PROTOCOL TITLE:

fMRI Studies of Working Memory and Cognitive Control

PRINCIPAL INVESTIGATOR:

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VERSION NUMBER/DATE:

Include the version number and date of this protocol.

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	9/30/19	Previously approved protocol changed to RAMP	no
2	6/10/20	Added COVID-19 precautions	yes
3	4/30/21	Revised COVID-19 precautions	no
4	8/24/2021	Added New COVID-19 Precautions	yes
5	2/21/2023	Added community recruitment to section 13.1	No
6	5/11/2023	Added earplug risk information to section 15.1	Yes
7	6/28/2024	Added recruitment site	no

Table of Contents

1.0 Study Summary

Study Title	fMRI Studies of Working Memory and Cognitive Control
Study Design	Experimental/Control Design
Primary Objective	The purpose of the proposed research is to identify brain areas that correlate with working memory and cognitive control using functional magnetic resonance imaging (fMRI).
Secondary Objective(s)	
Research Intervention(s)/ Investigational Agent(s)	NA
IND/IDE #	
Study Population	Healthy young adults
Sample Size	400
Study Duration for individual participants	1-2 hours
Study Specific Abbreviations/ Definitions	fMRI – functional magnetic resonance imaging

2.0 Objectives*

2.1 Describe the purpose, specific aims, or objectives.

The purpose of the proposed research is to further our understanding in the mechanistic operations of working memory and cognitive control. We are interested in the brain mechanisms underlying working memory and cognitive control abilities. Our goal is to identify brain areas that directly correlate with working memory and cognitive control through the use of functional magnetic resonance imaging (fMRI). fMRI is a well-established, non-invasive technique used by thousands of labs around the world to study brain function.

2.2 State the hypotheses to be tested.

We hypothesize that areas in the prefrontal cortex (PFC) and posterior parietal cortex (PPC) are active during working memory and cognitive control. We hypothesize that activity in these regions directs the selection, retention, and manipulation of representations elsewhere in the brain.

3.0 Background*

3.1 Describe the relevant prior experience and gaps in current knowledge.

Cognitive control refers to the ability to align behaviors in accordance with goals and contextual circumstances. This ability often depends upon maintaining information (e.g. instructions, goals) when it is no longer available to the senses – referred to as working memory. Cognitive control and working memory are central to higher-level cognition, but their mechanistic operations are poorly understood.

3.2 Describe any relevant preliminary data.

NA

3.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

fMRI is one of the best non-invasive tools that researchers have for studying human brain function. The ability to associate brain regions with cognition is of central importance for our understanding of mental and neural function. Furthermore, basic understanding of mental and neural function will improve our understanding of impairments observed in psychiatric and neurological disorders.

4.0 Study Endpoints*

4.1 Describe the primary and secondary study endpoints.

NA

4.2 Describe any primary or secondary safety endpoints.

NA

5.0 Study Intervention/Investigational Agent

1.1 Description: *Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.*

NA

5.1 Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

NA

5.2 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

NA

6.0 Procedures Involved*

6.1 Describe and explain the study design.

In the proposed research, we will use computer-based tasks that engage cognitive control and/or working memory. Typical paradigms will involve presenting stimuli, such as words, letters, pictures, or sounds. In tasks involving working memory, participants will be asked to retain in mind some aspect of the stimulus after it is no longer present on the monitor. In tasks involving working memory and/or cognitive control, participants will make decisions on stimuli that are based on previous instruction and previous stimuli. While performing the proposed tasks, MRI data will be collected. Subjects will be screened by the MR technologist, and will be excluded if they meet any exclusion criteria. Subjects will be given instructions about the task and the MRI scanning environment. If there is any concern about claustrophobia, participants will be encouraged to try the mock scanner before entering the MRI scanner. The mock scanner is located next door to the MRI scanner and provides a simulated MRI environment. If they are uncomfortable with the enclosed environment (at any time), they can exit the study and receive compensation for their time. Otherwise, participants will then be given a short practice session on the task either before entering the scanner, or during collection of preliminary and/or structural images. After being positioned in the scanner by the technologist, the technologist will acquire initial calibration scans. A structural image of the head and brain may be acquired before or

