This document should be used to develop a consent form for: Investigator-initiated studies, and studies without an informed consent template from an industry sponsor or cooperative group.

**Prior to uploading the consent document into iStar, delete all text and instructions in blue and all sections which are not applicable to your research.**

* We recommend that prior to filling out the informed consent form, first review all sections of this template.
* This template has been created for both biomedical and social behavioral studies.
* The Blue text will help provide guidance. Please review carefully.
* Please delete all blue text when completed writing the informed consent form.
* Use font size 12 and leave a one-inch right margin to accommodate the IRB stamp.
* Remove any redundant spacing, i.e., double spacing between paragraphs, etc.
* This informed consent form document should be consistent with the information in the iStar application.
* Use simple language (layman’s terms) and be concise.
* Do not refer to non-medical doctors as “Dr.” in the consent form. Use the name of the individual and his/her degree; for example, “Tommy Trojan, PhD.”
* If the individual does not have a valid California medical license, the individual cannot be referred to as “Dr.” and cannot use “MD” after his or her name in the consent document. To do so would be considered a misdemeanor under California Business and Professions Code section 2054.

## What if I am using DoD affiliated personnel?

If the research involves DoD-affiliated personnel and the participant is unable to provide informed consent and consent will be obtained in advance from the participant’s legal representative, the research must be intended to benefit the individual participants.

## California Experimental Subject’s Bill of Rights

The California Experimental Subject’s Bill of Rights must be used for research that meets the definition of a “medical experiment” under Section 24174 of the California Health and Safety Codes:

1. The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, as defined in Section 109920 or 109925, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice of research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.
2. The investigational use of a drug or device as provided in Sections 111590 and 111595.
3. Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

**Please read, then delete this text.** The USC IRB has interpreted this definition to include almost all studies involving biomedical procedures, placebo controls, innovative therapy and/or normal volunteer participants.

For non-biomedical studies, the IRB may recommend use of the Experimental Participants Bill of Rights, though it is not required by law.

**Please read, then delete blue text.** The signature lines for “Parent or Legally Authorized Representative” and “If signed by other than the research participant” line from the Bill of Rights should be deleted as appropriate.

**Please read, then delete blue text.** The language in the Subject’s Bill of Rights may not be modified.

**Delete if not applicable** If the research is NOT a medical experiment, delete the Experimental Subject’s Bill of Rights page from the consent form.

**Study Title:**

**Principal Investigator:**

## Experimental Subject’s Bill of Rights

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

**California Law Requires That You Must Be Informed About:**

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs, or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed and dated written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

I have carefully read the information contained above and I understand fully my rights as a potential subject in this study.

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Research Participant)

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Parent or Legally Authorized Representative)

If signed by other than the research participant, indicate relationship: \_\_\_\_\_\_\_\_\_\_\_\_\_

## Informed Consent for Research

**Study Title:**

**Principal Investigator:**

**Department:**

**24-Hour Telephone Number:** Required for biomedical research involving greater than minimal risk.

Introduction

**Delete if not applicable.** When a parent/legal guardian is consenting for a child, the following statement is required.If you are reading this form as the parent/legal guardian of a participant, “you” also refers to your child.

**Delete if not applicable.** For consent obtained from a Legally Authorized Representative, the following is required. If you are giving consent for another person, “you” refers to that person.

We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or your personal doctor. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. A copy of the signed form will be provided to you for your records.

Key Information

Please read, then delete blue text. *If your consent form is longer of 5 pages, the Key Information section is required. \*\*\*\*The Bill of Rights do not “count” towards the total number of pages. \*\*\*\**

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

1. Being in this research study is voluntary–it is your choice.

2. You are being asked to take part in this study because fill in study-specific detailsin 1 sentence. The purpose of this study is fill in study-specific details in 1 sentence. Your participation in this study will last fill in study-specific details in 1 sentence. Procedures will include provide a brief list of the **major procedures** in 1-2 sentences.

3. There are risks from participating in this study. The most common risks are provide a brief list of the major risks in 1-2 sentences. More detailed information about the risks of this study can be found under the “Risk and Discomfort” section.

