UF | Institutional Review Board
UNIVERSITY of FLORIDA

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?

Sex Differences, Cognitive Training & Emotion Processing

3. Who do you call if you have questions about this research study?

Principal Investigator: Sara Jo Nixon, Ph.D., 352-294-4920
Co-Investigator: Ben Lewis, Ph.D., 352-294-4920

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 whether computerized training tasks can change cognitive performance (e.g., memory, learning, problem solving) in men and women with diverse backgrounds. We are particularly interested in whether incorporating emotional stimuli (e.g., faces displaying emotions) into training can affect performance outcomes.
- If you complete this phase of the study you will be asked to complete computerized training sessions over a 3 week period. 2-5 days after completion of training you will be asked to complete a post-training assessment. You will be asked to complete 3 short follow-up phone interviews, occurring approximately 30, 60, 90 days after your post-training assessment. **The total amount of time that may pass from start to finish is about 4 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 pre-training assessment, including several computerized activities which will assess learning, memory, and problem-solving skills. You will also be asked to complete brief questionnaires regarding current mood.
- You will be asked to complete computerized training activities up to twelve times over a three-week period. You will be randomly assigned to one of two possible training groups. Each group will be exposed to different task stimuli.
- 2-5 days following completion of training, you will be asked to complete a post-training assessment, including several computerized activities which will assess learning, memory, and problem-solving skills. You will also be asked to complete brief questionnaires regarding current mood.
- You will be asked to complete three short follow-up phone interviews, occurring approximately 30, 60, and 90 days after your post-training assessment. During this follow-up you will be asked about recent use of

alcohol and other drugs, as well as your relationships with family, friends, and in the workplace. You may complete the follow-up interview by phone or in-person in our laboratory.

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. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

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 <u>not</u> a treatment study. The alternative is not to 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.

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 pre-training assessment, including several computerized activities which will assess learning, memory, and problem-solving skills. You will also be asked to complete brief questionnaires regarding current mood. Completion of these will take approximately 60 minutes.

- You will be asked to complete computerized training activities up to twelve times over a three-week period. You will be randomly assigned to one of two possible training groups. Each group will be exposed to different task stimuli. Each training session will take approximately 45 minutes.
- Approximately 2-5 days following completion of training, you will be asked to complete a post-training assessment, including several computerized activities which will assess learning, memory, and problem-solving skills. You will also be asked to complete brief questionnaires regarding current mood. Completion of these will take approximately 60 minutes.
- You will be asked to complete three short follow-up phone interviews, occurring approximately 30, 60, and 90 days after your post-training assessment. During this follow-up you will be asked about recent use of alcohol and other drugs, as well as your relationships with family, friends, and in the workplace. Each interview will last approximately 30 minutes. You may complete the follow-up interview by phone or in-person in our laboratory.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens 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 the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

Your participation in this study will include:

- Completion of a computerized pre-training assessment lasting approximately 60 minutes
- Up to 12 computerized training sessions lasting approximately 45 minutes each
- A post-training assessment lasting approximately 60 minutes
- Up to three follow-up interviews lasting approximately 30 minutes each

Total participation time: ~13 hours

Total participation length: ~4 months

9. How many people are expected to take part in this research study?

Up to 100 people are expected to complete this study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. 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. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members 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.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. 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. However, your completion of the computerized training sessions may result in some improvements in cognitive function.

11b. How could others possibly benefit from this study?

The results of this study may provide new information regarding the relationships between cognitive processing in men and women and how computerized training may improve these processes. Information gathered in follow-up interviews may improve our understanding of how these processes may be related to measures of interpersonal relationships and the use of alcohol or other substances.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the study investigators listed in question 3 of this form, or other research staff may benefit if the results of this study are presented at scientific meetings or in scientific journals.

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

Participating or not participating in this study does not affect your access to usual clinical care. The alternative is to not participate. If you do not wish to participate, tell the Principal Investigator and do not sign this form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from the study, information about you will no longer be collected. Information that has been collected up to that point may be used in data analysis.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- The study is cancelled and/or discontinued for other administrative reasons
- If you are unable to complete at least three sessions in the first week.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

No. There will be no cost to you for participating in this Research Study.

15. Will you be paid for taking part in this study?

Yes. You will receive $25.00 for completing the pre-training assessment. You will receive an additional $25.00 for completing the post-training assessment 2-3 weeks from now. You will receive an additional $20.00 for completing each of the follow-up interviews.

You will receive $15.00 for each of the first eight computerized training sessions you complete. After completing 8 training sessions, you will receive $20.00 for each of the additional sessions (sessions 9-12) completed.

The total possible payment for this study is $310.00. Your payments will be made with cash, check, or prepaid debit card. If the follow-up is conducted by phone, your payment will be made by mail within ~3-4 weeks of 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 study coordinator.

16. What if you are injured because of the study?

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.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, 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 Principal Investigator 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 and used as part of your participation in the study. This information can be gathered from your self-reports regarding your health status, mood, and mental health. This information will be created by participating in screening and study procedures. 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 and contact info (for payment and to schedule training sessions, tasks, and follow-up interviews)
- Information provided by you during the previous screening phase of the study, as well as during follow-up interviews, including neurocognitive data, medications, psychiatric symptoms, and cognitive performance
- Responses to questionnaires and interview materials concerning mood, mental health conditions, and substance use
- Behavioral measures gathered when performing tasks and training activities
- Social Security Number for the purposes of payment

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

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, photographs, 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 and 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. 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.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To examine to what extent computerized training tasks can positively affect cognitive (e.g., learning, memory and problem-solving) and emotional processes in a diverse sample of men and women

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

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 research, such as the Department of Health and Human Services, and the Office of Human Research Protections .

Otherwise, your research records will not be released without your permission except under the guidelines of the Certificate of Confidentiality. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

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 in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date