***INSTRUCTIONS: Delete this section before sending to the IRB office with your application.***

*The language of this consent form should be modified as appropriate for your study, using tracked changes. Provide relevant information in the sections below,* ***replacing italicized directions/guidance (anything in this font color) with information specific to your study****, and removing any directions that do not apply to your research.* ***Provide a tracked changes version and a clean version of this form with your IRB submission****.*

Cornell Magnetic Resonance Imaging Facility

Consent Form

I am asking you to participate in a research study. This form is designed to give you information about this study. I will describe this study to you and answer any of your questions. Please read this form carefully and ask any questions you may have before agreeing to take part in the study. I will give you a copy of this form to keep with you.

Project Title:*[Provide the title of the study]*

Contact person: *[Name], [Email], [Phone Number]*

Principal Investigator: *[Name], [Department], [Phone]*

;

**KEY INFORMATION**

Provided is a short summary of this study to help you decide whether you want to participate. More detailed information is listed later in this form.

* The purpose of the research is Click here to provide a brief summary;
* You will be asked to Click here to provide a brief summary of study procedures;
* Your participation in the study is expected to take Click here to provide length of time;
* Click here to describe reasonable, foreseeable risks or discomforts to the prospective participant;
* Click here to describe any expected benefits to the prospective participant or others; if none, state as such and mention any benefit to society; and
* Your participation in this research is voluntary. Click here to provide any additional information about the voluntary nature of participation, and/or to describe any alternatives to participating in this study.

**DETAILED INFORMATION**

**What the study is about:** You are being asked to participate in a research study conducted by *[principal investigator’s name]* of Cornell University. The purpose of this research is *Click here to add content.* Your participation will help us gain knowledge about *Click here to add content*

**What we will ask you to do:** If you decide to participate in this study, you will be asked to do specific tasks. You may not be eligible to participate in the study if you cannot meet the criteria described below. You may choose to withdraw from the study at any time during these procedures.

You will fill out a safety screening form to assess whether there are any factors which could affect whether you may enter the magnetic resonance imaging (MRI) room. You may also be asked to fill out study specific background questionnaire(s). You will then be asked to remove any metallic objects you may be carrying (for example, wallets, watches, earrings or piercings) and possibly to change clothing into a gown that we will provide (if deemed necessary because of large zippers, etc.).

If you meet the eligibility requirements, then you will be asked to enter the MRI scanner, which is a large, tunnel-shaped machine. MRI does not involve any ionizing radiation (i.e., does NOT involve exposure to radioactive materials). MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the inside of the body. You will first be asked to lie still on a table outside of the MRI scanner. Your *[head or other body part, as appropriate]* will be kept still with padding so it cannot move; you should, however, be comfortable at all times. Once you are comfortable, the table on which you are lying will be moved inside the MRI scanner. Make sure to stay as still as possible (no sneezing, scratching, stretching, etc.). **You will be able to communicate with the scanner operator and/or researcher at any time, and you will be in view of the researcher.** An alarm squeeze-ball will be provided to you to alert the scanner operator at the control console if you need to communicate to them directly at any time. This will alert the scanner operator to pause the scan and speak with you immediately.

*[****Describe the use of other approved peripheral devices here****. If applicable, include:*

*The scanner's built-in optical pulse oximeter will be placed around your fingers and the pneumatic respiratory belt will be strapped around your upper abdomen, respectively, to record cardiac and respiratory waveforms during functional scans. You will hold a button box in your right hand to make manual responses during the task.]*

*[****Describe non-MRI-related study methods here.*** *If applicable, include:*

*Please answer all questions or complete all tasks if you can, and to the extent you are comfortable. Even if you are uncertain about a question or task, we prefer that you record a response rather than leave it blank]*

Your participation in this study is expected to take a total of approximately *Click here to add #* hour(s), including *Click here to add # of minutes/hours* in the scanner.

**Ineligibility for participation:**

**An MRI safety screening will be completed prior to MRI scanning. If you have a contraindication to MRI, you will not be able to participate in the MRI scanning portion of the study, but may be eligible to participate in other parts of the study.**

***Study-Specific Enrollment Criteria:***

*[For Example: Because of the effects of medication and mental illness on the brain, you will be asked a series of questions about whether you are presently taking or have ever taken medication for depression, anxiety, and other forms of mental condition (e.g., schizophrenia). You will be asked about your history of neurological and psychiatric illness. If you have previously taken such medications or are currently taking any you should not participate in this study. If you feel uncomfortable in discussing such information, you should not participate. You do not need to tell us why you have chosen not to participate.]*

**MRI Risks**: MRI is a noninvasive and generally safe procedure. We know of no risks and adverse effects resulting from exposure to the magnetic fields and radio signals used in this study. Potential risks associated with the MRI procedures are rare and precautions to minimize these risks are detailed here.