4. Include for a study with direct benefits to participation, otherwise delete. The possible benefits to you for taking part in this study may include provide a brief statement of the benefits to participating.

Include for a study with no direct benefits to participation, otherwise delete. You may not receive any direct benefit from taking part in this study. However, your participation in this study may help us learn provide a brief statement of the benefits to society.

5. If you decide not to participate in this research, your other choices may include provide a brief statement of the alternatives to participating, such as alternate treatments, alternate course assignments, not participating, etc.

Purpose Required

The purpose of this study is fill in study-specific details in 2-3 sentences. We hope to learn fill in the main objective. You are invited as a possible participant because list the main qualification for participation. About fill in number participants will take part in the study. Include if applicable, otherwise delete This research is being funded by insert name of sponsor/funding source.

Procedures Required

Please make sure your procedures address the following:

* **If Biomedical please address, otherwise delete.** Identify which procedures are done for standard of care (if applicable) and which procedures are done solely for the research. Include the duration of each procedure, the frequency, and the total length of time the participants are involved in the study.
* If you decide to take part, this is what will happen Describe the procedures in chronological order.
* If applicable, describe the participant’s assignment to a study group. Describe randomization (“like pulling a number from a hat,” “like rolling the dice,” or “like flipping a coin”). Describe the participant’s chances of receiving the intervention, study drug, or device using a phrase such as “two out of three chances” rather than using a percentage. Describe double blind (“You and the investigator will not know what drug you are taking.”). Define placebo (“a pill or liquid without any study drug”).
* State if any procedures will be conducted at the USC Clinical Trials Unit (CTU).
* If the research targets American Indian/Alaskan Native (AI/AN), Native Hawaiian Tribes/Communities and/or Indigenous communities as a subject population, the consent document must include the process and procedures to seek consent of the individual participant as well as the tribe(s) and the tribal community(ies).

**If Biomedical please address, otherwise delete.** If you are testing for any reportable diseases, add the following, otherwise, delete. This research requires testing for insert HIV, hepatitis, tuberculosis, sexually transmitted diseases, etc. If you test positive, California law requires that we report your results to the local health department. We will refer you to a health care provider for medical care.

**If Biomedical please address, otherwise delete.** For research involving biospecimens, indicate whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions, otherwise delete. Most tests done in research studies are for research purposes only and have no clear meaning for health care.

Option 1:

Because of this, you will not receive test results.

-or-

Option 2:

Research test results will be provided to you under the following conditions: include the conditions under which test results will be provide.

If Biomedical please address, otherwise delete. Genetic Testing and Genetic Research Information:

Guidance for Investigators, please delete after review.

Genetic Testing: Genetic testing requires that the genetic test have a known association with a human trait or medical condition, be performed in a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory and have the intent to release the results to participants and/or their health care providers. Furthermore, a genetic counselor should provide the results or be made available to the participant for the purpose of answering questions about the implications of the genetic testing results. All other forms of genetic testing are considered genetic research.

Genetic Research: Testing of blood or tissue for genes without known associations with a human trait or medical condition is considered genetic research. Genetic testing (as outlined above) is also considered genetic research if the following criteria are met: (a) the testing is performed in a non-CLIA laboratory, and (b) there is no intent to release the results to research participants.

Large Scale Genomic Data & DoD Affiliated Personnel: Studies involving large scale genomic data (LSGD) collected from DoD-affiliated personnel is subject to requirements for additional Component-level security review and will require a Certificate of Confidentiality from the NIH. Research cannot be conducted until approval from the relevant DoD office.

Genetic Testing Delete if not applicable.

You are being asked to participate in genetic testing. Your insert tissue/blood/saliva/ other sample will be tested for insert types of tests. You and your doctor will be given the results of this genetic testing. A genetic counselor may be available with the results of this genetic testing. You and/or your health plan/insurance may have to pay for any additional services.

Genetic Research Delete if not applicable.