after the functional imaging data. The remaining time in the scanner will be used to collect functional imaging data while subjects perform the task. Response time and accuracy data will be recorded during the task. We will relate these measures to the fMRI data from the scanner, in order to understand the relationships between neural activity and behavioral performance. For some studies, eye tracking will be performed. This will involve positioning a camera focused over one of the eyes and recording video of eye position. Such data will be useful to monitor eye position and pupil dilation. Knowledge of eye position is important in tasks that utilize spatial stimuli (e.g. location) and when mapping out areas of the brain that respond to stimuli as a function of their position on the eyes (e.g. visual cortex).

6.2 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.

Below is a description of the kinds of tasks that participants may perform in a piecemeal fashion. It is likely that elements from multiple such tasks will be combined into a single task. Hereafter, stimuli will refer to letters, numbers, words, pictures, or sounds. Unless otherwise specified, stimuli will be affectively neutral. In general, tasks will range in duration from 5-10 minutes to 1-2 hours. Breaks will be given every 5-10 minutes. Multiple sessions may be performed. Based upon performance on the tasks, we may contact participants to perform other related tasks. Returning to perform other tasks will be optional and have no bearing upon the tasks the participants have already completed.

- Computer-based Tasks
    - Short-term memory
        a. In this task, participants are presented with a set of stimuli to remember. After a delay, participants will receive a test item. The test item can either be an old/new stimulus requiring a recognition decision (i.e. was the stimulus a member of the set?) or it can be a stimulus to be transformed to match a stimulus in the set (e.g. rotate a grating until it matches a grating in memory).
    - Span
        a. In this task, participants will be presented with a list of stimuli to remember. In some cases, they will be asked to make judgments in-between the presentation of memoranda (e.g. assess the validity of a simple

arithmetic expression). Upon termination of the list, participants will be asked to reproduce the list.

- Change-detection
    a. In this task, participants will see a collection of stimuli, followed by another collection of stimuli. They will respond with whether the collection changed or not.
- Sequence Memory
    a. In this task, participants will learn a predefined stimulus sequence. Participants will make judgements regarding whether the presented stimuli follow the predefined sequence or not.
- Alternative forced choice
    a. In this task, participants will judge the categorical status of stimuli. Categories include word/non-word judgements, semantic judgements, number judgements (e.g. is the number odd or even), object category judgments (e.g. face, scene), and spatial judgments (e.g. which direction does an arrow point).
- Cued attention
    a. In this task, participants will be directed to attend to a particular stimuli, regions of space, or location of sound. Participants will make either alternative forced choice or memory judgements regarding the attended stimuli.
- Task-switching
    a. In this task, participants will switch among two or more tasks of the nature described above.
- Retinotopic mapping
    a. In this task, stimuli will be used to map out the visual field within the brain. Stimuli will consist of high contrast checkboard images that efficaciously recruit visual cortex. Stimuli will be moved around the visual field such that mapping between visual

location and brain location can be determined.

- Doors Task
    a. Participants will be shown graphics depicting doors, and will be asked to choose a door. After picking a door, participants receive feedback on the screen indicating whether they have won or lost on that trial. The participants' goal is to do their best to win as much money as possible. In this task, participants will receive a monetary bonus for correct guesses, which will total between $0.00 and $10.00 depending on how many correct guesses they make. This task will take approximately 5-10 minutes.
- Motivated Behavior Task
    a. Participants will be given the opportunity to complete a specified number of trials for a specified reward. Trials will entail trials of the tasks described above or other simple cognitive tasks such as arithmetic.