Collision Hazard. The magnetic field near the magnet of the MRI scanner is strong enough to attract certain metals, such as steel, with great force, causing them to fly down the bore of the magnet. We have established a security zone around the magnet and all people are required to remove all metal objects from their clothing prior to entering the security zone.

Quench Hazard. The MRI scanner uses cryogens (liquid nitrogen and liquid helium) to maintain the magnet. In the extremely unlikely event that the magnet quenches, these liquids will rapidly become gaseous. The MRI room has an emergency vent to insure against harmful effects if this occurs, but if the vent were to fail, the nitrogen and helium gases could fill the magnet room and cause dizziness and fainting if breathed for more than a few moments. However, the scanner operator will immediately be aware of the quench and provide assistance to anyone inside the magnet room.

Radio Antenna Effects. If metal wires or electrodes are attached to a person being imaged, radio signals from the MRI scanner may induce sufficient heat in the wires to cause burns where the wires or electrodes contact the skin. The scanner operator will inspect and arrange any such leads to minimize the risk of induced heating.

Biological Hazards. To date, no harmful biological effects have been demonstrated at the magnetic field strengths and exposure times utilized by the MRI system, and the likelihood of any significant biological effect is considered to be extremely low.

Nerve Stimulation. When undergoing certain types of imaging with hands clasped, some individuals may experience minor nerve stimulation, such as muscle twitches and “tingling” sensations, due to rapid switching of magnetic fields. The subject will be instructed not to clasp their hands if this type of imaging is

used. There are no known risks associated with these effects. The magnetic fields created by devices used in our research are within the limits specified by the U.S. Food and Drug Administration (FDA).

Fear in Narrow Spaces. The narrow tunnel of the MRI scanner is confining and can be scary for those people afraid of small spaces. If you feel frightened when getting into the scanner tunnel, you may elect not to continue to participate in the study.

Hearing Protection. The MRI scanner produces tapping sounds during operation, which may reach objectionable levels during some types of imaging. To minimize any discomfort, you are provided with disposable earplugs that suppress external noise levels but do not eliminate voice communication with the scanner operator.

Reactions to ECG Electrodes. There may be skin irritation, redness or chafing associated with ECG electrode patches. The skin area to be applied with electrodes will be cleaned with alcohol pads. The skin discomfort disappears quickly when the patches are removed.

**Other Study Risks:** *[Describe non-MRI-related study risks and protections here, or say none are expected]*

**Benefits: There are no direct benefits to you associated with participating in research that involves MRI; however, your participation may help us learn about** *Click here to add content***.**

**Compensation: *[****Indicate whether the participant will receive compensation or payment for being in the study and any conditions for compensation, including whether or not any payment will be received if the participant withdraws before completing all study procedures. If participants will not receive any compensation, state that there is no payment for taking part in the study.]*

**Confidentiality: We will keep all information regarding your** participation in this study confidential, and will not store your identifying information with your data or images. Servers and computers where the data and images are stored are password protected. Any paper surveys will be kept in locked rooms. Your images and data will be assigned a code number, which will be used in place of your name to allow linkage of data if follow up is necessary. The list connecting your name with this number will be kept in a locked room. We will review our data storage requirements periodically to determine if data need to be discarded. We may retain your de-identified data for future research. Only people authorized by the Principal Investigator will be granted access to the data. We may also need to collect some identifying information for administrative purposes (i.e., for study compensation, Cornell parking services, and/or an unexpected finding report), but this will not be linked to the research records. In the unlikely event of an emergency, we will also need to provide your information to medical and/or emergency assistance personnel. The data will be used for research and educational purposes, such as teaching, publications, and/or presentations and may be viewed by students, other trainees, and professional colleagues. In any sort of report we make public, we will not include any information that could reasonably identify you.

The MR images are acquired without any identifying information. All MR images acquired in this research study will be kept by the CMRIF in strict confidentiality in the same manner as clinical MRI images at Weill Cornell Medical Center. Images will be viewed and stored using the same hardware equipment as that used in clinical studies which have certified protection. Additionally, image data will be stored on secured and password protected servers within the CMRIF research facility. No identifiable subject information is saved on the image header or these data servers. All file transfers will take place over secured CU or WCM computer networks and all workstations are equipped with password and firewall protection to prevent unauthorized access.

