**UNIVERSITY OF SOUTH CAROLINA**

**CONSENT TO BE A RESEARCH SUBJECT**

 **[Study Title]**

*Instructions are in italics. These statements should be removed on the actual consent form. Blue font should be changed to black on the actual consent form.*

**KEY INFORMATION ABOUT THIS RESEARCH STUDY:**

You are invited to take part in a research study being done by (insert PI name). I am a (insert professor/doctoral candidate/graduate student) in the Department of (insert department name), at the University of South Carolina. The University of South Carolina, Department of (…), (or insert study sponsor name) is sponsoring this research study. The purpose of this study is to (insert description of purpose). You are being asked to take part in this study because you are (. . .). This study is being done at (insert name of site or sites) and will have (insert number of) subjects.

Below is a short summary of this study to help you decide if you want to be in this study. More details about this study are listed later in this form.

*The regulations require that each consent have a “concise summary” that provides information that a reasonable person would want to have in order to make an informed decision about whether to participate.*

***Summary must include the following:***

*- The expected duration of the subject’s participation and the procedures to be followed in the research;*

*- Reasonably foreseeable risks or discomforts;*

*- Benefits to subjects or others that may be reasonably expected from the research; and*

*- Appropriate alternative procedures or courses of treatment, if any that might be advantageous to the prospective subject*

*For complex studies, this section may be longer and introduce areas that will be covered in greater detail later in the form. Studies involving simple procedures and minimal risk may cover many required elements of informed consent in this section and are not required to be repeated on other sections of the consent form (e.g. if all risks can be covered succinctly in this section, no separate risk section is required.)*

 **PROCEDURES**:

*Outline in chronological order (i.e. the order in which the procedures will be encountered by the subject) the procedures to be followed. Using simple terms, give sufficient detail for the subject to understand the full extent of his/her participation.*

If you agree to be in this study, you will: *(These are examples; use only if applicable to your study.)*

* 1. Be placed in a research group or control group. You do not have a choice about which group you will be placed. *(As appropriate, describe the differences in the group activities.)*
	2. Complete a survey/interview about (…).
	3. Have your discussion/interview recorded to be sure the study team has correct notes about the details you provide.
	4. Have a Magnetic Resonance Imaging (MRI) exam once per week for two weeks. For the MRI exam, you will lie down on a narrow bed, which will then be placed in a tunnel that is 6 feet by 22 inches wide, and open at each end. You will lie still for about one hour, during which time you will hear loud noises. You may feel warm during this procedure.
	5. Provide a blood sample from a vein in your arm. Each sample will be about (insert #) teaspoons; a total of about (insert #) tablespoons will be drawn for the whole study.
	6. Give consent for the study team to review your medical records to gather information about (…).

**DURATION**:
Being in the study involves (insert number of) visits over (insert number of) days/weeks/months. Each study visit will last about (insert number of) minutes/hours.

**RISKS/DISCOMFORTS**:
*Give details of all risks and or discomforts. List risks in order of severity and frequency.

The following are examples of standard language for common risks:*

Focus Groups:
Others in the group will hear what you say and could tell others. The study team cannot promise what you say will be kept private, but they will ask that you, and all other group members, keep what is shared private.

Loss of Confidentiality: *(This is appropriate if dealing with* ***identifiable and potentially sensitive*** *information.)*There is the risk that what you share or your name will not remain private. The study team will take many steps to keep what you share and your name private. Details about those steps are given later in this consent form.

Drug (state drug name):
If you receive Drug XXX, the following side effects are likely (….). These side effects are serious but have occurred in less than (insert number) of prior human studies where Drug XXX was used in about the same doses. If (insert side effects) occur(s), it will be treated by (insert emergency plan), (and you will be taken off the study). Other side effects, which are less severe, but may occur more often, are (insert additional information).

Placebo:
If you are in the group that receives placebo (not the drug), your (insert exact diagnosis) will go without being treated for (insert number of) weeks.

MRI:
Because the MRI machine acts like a large magnet, loose metal objects can cause harm to you and others in the MRI room; thus, items like, key chains or jewelry are not allowed in the MRI room during your exam. If you have a piece of metal in your body, such as a small bit in your eye, clips on a blood vessel, ear implants, spinal nerve devices, or a pacemaker, you will not be allowed into the MRI room and cannot have an MRI.

Having an MRI may cause feelings of claustrophobia and discomfort by the loud banging noises during the test. You will be asked to wear earplugs to reduce the noise and protect your hearing.

Blood Draw:
The risks of drawing blood include brief discomfort from the needle stick, bruising, and infection. Fainting could occur.

DEXA / DXA:
The exposure levels from the DEXA (or DXA) X-ray unit are very low. While the radiation used for the DEXA scan has no observable radiological or biological effect, there is always a risk associated with radiation exposure, even very low exposure.
If you want more information on the exposure levels, contact the research study principal investigator listed on this document.

**BENEFITS**:
Taking part in this study is not likely to benefit you. However, the finding from this study may help people know more about (insert brief explanation, using simple words and being careful not to inflate the importance of the study).

*or:*

You may benefit from taking part in this study by (insert brief description).

**COSTS**:
*Any additional costs that may result from participation in the study must be listed.*

*(Example 1)* There will be no costs to you for being in this study other than any costs related to getting to and from the research site.

*(Example 2)* You will not be charged for any of the study treatments, tests or processes. The costs of Drug XXX, having people give you study drug, blood tests, x-rays, or MRI exams will be covered by this study.

*(Example 3)* The cost related to this study treatment program will be charged to you or your insurance provider; however, because this treatment is experimental (in testing) your insurance provider may refuse to pay for the cost. Your insurance provider may refuse to pay for this treatment program after you have already received your treatment and you will have to pay for your care.