- Written tasks
    - Raven's Progressive Matrices
        a. In this standardized measure of intelligence, participants decide which among several images completes a logical matrix of images
    - Self-reported tasks
        a. At the end of an experimental session, we may ask participants to answer questions regarding their strategic approach to tasks. Examples of questions include whether participants verbally rehearsed material to themselves, whether they named images, and whether they maintained vigilance. In all cases, questions will be about task performance. No personal information will be requested for these tasks.
    - Screening
        a. Participants will be screened to be fluent in English, between the ages of 18-30, and to have no contraindications for MRI. Participants will also be screened such that

they do not belong to populations vulnerable to the Coronavirus Disease (COVID-19) and have not been exposed. They will also be asked to indicate whether they have received a full FDA-authorized COVID-19 vaccination series, the specific vaccine product they received, and the date of complete vaccination.

- Demographics
    a. Demographic information including age, gender, race, and ethnicity will be collected. This information will be used for reporting purposes to demonstrate fair inclusion. Participants will be informed that providing this information will be optional. This information has no direct bearing upon the research to be performed

6.3 Describe:

- *Procedures performed to lessen the probability or magnitude of risks.*
- *All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.*
- *The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)*

To lessen the probability or magnitude of risks, researchers will stop testing or administer breaks if participants feel frustrated, tired, and/or uncomfortable while scanning.

We will stop testing or administer breaks if participants feel frustrated or tired. Additional risks and preventions include: 1) Magnetic field attracting ferromagnetic objects: Subjects will be screened for metallic objects prior to entering the scan room to minimize this risk and anyone with a questionable history of metal will not be allowed to enter the scanner room. 2) Claustrophobia: Any participant reporting the experience of claustrophobia will be removed from the magnet immediately, debriefed, and given compensation for their time. 3) Noise: All participants will be required to wear ear plugs to shield them from scanner noise while allowing communication from the technician. If the noise is overly bothersome to the subjects, they will be removed from the magnet immediately. Please note: The occurrence of any adverse events associated with this study and its procedures, as well as any changes in risk level

will be monitored by the principal investigator and coinvestigators of this study, as well as the scanner technician.

The source records that will be used to collect data about subjects will be retained in digital format. Digital information will be stored on password protected local machines, or on secure cloud-based services such as Google Docs, also requiring a password.

Due to the COVID-19 national emergency and pandemic, in cases where participants or study staff have not completed a full FDA-authorized vaccination series at least 14 days before the study session, researchers will also apply the following precautions in conducting this research:

- No persons deemed as higher risk by the CDC will be included in the study. Participants will be screened such that they meet these requirements.
- COVID-19 related risks will be mitigated as much as possible. This will be done through screening for exposure to COVID-19, regular cleaning and disinfecting study areas, reducing in-person interactions, and use of personal protection equipment.
- Unvaccinated participants will be unable to participate in this study if they have tested positive or if they were in close contact with a positive COVID-19 case within the last ten days.

For in-person study activities involving prospective subjects and study staff, we will as part of our screening and eligibility procedures implement the option of informing subjects and staff that their voluntary disclosure of their full COVID-19 vaccination status is an alternative to the requirement for COVID-19 precautions such as social distancing, use of masks, and other safety precautions. In doing so, we will use the following language: “In order to protect against COVID-19 or Coronavirus, if you come to the lab we are required to follow certain precautions like social distancing and use of masks. However, we don’t have to do this for persons who have completed a full COVID-19 vaccination. You may if you’d like share with us information about your COVID-19 vaccination, but this is your decision and is not required. You can still come to the lab and we will follow our usual COVID-19 precautions."

To implement this COVID-19 vaccination option, we will make a note in our study records for each prospective subjects and

staff who choose to disclose their COVID-19 vaccination information.

6.4 What data will be collected during the study and how that data will be obtained.

The data that will be collected during the study includes identifying information. Additionally, brain activations, accuracies and reaction times to tasks will be collected. The data will be obtained using computerized-based tasks or written tasks while being tested in the MRI scanner.

6.5 If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.

In some cases, performance in some tasks will trigger eligibility for other tasks. In these cases, procedures will be identical to those described above.

