**Creating a New IRB Protocol and Requesting an Amendment to an Existing Protocol**

The first question to ask yourself when creating a new IRB protocol is: Do I actually need a new IRB protocol? That’s because in many cases we already have an existing protocol in the lab that your study fits under. The current lab protocols are categorized by methods: 1) Behavioral, 2) fMRI , 3) TMS, and 4) TMS-fMRI. Unless your new study is drastically different from the type of information in existing protocols you won’t need to create a new one, and may only need to submit a modification (see request an amendment section) or do nothing at all but be added to a protocol.

If you are new to the lab you need to ask Doby to add you to the labs existing protocols so that you are officially allowed to handle data associated with them and also have access to the protocols on IRBWise if you need to submit modifications.

**Steps to create a new IRB protocol:**

1. Go to <https://gtapps.gatech.edu/irb/> and log in with your usual GT username and password. If you come to a page with a lot of text just and don’t see protocols just click the IRBWise logo in the top left part of the screen.

2. Now you should be on a page with 2 tabs: alerts, my protocols and my account. Click on my protocols and you will see the lab protocols you have been added to.

3. In the top right corner of the screen click on New Protocol. Alternatively, in the top right corner there is a drop down menu Tasks, select Submit New Protocol.

4. Follow instructions at the top and fill out the form, not filling out any irrelevant sections. At the end of this wiki you will find an example of some of the written sections for this form. If you have any questions about how to fill out this form ask a lab mate who has experience with IRB’s or ask Doby directly.

5. When you are done choose the option to send to PI (Doby) before submitting.

**Steps to request an amendment:**

1. Go to <https://gtapps.gatech.edu/irb/> and log in with your usual GT username and password. If you come to a page with a lot of text just and don’t see protocols just click the IRBWise logo in the top left part of the screen.

2. Now you should be on a page with 2 tabs: alerts, my protocols and my account. Click on my protocols tab and choose the correct protocol you want to request an amendment for. Then in the top right corner there is a drop down menu Tasks, select Request an Amendment.

3. Fill out the form and choose the option to send to PI (Doby) before submitting.

**Example of some of the written sections of new protocol form:**

**Protocol Description:**

Previous research on the topic of sensory perception has shown that our sensitivity for the detection and discrimination of sensory cues can change according to their ecological significance (i.e. emotional content). This is especially relevant in the context of threat processing, where the ability to discriminate between sources of threat and safety is critical for modulating adaptive behavior. Threat processing can be examined experimentally using the well-established Pavlovian conditioning paradigm, where participants are exposed to conditioned stimuli that either predict an aversive outcome or reprieve from that outcome. The mechanisms that modulate changes in perceptual decision making associated with emotional content, and the contexts that determine whether perception of a threat stimulus is enhanced or impaired, are still poorly understood. One of the most fruitful approaches in understanding the mechanisms behind visual perception in humans is the use of function magnetic resonance imaging (fMRI). fMRI is a noninvasive technique that measures brain activity by detecting changes in blood flow. In the proposed studies, we will use fMRI to examine how the emotional content of a stimulus (i.e. sensory cues that signal safety or threat) influences visual perception at neural and behavioral levels in healthy individuals. A central symptom of many anxiety disorders is the tendency to react fearfully to events or objects that are relatively benign due to a distortion in the way these items are perceived. As such, the findings will clarify the typical function of a key mechanistic component that becomes dysregulated in a wide variety of economically and socially costly anxiety disorders.