**PAYMENT TO PARTICIPANTS**:
*Using simple terms include amount, payment schedule, and method of payment (checks, cash, gift cards, or course credit). When appropriate payment should be prorated and made as the study progresses and, for long-term studies should not be contingent upon the participant completing the study. If participants are not compensated, then state so.*

You will not be paid for being in this study.

*or:*

You will be paid (insert amount and type of payment) for being in this study. If you do not complete the study, you will receive (insert prorated amount) for each study visit.

**INCIDENTAL FINDINGS:** (*If applicable. MRI is used as an example. Other procedures may yield incidental findings*)
Some MRI scans can detect medical conditions, such as cancer, brain injury, and abnormal blood vessels; however, this functional MRI is carried out purely for experimental purposes and we are not looking for brain disorders. Furthermore, the study researchers are not trained in diagnosing brain disorders; therefore, the researchers are not qualified to offer any medical opinions concerning your scan (good or bad). It is possible that the study researchers will notice something in your scan that appears unusual and/or abnormal, if this occurs, the researchers will inform you of the finding and provide you with a copy of your scan, which you may take to a medical expert for further review and diagnosis. Being told about such a finding may cause anxiety as well as suggest the need for additional tests and financial costs. Any costs associated with clinical follow-up(s) are you and/or your insurance carrier responsibility. **If you do not wish to be informed of this type finding, you should not participate in the study.**

**COLLECTION OF IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS:**

Information about you or your biospecimens (for example, blood, saliva, urine) may be used for future research studies or may be shared with other researchers; however, this only will be done after identifiers linking the information/biospecimens to you are removed. This will be done without further consent from you.

*or:*

Your information or biospecimens (for example, blood, saliva, urine) collected as part of the research study will not be used for future research studies.

**COMMERCIAL PROFIT**: *(If applicable)*

*A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

**RETURN OF CLINICALLY RELEVANT RESEARCH RESULTS**: *(If applicable)*

*A statement regarding whether clinically relevant or personal research results will be disclosed to subjects, and if so, under what conditions.*

**WHOLE GENOME SEQUENCING**: *(If applicable)*

*For research involving biospecimens, include a statement whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*

**ALTERNATIVES**:*(If Greater than Minimal Risk Study, include the statement below. This applies only to treatment studies.)*

If you choose not to be in this study, you could receive other treatment(s) for your (insert exact diagnosis). The standard therapy for (insert exact diagnosis) is (insert standard therapy treatment).

**NEW INFORMATION**:*(If Greater than Minimal Risk Study involving medical treatment, include the statement below.)*

If there are important new findings during the research study that could impact your willingness to continue taking part, you will be notified.

**USC STUDENT PARTICIPATION**: *(If applicable)*

Participation in this study is voluntary. You are free not to participate, or to stop participating at any time. Your participation, non-participation, and/or withdrawal will not affect your grades or your relationship with your professors, college(s), or the University of South Carolina.

If research credit is required for successful course completion, other alternative means for obtaining credit are available and you may discuss these options with your course instructor.

**CONFIDENTIALITY OF RECORDS**:
*Describe safeguards that will be implemented to protect confidentiality. This section should provide a clear description of how confidentiality will be protected under the specific circumstances, including the sensitivity and type of information being collected.*

Information obtained about you during this research may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. All records in South Carolina are subject to subpoena by a court of law. The investigators associated with this study, the sponsor, and the Institutional Review Board will have access to identifying information. Study information will be securely stored in locked files and on password-protected computers.

**CONFIDENTIALITY CERTIFICATE**:*(If a NIH- funded or U.S. Department of Health and Human Services Confidentiality Certificate has been obtained, include the following paragraph.)*

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed.  This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know.  The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.  The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA).  The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research.  The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

**RESEARCH RELATED INJURY**:*(If Greater than Minimal Risk Study, include the statement below)*

*Sponsors of industry sponsored research studies often request that their own wording to address treatment and compensation for study related injuries. A statement regarding responsibility for payment of emergency medical care related to the industry sponsored research study is required. In most cases, sponsors are willing to pay for costs incurred for treatment of injury or illness directly related to the research study. If partial or no compensation is available, it should be stated clearly.*

*For research that is NOT industry sponsored, include the following or a modified version to suit specific circumstances:*

In the event you are injured while taking part in this research study, a member of study team will provide first aid using available resources. If needed the team will arrange for you to be taken to the nearest emergency medical facility. The University of South Carolina has not set aside funds to pay you for any injury, problem or related medical care that may arise from being in this study. Any study-related injury should be reported to the study team right away.

**CLINICAL TRIAL REGISTRY DATABANK**: (*For applicable clinical trials, include the statement below.)*

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

**VOLUNTARY PARTICIPATION**:

Taking part in this research study is voluntary. You are free not to take part, or to stop taking part at any time. If you withdraw from this study, the information you already have given to the study team will be kept private. If you wish to withdraw from the study, please call or email the main researcher who is listed on this form.

Concerns about your rights as a research subject are to be directed to, Lisa Johnson, Director, Office of Research Compliance, University of South Carolina, 1600 Hampton Street, Suite 414D, Columbia, SC 29208, phone: (803) 777-6670 or email: LisaJ@mailbox.sc.edu.

I have been given a chance to ask questions about this research study and my questions have been answered. **If I have any more questions about my taking part in this study, or a study related injury, I am to contact (insert study researcher’s name) at (insert working phone number) or email (insert working email address).**

I agree to take part in this study. I have been given a copy of this form for my own records.

If you wish to be in the study, you should sign below.

Signature of Subject / Participant Date

Signature of Qualified Person Obtaining Consent Date