



## Suggested Content and Language for Informed Consent Forms

The following list represents topics that you may wish to address when preparing your informed consent forms. The language and format shown here is consistent with official university policy and may be adopted and/or amended to suit individual researcher needs and concerns.

### 1) **Research Description**

The goal of these experiments is to investigate how the brain functions.

<Insert your study rationale and/or description here>

You are being asked to participate because you are a normal healthy adult. Your participation allows us to determine basic principles of brain organization. The data obtained through your participation may be included with that from other subjects as part of a scientific study to appear in the peer-reviewed literature.

### 2) **Data Collected**

Several types of Magnetic Resonance Imaging (MRI) data may be collected as part of this investigation.

<Insert general description of procedure here to include estimated time in scanner>

This procedure will include one or more of the following MR protocols: <Add or delete protocols as necessary>

- i. Low-resolution "scout" image(s) for use in aligning the scanner's field of view (~10 seconds each)
- ii. High-resolution anatomical image(s) of your brain structure for use in data processing (~10 minutes each)
- iii. Functional images that track brain activity during behavioral task performance (~15 minutes each)
- iv. A diffusion-weighted image for assessing white matter fiber orientation and brain modeling (~10 minutes)

Overall these procedures should take approximately <Insert approximate time in minutes> minutes of your time.

### 3) **Statement of Health Risks**

The risks of participation in the MRI scanning procedure are minimal. Special considerations are made for the following:

- a. **Metal:** The MRI machine produces a constant, strong magnetic field (3 Tesla). If you have metal implants and clips within your body they may be influenced by the magnetic field and shift in position. If you have such implants you must inform us and withdraw from the study. Metal earrings and necklaces also must be removed prior to the study. If you have shrapnel, surgical implants, or other pieces of metal in your body that cannot be removed, you may not be able to participate in studies involving the MRI scanner. In many cases, people having dental appliances in their mouths can participate but should notify the investigator to be certain.
- b. **Induced Currents:** Due to changing magnetic fields during the course of operation, there is a possibility that you will experience a localized twitching sensation. This is not unexpected and should not be painful.
- c. **Hearing:** Functional MRI scanning produces a loud (92 dB) high frequency tone that can cause hearing damage if appropriate hearing protection is not used. Adequate hearing protection in the form of foam ear-plugs will be provided and required.
- d. **Claustrophobia:** The functional scanning coil fits closely around your head, so if you feel anxious in confined spaces, you may not want to participate. If you decide to participate, and then at a later time decide to discontinue, just let us know and we will stop the experiment.
- e. **Anxiety:** You may also experience some boredom and/or anxiety from being required to lie still for the duration of the scan.

<If the study will use contrast media, insert the following>

If you have had a previous reaction to Gadolinium-based contrast agents or a history of severe allergies, please notify the operator/investigator.

**Initial here to indicate that you have read, understand, and agree with all statements made on the screening form and that you do not have any contraindications \_\_\_\_\_**

**4) Participant Injury**

In the unlikely event that you are injured as a result of your participation in this study, the research staff will assist you in obtaining appropriate medical treatment. However, you will be responsible for any costs associated with medical treatment.

**5) Incidental Findings**

These procedures are carried out purely for experimental purposes. The MRI scans that are acquired in this study are not the same as those acquired during a clinical examination as requested by a Medical doctor. Therefore they are not useful to investigate any brain abnormalities. Furthermore, the investigators who will analyze these images are not medical doctors and are not trained to evaluate these scans. It is possible however that a brain abnormality may be noticed. If this happens you will first be contacted by the principal investigator and shown the abnormality. You will then be referred to a clinician whom you may consult with regarding the nature of the abnormality.

Initial here to indicate your acceptance of this incidental findings agreement \_\_\_\_\_

**6) Participant Compensation**

You will receive experimental credit for participation in the study based on the total number of hours you devote to this study (e.g., One hour of credit per hour of participation). There are no anticipated costs to you for participating in this study. Once you have completed the MRI study, you will receive a copy of your MRI scan on CD ROM. If you are not a student, you may be paid for your participation using the following guidelines:

At the rate of: <insert your hourly rate here>  
Travel reimbursement: <if needed, insert travel stipend>

**7) Participant Identification**

You will be identified on all research records solely by a number, ensuring confidentiality of all data. Any information that is obtained in connection with this study and that could identify you will remain confidential and will not be released or disclosed without your further consent, except as specifically required by law. If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

**8) Data Confidentiality**

All information you have provide will be kept confidential except as required by law. Your name will not be used in any publication that may result from this study. The Office of the Committee for the Protection of Human Subjects may request access to this form to ensure procedures designed to protect research participants are being properly followed. The manufacturer of the MRI scanner (Siemens) may request the use of images acquired in this study, although they will not have access to the names of any subjects. Your data may also be shared with other researchers around the world or with a publicly available data archive. In such cases, every reasonable effort will be made to remove identifiers from the data that would indicate any connection to you (e.g. the removal of your name, address, SSN, etc.).

**9) Expiration Date on the Viability of the Collected Data**

In addition to the MR data gathered during this study, data concerning your age, gender, handedness, task performance, etc. will also be collected. All data gathered from this study will be maintained by the investigator for three years or as required by journal, federal or state regulation.

**10) Voluntary Withdrawal**

Participation in this study is voluntary. You are free to withdraw your consent and discontinue participation in the study at any time throughout the study without negative consequences to your grades or relationship with USC.

Initial here if you would prefer to withdraw from this study for any reason \_\_\_\_\_

**11) Investigator Contact Information**

This research is being conducted by faculty and researchers of the University of South Carolina. For further information about this study, you may contact:

Investigator or Contact Person(s): <investigator name or contact here>  
Department or Affiliation: <department or affiliation here>  
Phone Number: <investigator or contact phone number here>  
Email Address: <investigator or contact email address>

If you should have any questions concerning your rights as a research subject, you should contact Thomas Coggins, Office of Research Compliance, University of South Carolina, 29208, (803) 777-4456.

**12) Participant and Witness Signatures**

Your signature indicates that you have read this informed consent form.

Participant Signature \_\_\_\_\_ Date \_\_\_\_\_

Witness Signature \_\_\_\_\_ Date \_\_\_\_\_