You are being asked to participate in genetic research. Results of this genetic research will not be used in your medical care. The results will not be given to you, the study doctor, or your personal doctor.

Whole Genome Sequencing Delete if not applicable.

The research will include whole genome sequencing (determining the order of DNA building blocks) in your genetic code.

Whole genome sequencing is the mapping out of a person's unique DNA. Your genome is the unique blueprint for your body. Sometimes, because of new or inherited genetic mutations, your genes can cause a disease or increase your risk for disease.

Genetic Testing Delete if not applicable.

A federal law, called the [Genetic Information Nondiscrimination Act (GINA) 2008](http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf), protects people from genetic discrimination in health insurance and employment. Genetic discrimination is the misuse of genetic information.

It is against the law for health insurers to request, require, or use genetic

information to make decisions about your eligibility for health insurance or your health insurance premium.

It is against the law for employers to use genetic information to make decisions about hiring, firing, promotion or pay; or to limit, segregate classify or otherwise mistreat an employee. It is also illegal for an employer to request, require, or purchase genetic information.

Sometimes health insurers need genetic information to make decisions about

paying for certain tests or treatments. It is legal for them to ask for this information.

However, once they have it, they cannot use it to discriminate against you in the

ways described above.

MRI Delete if not applicable.

Guidance for Investigators, please review all options, and choose the appropriate selection.

fMRI at Dornsife Delete if not applicable.

You have agreed to be a research subject in a study by name of principal investigator for which a Magnetic Resonance Imaging (MRI) scan is going to be performed.

Because the Dornsife Cognitive Neuroimaging Center is a research unit, not a clinical/diagnostic MRI center, the MRI scans obtained at the Dornsife Cognitive Neuroimaging Center are not meant to provide clinical/diagnostic information. Most scans performed in normal human subjects are without abnormalities. However, on occasion, though rarely, something abnormal may be present, what is called incidental findings.

Youhave been informed that, because the Dornsife Cognitive Neuroimaging Center is not a clinical/diagnostic center, the DNI has no neuroradiologist staff members (medical doctors who can comment on MRI scans), and therefore we cannot tell if your scan shows or does not show any abnormality. But, because detecting and investigating such potential abnormalities may be relevant to your health, you were told that the Dornsife Cognitive Neuroimaging Center established a partnership with Children’s Hospital Los Angeles Medical Group, Inc., where a neuroradiologist (Dr. Marvin Nelson or one of his colleagues) will review the structural scans that are part of the research scans obtained at the Dornsife Cognitive Neuroimaging Center. If they detect any image that suggests an abnormality, they will contact you or a physician of your choice, to inform about the findings and suggest further evaluation if needed.

Your identity, along with your physician’s identity, will only be disclosed to Dr. Nelson should he need to contact you. However, should an incidental finding be detected that potentially may make you ineligible for brain studies, your name will be kept on a roster maintained confidentially at the DNI. If you elect to volunteer for another study, the researcher may ask the DNI if your name is on that list (the researcher has no direct access to the list). The researcher will simply be told if your name is on the list. No further information will be disclosed.

MRI at USC Dynamic Imaging Science Center (DISC) Delete if not applicable.

The USC Dynamic Imaging Science Center (DISC) is a research unit, not a clinical or diagnostic Magnetic Resonance Imaging (MRI) center. The MRI scans obtained at DISC, such as the scan you are about to undergo, are research scans. They are not meant to provide medical diagnostic information. Many types of abnormalities will not be detected by this imaging, and you should not rely on this scan to find out if you are healthy or sick, or as a substitute for your usual medical care. If you are having symptoms, see your doctor.

However, on occasion, abnormalities may be seen on these research scans purely by chance. These rare occurrences are called incidental findings. Because DISC is not a clinical/diagnostic center, the center does not have radiologist staff members (medical doctors who can comment on MRI scans), and therefore we cannot tell if your scan shows or does not show any abnormality.

MRI at USC Center for Imaging Acquisition (CIA) Delete if not applicable.