6.6 For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

NA

7.0 Data and Specimen Banking*

7.1 If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

NA

7.2 List the data to be stored or associated with each specimen.

NA

7.3 Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

NA

8.0 Sharing of Results with Subjects*

8.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the

subject's primary care physicians) and if so, describe how the results will be shared.

The MRIF contracts with The Mind Research Network (MRN) for screening of all subjects. To this end, subjects electing to partake in the IF program will have their T1 and T2 weighted scan data sent to MRN via encrypted data link. Other scans such as Susceptibility Weighted Images (SWI), Diffusion Weighted Images (DWI), and Fluid-attenuated Inversion Recovery (FLAIR) can also be send to MRN for review, if needed.

The MRN Contracted Radiologists will review images provided to them, and do not have access to additional clinical information. The MRI scans are collected under research protocols and are not obtained for clinical purposes.

The research MRI scans are not a substitute for a clinical scan and might not show problems that may be picked up by a clinical scan. If MRNs find an abnormality that requires follow-up, they may also mail a copy of the report to the subject, or contact them (with their permission), to help answer questions.

All MRN radiology reviews are completed within 30 days and are forwarded as a de-identified report directly to the MRI Technologist. All reports are then printed and mailed via US Postal Service to the subject's mailing address. They are provided with the contact information of the MRI Technologist in case they have questions. Any returned reports will be recorded and the hard copy destroyed.

9.0 Study Timelines*

9.1 Describe:

- *The duration of an individual subject's participation in the study.*
- *The duration anticipated to enroll all study subjects.*
- *The estimated date for the investigators to complete this study (complete primary analyses)*

The duration for each individual's participation will be between 1 and 2 hours per session. Participants will participate in at least 1, and potentially several sessions. It may take up to several weeks to complete an entire task. The duration anticipated to enroll all study subjects is 72 months.

10.0 Inclusion and Exclusion Criteria*

10.1 Describe how individuals will be screened for eligibility.

Participants will be screened in order to minimize risks associated with fMRI. Screening will proceed in two phases. First, the screening form will be sent to the participant via e-mail (see Appendix). The participant will be asked to respond with whether the answer to any question on the screening form is "yes." At this phase, the participant does not need to indicate to which question the answer is "yes." If the response is "yes" to any question, the participant will be excluded. If the participant passes the first phase of screening and remains interested in participating, the participant will be invited to perform the study. Participants will read the consent form and any questions will be answered. After answering questions, the participant will once again be presented with the screening form. In this case, the participant will fill-out the screening form. If the answer is "yes" to a given question, the participant may be asked to elaborate. A "yes" response may occur in the second screening, but not the first, if circumstances changed since the initial screening. The individuals included in this study will be adults from ages 18 to 30.

We will also exclude from study individuals who are vulnerable to or may have come in contact with COVID-19. We will include individuals who have completed a full FDA-authorized vaccination series at least 14 days before the study session, and individuals who have not been fully vaccinated provided that they pass the screening process. As with the other screening forms, the COVID-19 screening form will be sent to the participant via e-mail (see Appendix). The participant will be asked to respond with whether the answer to question #1 on the form is "yes" or if, alternatively the answer to #1 is "no" and the answer to any other question on the screening form (#2 through #8) is "yes." Question #1 asks participants to indicate if they have received a complete vaccination series, the specific FDA-approved vaccine product they received, and the date of vaccination. At this phase, the participant does not need to indicate which to which of the other questions the answer is "yes." If the response is "yes" to any questions including #2 through #8, the participant will be excluded. If the participant passes the first phase of screening and remains interested in participating, the participant will be invited to perform the study. Participants will read the consent form and any questions will be answered. After answering questions, the participant will once again be presented with the screening form. In this case, the participant will fill-out the screening form. If the answer is "no" to #1 and "yes" to any of the other questions (#2 through #8), the participant may be asked to elaborate. A "yes" response may occur in the second screening, but not the first, if circumstances changed since the initial screening.