**Research Design Description:**

Participants will come in for single session lasting up to 2.5 hours in which they will complete tasks on visual perception in the MRI environment. They will be given a detailed explanation of what to expect during the study, and will then be asked to sign a consent form. They will then answer demographic questions (e.g., age, handedness, etc.) and one questionnaire measuring trait levels of anxiety. 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 (15 min). If there is any concern about claustrophobia, participants will be encouraged to try the simulator environment at CABI before entering the MRI scanner. If they are uncomfortable with the enclosed environment (at any time), they can exit the study and receive compensation for their time. Before entering the MRI environment participants will complete a short practice session of the tasks. After being positioned in the scanner by the technologist, a physiological monitoring device will be applied to the finger (5 min). The technologist will acquire initial calibration scans (5 min), followed by a structural image of the head (5 to 10 min). The remaining time in the scanner will be used to collect functional imaging data while subjects perform the tasks. First, the subjects will complete the aversive conditioning phase where they view the conditioned stimuli (e.g. geometric patterns/gratings, moving dots, faces, pictures depicting emotional content etc.), some of which will be paired with an aversive sound. Specifically, in the conditioning phase, one conditioned stimulus (the CS+) will be paired with an aversive human scream. The other conditioned stimulus will serve as a safety cue (the CS-) that is never paired with the loud scream. Safety is operationalized as the absence of an aversive outcome. Use of a loud human scream as the aversive outcome is standard in the field of aversive conditioning, and is, in fact, the paradigm that is preferred for use with children and adolescents (e.g. Britton et al., 2013; Glenn et al., 2012) in lieu of the electric shock paradigm often utilized with adults (for a review see: Lonsdorf et al., 2017). Participants will receive explicit instructions that they will hear an aversive sound that will co-occur with certain stimuli. The conditioning phase will consist of 24 CS+ trials (followed by the aversive sound) and 24 CS- trials (without the aversive sound) in pseudo randomized order. In some cases, the conditioning phase will last for longer but will have half the number of CS+ presentations paired with the aversive sound. In this case the conditioning phase will have 24 CS+ trials (with the aversive sound), 24 CS+ trials (stimulus presented without the aversive sound) and 48 CS- trials (without the aversive sound). Prior to entering the scanner, participants will be given a short practice session including truncated conditioning and perceptual tasks. They will also be given the necessary screening forms and prepped for the MRI environment (30 min pre scanner). All tasks involve viewing stimuli on a computer screen and making a decision while being scanned using MRI. To ensure that the associations learned during the conditioning phase do not extinguish, zero to four presentations of the aversive sound will be administered during the perceptual task. The final phase of the experiment includes 24 extinction trials where participants are exposed to both the CS- and the CS+ without the aversive sound. This is done to extinguish the learned association between the CS+ stimulus and the negative outcome. Postscan debriefing will include the description of the design and rationale. Participants will be encouraged to ask questions or make any comments regarding the study and will be given the contact information for the research team in case any questions may arise. Response time and accuracy data will be recorded during the task. The perceptual task will involve judging the identity of the conditioned and other visual stimuli (which will include geometric patterns/gratings, faces, pictures depicting emotional scenes, houses, colors, moving dots, etc.) or auditory stimuli (which will include pure tones that could also be masked by noise). For example, subjects will be shown black and white gratings with different orientations (one orientation associated with the CS+ and another with the CS-) that are embedded in varying degrees of visual noise and will be asked to respond with the orientation direction. In some tasks, participants may be given additional instructions such as, for example, providing a confidence rating on the judgment that they performed, modulating the speed of their response (so that they emphasize speed of response on some trials and accuracy of response on other trials), or taking into account an additional cue about the stimulus (such as, "on this trial, the grating will have clockwise tilt with 75% probability"). For example, a particular task may involve presenting two gratings (the CS+ and CS- stimuli), one to the left and one to the right of fixation, while cueing one of them. Participants will be expected to maintain fixation in the middle but attend covertly to the cued grating. We will investigate participants' accuracy and confidence level for the cued and uncued gratings in order to better understand how the emotional content of a stimulus changes the objective and subjective components of perception and attention. We will also relate these measures to the fMRI data from the scanner, in order to understand the brain mechanisms that allow people to perceive stimuli with differing ecological significance and modulate their normal perceptual experience by using attention and other topdown processes.

**Duration of study:**

Participants will come in for a single session lasting up to 2.5 hours. They will be in the MRI scanner for no more than 90 minutes.

**Data collected:**

Data collected will include structural and functional MRI, response time and accuracy data on the cognitive tasks, and physiological measures such as heart rate/pulse and respiration during the scan. We will also administer one questionnaire measuring state and trait anxiety levels, as well as standard information about demographic and health information using the approved CABI forms.

**Benefits:**

The study will not directly benefit the participants. However, it will help us deepen our understanding of the mechanisms that modulate changes in perception associated with emotional content in the human brain. fMRI subjects will receive a picture of their brain, which many consider a benefit. All subjects may benefit from the knowledge that they are contributing to the understanding of the influence of emotional factors on visual perception, providing a basis for the comparison of typical mechanisms with the atypical functioning found in a myriad of anxiety disorders.

**Risks:**

We believe this study poses minimal risk to the participant. All of the assessment instruments and stimuli used are consistent with mainstream research practices in research on the neuroscience of emotion. Some of the auditory (aversive noise during conditioning) and visual stimuli (pictures of emotional scenes e.g. crying child, scenes of war, aggressive animals) are by definition unpleasant for most people. However, in our experience, people generally only have mildly aversive reactions to these types of stimuli, since they are clearly artificial and presented in the context of a professional research laboratory (Low Risk). The intensity and duration of the aversive auditory stimuli (human scream) will be well below a level that poses any risk for hearing damage. Additionally, the conditioning phase will be programmed so that no more than 3 CS+ trials (with the aversive sound) will occur consecutively. In order to extinguish the expectation of a negative outcome with a certain stimulus (CS+), the final phase of the experiment will include extinction trials where participants view repetitions of the CS- and the CS+ without the aversive sound. The pictures of emotional scenes are drawn from commonly used research databases and have been used by other investigators in IRB approved research studies conducted throughout the U.S and the rest of the world. Importantly, participants will be told that they can discontinue the task/study at any point for any reason and will be informed of the aversive sound and/or visual component during the consent process.