The USC Center for Imaging Acquisition (CIA) is a research unit, not a clinical/diagnostic Magnetic Resonance Imaging (MRI) center. The MRI scans obtained at the CIA, such as the scan you are about to undergo, are research scans. They are not meant to provide medical diagnostic information. Many types of abnormalities will not be detected by this imaging, and you should not rely on this scan to find out if you are healthy or sick, or as a substitute for your usual medical care. If you are having symptoms, see your doctor.

However, on occasion, abnormalities may be seen on these research scans purely by chance. These rare occurrences are called incidental findings. If we happen to learn information revealing a likely life-threatening or grave condition that can be avoided or treated, we will notify you, unless you inform us that you do not wish to know. You may authorize the release and communication of these findings to your personal doctor. These findings may require additional testing or treatment. You will be responsible for the cost of any additional tests or related treatment.

Risk and Discomforts Required

Identify each procedure, drug, or device with a subheading and describe the risks. Describe the reasonably foreseeable risks or discomforts (whether physical, psychological, reproductive, privacy, legal, social, or economic) that may result from study procedures, (e.g., answering study questions, participating in focus group, using investigational products). Do not say that there are no risks; there is always the risk of breach of confidentiality.

Possible risks and discomforts you could experience during this study include:

If the study involves research-related radiation exposure, you must submit the study to the [USC Radiation Safety Committee](https://ehs.usc.edu/research/rad/radiation-safety-committee/) and use the radiation language provided by the committee.

If the study involves biopsies, endoscopies, or imaging done for research purposes, you must also include the risks of any sedatives, anesthetics, or contrast agents that may be used.

Blood Draws Delete if not applicable.

Mild pain or discomfort, bruising and swelling around the puncture site, dizziness or fainting, or infection (rare).

Surveys/Questionnaires/Interviews Delete if not applicable.

Some of the questions may make you feel uneasy or embarrassed. You can choose to skip or stop answering any questions you don’t want to.

Breach of Confidentiality Required

There is a small risk that people who are not connected with this study will learn your identity or your personal information.

USC Student Participants Delete if not applicable. Include for greater than minimal risk studies asking USC students questions about behaviors which may violate laws and/or USC policies.

There is a risk that people who are not connected with this study will learn your identity or your personal information. You will be asked questions about activities that if you are under 21 years old may be illegal and/or not in compliance with university policy. Although highly unlikely, if your information becomes public, it might result in the university taking action such as referring you to Campus Support and Intervention (CSI) or Trojans Care 4 Trojans (TC4T).

If enrolling American Indian/Alaskan Native (AI/AN), Native Hawaiian and/or other Indigenous Participants Delete if not applicable. Indicate the risks and/or harms to the AI/AN, Native Hawaiian or Indigenous community(ies), including harms to individual tribes/communities (tribal/community harm can differ between tribes/communities) [please review this guidance](https://hrpp.usc.edu/irb/american-indian-alaskan-native-populations/).

Reproductive Risks Delete if not applicable. Include any known risks to women (including pregnant women and female partners), men, and unborn or nursing children.

We do not know whether this study drug or study procedure might hurt an unborn baby. You must use birth control while on this study. These are some birth control measures that you can use: insert methods.

If you are pregnant, you cannot take part in this study. If you could become pregnant, you must have a pregnancy test to make sure you are not pregnant.

If you are breastfeeding and do not want to stop, you may not take part in this study. Delete if not applicable.

Genetic Testing Risk Delete if not applicable.

Required when genetic testing results are returned to participants. Some people may find it upsetting to learn that they have certain mutations or errors in genes that could lead to future health problems for themselves or their children.

Unforeseen Risks Delete if not applicable.

There may be other risks that are not known at this time.

Department of Defense Delete if not applicable.

Department of Defense (DoD) risk section requirements. Delete if not applicable.

* Any information required by a DoD service Component review
* If the research includes any risks to DoD-affiliated personnel’s fitness for duty (e.g., health, availability to perform job, data breach), you must include language informing them about these risks and that they should seek Command or Component guidance before participating.
* If applicable, any potential risks for the revocation of clearance, credentials, or other privileged access or duty must be included.