10.2 Describe the criteria that define who will be included or excluded in your final study sample.

Inclusion: Because we are interested in the mental function of adults prior to any age-related decline, participants will be between the ages of 18-30. Participants will also need to be fluent in English and have acquired fluency prior to the age of 6 since English is required to understand the instructions and some tasks will use English words/letters as stimuli. Because of the visual presentation of stimuli, participants will need to have normal or corrected-to-normal vision. Exclusion: Left-handed people will be excluded. Many brain functions are lateralized (e.g. language is often processed by the left hemisphere). While such lateralization is typically very consistent in right-handers, brain lateralization is less predictable in left-handers which can confound localization of function. Participants must pass the MRI screening protocol, excluding people who have metal in any portion of the body, have medical complications, cardiac pacemaker cochlear implant, aneurysm clip, IUD shrapnel, history of metal fragments in eyes, neurostimulators, weight over 300 pounds, known problems of claustrophobia, history of psychiatric illness and/or neurological illness, or illicit drug use. Because alcohol has a transient effect on neural activity, subjects will be screened to have not consumed alcohol for the past 24 hours via self-report. Additionally, people with the following will be excluded: hearing impairments and permanent retainers on the top portion of their jaw. A screening form (attached) will be used to assess each subject's eligibility for participation.

10.3 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the above populations as subjects in your research unless you indicate this in your inclusion criteria.)

- *Adults unable to consent*
- *Individuals who are not yet adults (infants, children, teenagers)*
- *Pregnant women*
- *Prisoners*

Special populations will not be studied.

11.0 Vulnerable Populations*

11.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

NA

12.0 Local Number of Subjects

12.1 Indicate the total number of subjects to be accrued locally.

The total number of subjects to be accrued locally is 400.

12.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

NA

13.0 Recruitment Methods

13.1 Describe when, where, and how potential subjects will be recruited.

Recruitment will be conducted at Florida State University at least one hour before testing. Potential subjects will be recruited via voluntary responses to flyers posted around campus and responses to approved electronic postings (see Appendix). Flyers will also be posted around local areas (e.g. coffee shops, restaurants). Additionally, flyers will be given to participants who have volunteered for similar studies. (A paper flyer will be given to participants who have volunteered for similar studies after they have completed the study. These participants will have completed a study in a lab at Florida State University that uses similar methods to us and has agreed to hand out flyers for our studies to their participants). Volunteers will email or call a trained research technician who will screen the subject by the stated criteria. Potential subjects will be instructed to meet either in the Nee lab in the Psychology Building, Hajcak lab in the Psychology Building, or the MRI facility at the College of Medicine. All of these are private and secure locations requiring key card access.

13.2 Describe the source of subjects.

The source of subjects will be from Florida State University or the local community as long as subjects are eligible based on inclusion and exclusion criteria.

13.3 Describe the methods that will be used to identify potential subjects.

The methods used to identify potential subjects include the inclusion criteria and “no” responses to MRI screening questions.

13.4 Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

Materials to recruit subjects include an online advertisement and recruitment advertisements posted throughout Florida State University. These documents are attached, along with a sample recruitment email response from a researcher.

13.5 Describe the amount and timing of any payments to subjects.

Participants will receive $15 per hour or credit hours associated with the undergraduate Psychology course. Paid participants may also receive a performance-based bonus as incentive to perform the task to the best of their ability. Such incentives will only be available to paid participants and will be based upon accuracy and speed on the tasks and will tend to total $0-$5 per hour. In the event of a multisession study, paid participants may also receive a completion bonus. Participants that withdraw from the study prior to completion will receive prorated compensation (either monetary or credit hours) commensurate with the duration of participation. Lastly, monetary compensation or credit hours will be awarded once the study is complete, or after the subject withdraws from the study.

14.0 Withdrawal of Subjects*

14.1 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

Anticipated circumstances under which subjects will be withdrawn from the research without their consent include inattentiveness, damage to research equipment, clear misunderstanding of task instructions, and inappropriate behavior such as yelling or swearing.

