencies to whom certain reportable diseases must be reported

Authorization to Continue Research at New Institution *[Participants must give permission for research data to be taken to and used at another institution by personally initialing the appropriate line following this statement. The Investigators/Research Staff may not make that decision for the participant.]*

In the event the principal investigator of the Research Study identified above moves his/her research work to an institution other than Hartford Hospital (the "Successor Institution"), by initialing the line below, I authorize the principal investigator to retain records relating to my participation in the Research Study and further authorize the disclosure of my Protected Health Information to the Successor Institution and the continued use and disclosure of such information by the Successor Institution, the principal investigator and other researchers working under the principal investigator at the Successor Institution in connection with the Research Study as otherwise contemplated above. I understand in such event records relating to the Research Study will no longer be maintained at Hartford Hospital.

_____ Participant Initials

OR

I do not authorize the disclosure of my Protected Health Information to the Successor Institution, in the event the principal investigator leaves Hartford Hospital.

_____ Participant Initials

Why will this information be used and/or given to others?
Information about your health that might identify you may be given to others to carry out this research study and other possible research studies if you agreed to the use of your information for future research, as described in this research study consent form. The study team will analyze and evaluate the results of the study. The information may be given to the FDA. The information may also be used to meet the reporting requirements of governmental agencies.

Informed Consent for Research
The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed. The information may be reviewed by the HHC IRB. An IRB is a group of people that perform independent review of research as required by regulations to protect the rights and welfare of human subjects involved in research. No data or information is completely secure. Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here. Such information, however, may continue to be protected for recipients that are subject to the federal privacy regulations or other state or federal confidentiality laws or contractual confidentiality obligations.

What if I decide not to give permission to use and give out my health information?
By signing and dating this authorization form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. You may not be able to review some of your records related to the study until after the study is over. When the study is over, you may contact the study doctor to see your health data from the study and to correct any errors.

May I withdraw or revoke (cancel) my permission and participation in the study?
This permission will remain in effect from the date of your electronic signature. There is no expiration of this authorization. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address listed on the first page of this form. If you withdraw your permission, you will also be withdrawn from the study. When you withdraw your permission, no new health information that might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

K. 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, "Behavioral and Neural Target Engagement for ADHD Executive Working Memory Training – Phase II." and that you consent to the performance of the procedures listed above.

Participant's Signature	Printed Name	Date
Parent or Legally Authorized Healthcare Representative	Printed Name	Date
Person Obtaining Participant's Signature	Printed Name	Date

Please indicate below if you agree to be video recording of the interview (please know that you will never be video recorded without being notified first):

☐ I agree ☐ I do not agree Initials: _____

Please indicate below if you give us a permission to share your data with NDA:

☐ I agree ☐ I do not agree Initials: _____

Please indicate below if you give us permission to conduct consent, questionnaires and interviews remotely:

☐ I agree ☐ I do not agree Initials: _____