



INFORMED CONSENT FORM
to Participate in Research, and
AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent: _____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

2. What is the Title of this research study (this "Research Study")?

Cognitive Enhancement through Computerized Training

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Ben Lewis, Ph.D., 352-294-8724

4. Who is paying for this Research Study?

The sponsor of this study is the National Institutes of Health, with additional funding provided by the University of Florida Department of Psychiatry.



5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

- The purpose of this research study is to learn about cognitive abilities (e.g., memory, learning, problem solving) in men and women with diverse backgrounds.
- You will be asked to complete a short assessment and some brief questionnaires. Approximately 3 weeks later you will be asked to complete the same assessment and questionnaires a second time. Afterwards, you will be asked to complete 3 short follow-up phone interviews, occurring approximately 2, 4, and 6 weeks after your last assessment. **The total amount of time that may pass from start to finish is about 3 months.**

b) What is involved with your participation, and what are the procedures to be followed in the research?

- You will be asked to complete a short assessment, including several computerized activities which will assess learning, memory, and problem-solving skills. You will also be asked to complete brief questionnaires. Approximately 3 weeks later you will be asked to complete the same assessment and questionnaires a second time.
- You will be asked to complete 3 short follow-up phone interviews, occurring approximately 2, 4, and 6 weeks after your last assessment. During these follow-ups you will be asked about recent activities as well as your relationships with family, friends, and in the workplace.

c) What are the likely risks or discomforts to you?

- You may experience mild fatigue from concentrating over the course of testing. To prevent such fatigue, rest periods are scheduled between tasks.
- You may experience minor discomfort when discussing private topics such as substance use or your relationship with family and friends. You may choose not to answer any questions that make you feel uncomfortable. Information shared by you will be kept confidential.
- Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability.



d) What are the likely benefits to you or to others from the research?

- There is no direct benefit to you for participating in this study.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

- This is not a treatment study. The alternative is to not participate.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

Participation in the study will not affect your current or future clinical care.

7. What will be done only because you are in this Research Study?

- You will be asked to complete a short assessment, including several computerized activities which will assess learning, memory, and problem-solving skills. You will also be asked to complete brief questionnaires. Approximately 3 weeks later you will be asked to complete the same assessment and questionnaires a second time.
- You will be asked to complete 3 short follow-up phone interviews, occurring approximately 2, 4, and 6 weeks after your last assessment. During these follow-ups you will be asked about recent activities as well as your relationships with family, friends, and in the workplace.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information. After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.



8. What identifiable health information will be collected about you and how will it be used?

If you agree to participate in this study, the Research Team will collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Research Team needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. It may also be used to determine if you are eligible for other current studies conducted by the Principal Investigator. This information can be gathered from your self-reports regarding your health status, demographic information, mood, and mental health. This information will be created from your study visit and will be used for the purposes of research. It will not be entered into your medical record. Specifically, the following information may be collected, used, and shared with others for the purposes of conducting this research:

- Name, contact info, and social security number (for payment and scheduling)
- Information provided by you during the previous screening phase of the study, such as medical history, substance use, and psychiatric symptoms
- Responses to questionnaires and interview materials concerning mood, demographic information, mental and physical health conditions, substance use history, and responses to common situations
- Behavioral measures gathered during computerized tasks

This information will be stored in locked filing cabinets or on computer servers with secure passwords.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity, confidentiality, and privacy.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. 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 have been informed 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. That is, if you give written consent for the release of information to any person, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that to appropriate authorities.

The Principal Investigator listed in question 3 above will use or share your health information as described below to carry out this Research Study.

9. With whom will this health information be shared?

Your PHI may be shared with:

- the study sponsor (listed in Question 4 of this form);
- United States governmental agencies who are responsible for overseeing this research, the Department of Health and Human Services and the Office of Human Research Protections
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

Your participation in this study will include:

- Completion of assessment/questionnaires lasting approximately 90 minutes
- A second completion 3 weeks later lasting approximately 90 minutes
- Up to three follow-up interviews lasting approximately 30 minutes each

Total participation time: ~4.5 hours

Total participation length: ~3 months

**11. How many people are expected to take part in this Research Study?**

Up to 120 people are expected to complete this study.

**WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND
WHAT ARE YOUR OPTIONS?****12. What are the possible discomforts and risks from taking part in this Research Study?**

You may experience mild fatigue from concentrating over the course of testing. To prevent such fatigue, rest periods are scheduled between tasks.

You may experience minor discomfort when discussing private topics such as substance use or your relationship with family and friends. You may choose not to answer any questions that make you feel uncomfortable. Information shared by you will be kept confidential.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform the Principal Investigator listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call the Principal Investigator listed in question 3 in this form.

**13a. What are the potential benefits to you for taking part in this Research Study?**

There is no direct benefit to you for participating in this research study.

13b. How could others possibly benefit from this Research Study?

The results of this study may provide new information regarding cognitive abilities (e.g., memory, learning, problem solving) in men and women with diverse backgrounds. Information gathered in follow-up interviews may improve our understanding of how these processes may be related to measures of interpersonal relationships and quality of life.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Principal Investigator listed in question 3 of this form and other members of the Research Team may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

14. What other choices do you have if you do not want to be in this study?

This is not a treatment study. The alternative is to not participate.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Principal Investigator listed in question 3 of this form.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Principal Investigator listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with the Principal Investigator listed in question 3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:



- The study is cancelled and/or discontinued or other administrative reasons.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

The Sponsor will pay for all activities required as part of your participation in this study. There will be no cost to you. If you receive a bill related to this study, please contact Ben Lewis, Ph.D. at (352) 294-8724.

17. Will you be paid for taking part in this Research Study?

Yes. You will receive \$20.00 for completing the initial assessment. You will receive an additional \$20.00 for completing the second assessment approximately 3 weeks later. You will receive an additional \$20.00 for completing each of the follow-up interviews. The total possible payment for this study is \$100.

Your payment will be made either by cash, prepaid debit card, or by a check mailed within 6-8 weeks of study completion. If you are paid more than \$75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to nonresident aliens must be processed through the University of Florida Payroll and Tax Services department. If the payments total \$600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: <http://privacy.ufl.edu/SSNPrivacy.html>.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity. If you have any problems regarding your payment contact the Principal Investigator listed in question 3.

18. What if you are injured while in this Research Study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provide will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.



You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact the Principal Investigator listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.



SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization

Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing

Date