14.2 Describe any procedures for orderly termination.

NA

14.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

Procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection, include appropriate compensation for their time and safekeeping of their data in appropriate records. Identifying information will be retained in digital format. Digital information will be stored on password protected local machines, or on secure cloud based services such as Google Docs also requiring a password.

15.0 Risks to Subjects*

15.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility

of the risks. Consider physical, psychological, social, legal, and economic risks.

Risks for the study include:

- Frustration from poor performance on the task, fatigue, or eye-strain
- Probing for personal or sensitive information in surveys, interviews, or questionnaires.
- Risks from MRI:
    - Magnetic field attracting ferromagnetic objects. There is a potential risk of the main magnet field attracting ferromagnetic/metallic objects towards the magnet.
    - Claustrophobia. The magnet is a small enclosed space that can induce feelings of claustrophobia.
    - Noise. The scanner makes a bothersome/loud noise during the course of data collection. This can damage hearing if measures are not taken to protect the ears.
    - Earplug risk. Risk of trauma from the earplugs in cases where participants have cerumen (earwax) accumulated in their ears.

15.2 If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

NA

15.3 If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.

NA

15.4 If applicable, describe risks to others who are not subjects.

NA

16.0 Potential Benefits to Subjects*

16.1 Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits.

No direct benefit.

16.2 Indicate if there is no direct benefit. Do not include benefits to society or others.

No direct benefit.

17.0 Data Management* and Confidentiality

17.1 Describe the data analysis plan, including any statistical procedures or power analysis.

Data analysis will follow standard procedures detailed in the relevant literature including frequentist tests and Bayesian statistics when applicable. Power analyses will be performed on relevant past and/or preliminary data to inform planned sample sizes. If such data are no available, power analyses will be performed based on anticipated effect sizes.

17.2 Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.

The steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission include retaining information in digital format. Digital information will be stored on password protected local machines, or on secure cloud based services such as Google Docs also requiring a password.

17.3 Describe any procedures that will be used for quality control of collected data.

NA

17.4 Describe how data or specimens will be handled study-wide:

- *What information will be included in that data or associated with the specimens?*
- *Where and how data or specimens will be stored?*
- *How long the data or specimens will be stored?*
- *Who will have access to the data or specimens?*
- *Who is responsible for receipt or transmission of the data or specimens?*
- *How data or specimens will be transported?*

NA

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

This section is required when research involves more than Minimal Risk to subjects.

18.1 Describe:

- *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain*

safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

- *What data are reviewed, including safety data, untoward events, and efficacy data.*
- *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).*
- *The frequency of data collection, including when safety data collection starts.*
- *Who will review the data.*
- *The frequency or periodicity of review of cumulative data.*
- *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
- *Any conditions that trigger an immediate suspension of the research.*

NA

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

The steps taken to protect subjects' privacy interests include testing in a private and secure location requiring keycard access. Subjects will be consented and screened individually in a testing room, where he or she will have contact with trained personnel identified in this application. During the consenting process, the participant will only have contact with trained personnel identified in this application.

19.2 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

Subjects will be able to stop or leave at any moment. Additionally, trained personnel will deliver instructions and provide information regarding where to go if they have questions.

19.3 Indicate how the research team is permitted to access any sources of information about the subjects.

The research team is permitted to access any sources of information about the subjects using the digital formats storing subject information. Researchers will need to know the passwords or have access to view the information.