There is a slight risk for eyestrain and fatigue. To alleviate these, participants will be given the option to rest for 12 min for every 20 minutes of scanning. There is a slight risk for breach of subject confidentiality. To address this risk, information gathered from subjects pertaining to involvement in this study will be accessible only to the investigator and coinvestigators. All research data will be labeled with a research code number. The link between a participant's code number and their identity will be secured, stored separately from the deidentified, coded data, and also separately from consent forms signed by the participant. Any information about subjects or their treatment will be handled in a confidential manner consistent with other hospital medical records. At the termination of this research study, any records that personally identify participants will remain stored in a locked filing cabinet within a locked office for archival purposes. MRI poses several additional risks. 1) Magnetic field attracting ferromagnetic objects: There is a potential risk of the main magnetic field attracting ferromagnetic/metallic objects towards the magnet. 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: If this occurs at any time during their participation, the subject will be removed from the magnet immediately, debriefed, and given full study compensation. 3) Bothersome/loud scanner noise: All subjects will be required to wear ear protection shields 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. Subjects will be monitored for the duration of their participation in this study. The investigators of the study will promptly report to the IRB any expected adverse reactions of serious severity or unexpected adverse reactions of moderate or greater severity that are associated with the research and observed in conjunction with the conduct of this research study. Fatal or lifethreatening adverse reactions associated with this study will be reported to the IRB within 24 hours. Nonfatal or nonlifethreatening adverse reactions associated with this study will be reported to the IRB within ten days. Any major disputes between the research investigators and a research subject, or between research investigators, will be promptly reported to the IRB. The study investigators will closely monitor all participants for any such adverse events.

**Analysis:**

F tests and t tests will be carried out to compare participants' performance across different conditions in the study such as for cued and uncued stimuli. The functional MRI data will be analyzed in several ways: (1) using standard subtraction techniques, we will identify regions of the brain that are activated more during certain tasks, (2) using connectivity techniques, we will test how the strength of connection between different brain regions changes as a function of the task that participants are doing, and (3) using state of the art techniques that allow for the identification of fine grained information from the pattern of multiple voxels, we will attempt to uncover information that is present in the MRI signal that could not be revealed by standard subtraction techniques.

**Justify sample:**

A total of 100 participants are needed to ensure adequate statistical power for each study performed using the startup funds. Our past experience indicates that fMRI data from approximately 20% of subjects are unusable due to a variety of reasons, including 1) task noncompliance, 2) excessive movement in the scanner, which makes the data too difficult to interpret, 3) claustrophobia, and 4) self termination. In addition, each particular study generally requires between 20 and 30 participants in order to ensure sufficient statistical power. Thus, we expect to recruit roughly 100 participants over the given period.

**Inclusion criteria:**

Participants should be between 18 and 40 years old, have normal or corrected to normal vision.

**Exclusion criteria:**

Participants will be required to have corrected or normal hearing since auditory tasks are required. Participants must also 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, or illicit drug use.

**Protection:**

Vulnerable populations will not be specifically targeted in any of these studies. If a person from a vulnerable population is interested in participating, they will receive all the protections of other participants. In addition, nonnative speakers will receive additional verbal instructions as needed, and it will be emphasized to trainees that they do not need to participate in the study as part of their involvement in the lab. Every participant will be compensated in the same manner.

**Recruitment:**

Georgia Tech student subject pool, word of mouth, and flyers will be used. The study description for the subject pool, the script for recruitment by word of mouth, and the flyer have been uploaded the attached document section.

**Compensation:**

Participants will be given $20 per hour of participation. If they do not complete the study, they will still be compensated for the amount of time that they spent.

**Consent:**

Participants will be given the attached consent form to read and sign before the beginning of the study. The consent will be obtained by a member of the research team listed on this protocol. The consent will always be written. Participants will be encouraged to read carefully the whole consent form and ask questions about any issues.

**Non-native:**

Non native speakers will only be allowed in the studies if their command of English is

sufficient for them to understand the consent form and study instructions.

**Data management:**

At a minimum, data will be monitored monthly during lab meetings and any unusual events will be recorded. Investigator experience with research methodology ensures that the data collected will directly address the research questions.

Data will be fully deidentified. Any information that links the deidentified

data back to the participants will be kept under lock and key at all times. Participants' names will not appear on any of the data forms. All research data will be labeled with a research code number. The link between a participant's code number and their identity will be secured, stored separately from the deidentified data, and also separately from consent forms signed by the participant. The link will be accessible only to the investigator and coinvestigators listed on this protocol. However, the deidentified data will be shared freely with fellow researchers under the common expectation for openly sharing deidentified behavioral and fMRI data. The fMRI data are not sufficient to identify the person scanned. However, the anatomical MRI images contain enough information to identify participants. Therefore, we will alter these images using a standard "facestripping" procedure before sharing any anatomical images. Only the overall gender composition and group age statistics will be revealed about the participants in the study, which will not be sufficient to identify any participant personally.

All research data will be labeled with a research code number. The link between a participant's code number and their identity will be secured, stored separately from the deidentified data, and also separately from consent forms signed by the participant. The link will be accessible only to the investigator and coinvestigators listed on this protocol.

All data will be deidentified. Documentation will be retained for 3 years after the study is completed. After that time, the link between a participant's code number and their identity will be destroyed.