*[If the activities in the MRI facility involve an online survey, include the following:*

*We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet. Despite the precautions that we will take to safeguard the data from unauthorized access, please note that email and Internet communication can never be entirely private or secure.]*

*[If recruiting students from the Ithaca City School District, include the following:*

*In accordance with Ithaca City School District (ICSD) Guidelines, we will require that members of the research team notify ICSD administration (both building and district level) immediately if, in the course of responding to survey/interview questions, any study participant who is currently enrolled in the ICSD discloses information that provides reasonable cause to suspect child abuse or maltreatment.]*

We ask that you input your contact information into a secure database to be stored at Weill Cornell Medicine. Access to this database is highly restricted and maintained by the CMRIF Director and Advanced Image Processing Lab (IDEAL lab) at the Weill Cornell Medicine Department of Radiology (i.e., the “honest broker”). Only the “honest broker” will have access to decode this database and will only be accessed by the “honest broker” to identify you in case there is a suspicious finding on your MRI scan for which you will be notified. You can choose to not input your contact information. If you choose not to input your contact information, you may not be able to be notified in case there is a suspicious finding on your MRI.

**Incidental and Unexpected Results:** All MRI scans will be interpreted by a qualified Weill Cornell Medicine Department of Radiology physician. Please note that this research MRI exam is not optimized for clinical use and may be limited for clinical or diagnostic interpretation. The Principal Investigator will be informed of any suspicious results. MRI studies may reveal incidental findings that may or may not have clinical importance. It is the responsibility of the PI to communicate the results to you. If further work-up and/or treatment for these incidental findings is determined to be necessary, there may be risks and cost associated with those medical tests and/or treatments. You will have full responsibility for such costs and you have agreed to accept the risks associated with those additional tests and/or treatments if your physician believes they are necessary and if you decide to have them.

The scan done for this study is a research scan and not a clinical scan, and involves no intent to perform medical diagnosis.

Taking part in the study will require agreeing to be informed of a suspicious incidental finding that is discovered during participation. Please initial below if you agree to be informed of suspicious incidental findings discovered during the course of the research scans.

**(ACTION REQUIRED)**

Do you wish to input your contact information?

[ ]  Yes, I will input my contact information so that I can be contacted for a suspicious finding.

[ ]  No, I do not wish to input my contact information. I understand that I may not be able to be contacted if there is a suspicious finding on the MRI.

 **Your initials \_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_.** I agree to be informed of suspicious incidental findings discovered during these scans. I understand that the research team, radiologist, and the University are not responsible for follow-up examination or treatment. The decision as to whether/or not to proceed with further examination or treatment resides with me. I and/or my insurance company will be fully responsible for payment of follow-up examination or treatment. Life, medical or long-term disability insurance may be affected whether or not a finding is ultimately proven to be of clinical significance.

**Data Sharing:** De-identified data from the study may also be shared with the research community to advance science and health or to meet sponsor or journal requirements. We will remove or code any personal information that could reasonably identify you before data are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, it is possible that at some time in the future novel methods could be used to identify individuals by specific features of the brain, so we cannot guarantee anonymity of your personal data.

**May we contact you again?** We often like to follow up with our participants in order to complete surveys or participate in new experiments. All identifying information will be kept strictly confidential following the procedures for confidential data storage outlined above.

[ ]  Yes! You may keep my contact information to contact me again for follow-up questions or future studies.

[ ]  No, I do not wish to be contacted again, even to answer a question. I understand my identifying information will be kept, following the confidential storage procedures outlined above.

**Taking part is voluntary**: Taking part in this study is completely voluntary. If you decide not to take part or not to complete the study, it will not affect your current or future relationship with Cornell University. If you decide to take part, you are free to withdraw at any time.

**If you are injured by this research**: Emergency medical care is not available on-site. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Cornell University. If you think that you have suffered a research-related injury, contact *[principal investigator’s name]* right away at *[insert phone number]*.

**Withdrawal by investigator, physician, or sponsor**: The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

**If you have questions**: The main personnel conducting this study is *[principal investigator’s name]*, a *[insert role, e.g. professor]* at Cornell University. Please ask any questions you have now. If you have questions later, you may contact the research assistant *[research assistant’s name]* at *[email address]* or at *[phone number]*, and the principal investigator *[principal investigator’s name]* at *[email address]* or at *[phone number]*.If you have any questions or concerns regarding your rights as a subject in this study, you may contact the Cornell Institutional Review Board (IRB) for Human Participants at 607-255-6182 or irbhp@cornell.edu. You may also report your concerns or complaints anonymously through EthicsPoint online at [www.hotline.cornell.edu](http://www.hotline.cornell.edu) or by calling toll free at 1-866-293-3077. EthicsPoint is an independent organization that serves as a liaison between the University and the person bringing the complaint so that anonymity can be ensured.

You will be given a copy of this form to keep for your records.

**Statement of Consent**: I have read the above information, and have received answers to any questions I asked. I consent to take part in the study.

Your Signature Date

Your Name (printed)

Researcher Signature Date

Researcher Name (Printed)