20.0 Compensation for Research-Related Injury

20.1 If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

None

20.2 Provide a copy of contract language, if any, relevant to compensation for research-related injury.

Routinely, FSU, its agents, or its employees do not compensate for or provide free care for human subjects in the event that any injury results from participation in a research project. If you become ill or injured as a direct result of participating in this study, contact your regular medical provider. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be billed. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

21.0 Economic Burden to Subjects

21.1 Describe any costs that subjects may be responsible for because of participation in the research.

NA

22.0 Consent Process

22.1 Consent will be obtained:

- In person, onsite in the Nee lab or Hajcak lab, prior to the collection of data.
- There will be no waiting period available between informing the prospective subject and obtaining consent.
- There will be no process to ensure ongoing consent
- HRP-090 consent will not be used.
- The individuals listed in the application will tell subjects that the purpose of the study is to understand the mental processes involved in retaining information in mind when it is no longer available to the senses, and using retained information to guide behavior. The participants will also be informed of the duration of the experiment and the inclusion and exclusion criteria.
- Additionally, participants will be screened in order to minimize risks associated with fMRI. Screening will proceed in two phases. First, the screening form will be sent to the participant via email (see Appendix). The participant will be asked to respond with whether the answer to any question on the screening form is “yes”. If the response is “yes” to any question, the participant will be excluded. If the participant passes the first phase of screening and remains interested in

participating, the participant will be invited to perform the study. Participants will read the consent form and any questions will be answered. After answering questions, the participant will once again be presented with the screening form. If the answer is "yes" to a given question, the participant may be asked to elaborate. A "yes" response may occur in the second screening, but not the first, if circumstances changed since the initial screening. Steps that will be taken to minimize the possibility of coercion or undue influence.

- Consent discussion will occur prior to data collection. Data collection will not occur until subjects understand the study outlines and protocol.
- Researchers will inform subjects that participation is voluntary and they can leave at any moment.
- Researchers will ask participants questions regarding understanding of the study before proceeding.
- The consenting process will take as long as any subject needs to understand the experiment.
- Steps that will be taken to minimize the possibility of coercion or undue influence include understanding the task and a formal signature on the consent document before proceeding with data collection.

Non-English Speaking Subjects

- NA

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

- *NA*

Subjects who are not yet adults (infants, children, teenagers)

- *NA*

Cognitively Impaired Adults

- *NA*

Adults Unable to Consent

- NA

Adults Unable to Consent

- NA

23.0 Process to Document Consent in Writing

23.1 Describe whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not, describe whether and how consent of the subject will be documented in writing.

Yes, written consent will be obtained.

23.2 If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.

23.3 (If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)"to create the consent document or script.)

A consent document is attached.

24.0 Setting

24.1 Describe the sites or locations where your research team will conduct the research.

- *Identify where your research team will identify and recruit potential subjects.*
- *Identify where research procedures will be performed.*
- *Describe the composition and involvement of any community advisory board.*
- *For research conducted outside of the organization and its affiliates describe:*
  - *Site-specific regulations or customs affecting the research for research outside the organization.*
  - *Local scientific and ethical review structure outside the organization.*

The research team will identify and recruit potential subjects in the Nee lab or Hajcak lab in the Psychology Building at Florida State University. Consent and fMRI screening will occur in the Nee lab or Hajcak lab in the Psychology building at Florida State University. The research procedures will be performed in the College of Medicine at Florida State University. This is where the

MRI scanner is housed. There will be no composition and involvement of any community advisory board.

25.0 Resources Available

25.1 Describe the resources available to conduct the research: For example, as appropriate:

- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
  Much of the student population of Florida State University will be eligible for our studies. This is a large pool from which to draw which will ensure the ability to recruit and test the required number of participants.
- *Describe the time that you will devote to conducting and completing the research.*
  The research will be conducted over the next several years
- *Describe your facilities.*
  The Nee lab and Hajcak lab are equipped with testing rooms with computers designated for testing subjects and privacy for consenting and screening participants. The College of Medicine houses the MRI scanner and eye tracker where participants will perform fMRI experiments.
- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*
  A first aid kit is available at the TMS suite Emergent medical care is available through standard sources (e.g. 911).
- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*
  All persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions by completing the Human Subjects Research training offered by CITI and shadowing trained researchers.

26.0 Multi-Site Research*

*26.1 Study-Wide Number of Subjects**
If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

NA