USC Center for Imaging Acquisition (CIA) MRI Risks and Discomforts Delete if not applicable. If the procedure is performed for medical research this is required.

The MRI scanner does not expose you to radiation, but there are other possible risks and discomforts you could experience during this study which include:

Metallic Foreign Body

The scanner operates using a very strong magnet that can interact with some types of metal that may be in your body. If you have these metals in your body, either in an implanted device (like a heart pacemaker) or as a result of a prior injury (like shrapnel), it may not be safe for you to approach the MRI machine. Before you are allowed to approach the scanner, you will be asked to fill out a screening questionnaire to find out whether this applies to you.

Acoustic Noise

The MRI machine makes loud tapping or banging sounds while it is working. To shut out some of the noise, you will be given earplugs.

Discomfort from Lying Still

You may experience back, neck, or joint discomfort from lying still during the MRI scan. We will provide padding to make you as comfortable as possible. If you need to adjust your position, please let the MRI staff know.

Temporary Sensations

Because of the strong magnetic field, you might experience brief periods of muscle twitching, eye discomfort, dizziness, mild nausea, headache, or a sensation of flashing lights while the MRI table is sliding into or out of the scanner tunnel. These sensations should go away within a few seconds after the table stops moving.

Claustrophobia

There is little space inside the scanner, which may cause anxiety or discomfort for people who fear enclosed spaces.

MRI Contrast Injection Risk and Discomforts Delete if not applicable. Include if the procedure is performed for medical research.

You may be receiving an intravenous contrast medium to enhance the visibility of certain tissue. Possible side effects may include, but are not limited to nausea, vomiting, a warm flushed feeling, potential allergic reaction, including but not limited to hives, wheezing, difficulty breathing, kidney damage, and in very rare instances, anaphylactic shock (severe allergic reaction) and death.

MRI Gadolinium-Based Contrast Risks and Discomforts Delete if not applicable.

Recent publications in medical literature have reported that deposits of gadolinium-based contrast agents remain in the brains of some patients who undergo four or more contrast MRI scans, long after the scan was completed.  It is unknown if these deposits are harmful or if they may lead to harmful health effects.

Nephrogenic Systemic Fibrosis (NSF): People who are given a gadolinium-based contrast drug and who have kidney disease or are on dialysis are at risk for developing Nephrogenic Systemic Fibrosis (NSF), a serious but rare disease that causes the skin to thicken and become stiff. This can lead to joint contractures and stiffness. Symptoms of NSF may include: swelling hardening, and tightening of the skin, red and/or dark spots on the skin, burning or itching, and yellow spots on the whites of the eyes, joint stiffness, problems moving or extending the arms, hands, legs or feet, deep hip bone or rib pain, and muscle weakness. NSF can also affect other organs, including the lungs, liver, and heart. NSF can be an incapacitating and sometimes cause death. It can develop over a period of several hours to several weeks or months.

Risk of sharing data and biospecimens Delete if not applicable.

We will do our best to protect your data and biospecimens during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data and biospecimens. In either case, we cannot reduce the risk to zero.

Benefits Required

Money paid to participants, free medications, free medical care, extra diagnostic tests, or careful monitoring are not considered benefits of the research study and cannot be included.

The potential benefits to you may include list the possible benefits to participants.

-or-

There are no direct benefits to you from taking part in this study. However, your participation in this study may help us learn list possible benefits to society.

Required for studies involving American Indian/Alaskan Native (AI/AN), Native Hawaiian, and/or Indigenous communities. Delete if not applicable.

The potential benefits to you, and your tribe/community may include list the possible benefits to AI/AN, Native Hawaiian and/or Indigenous participants and their tribe/communities–each tribe/community must be listed.

Benefits of sharing data and biospecimens Delete if not applicable.

You will not receive any direct benefit from sharing your data and biospecimens. However, sharing your data and biospecimens may contribute to research that could help others in the future.

Privacy/Confidentiality Required

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who are required to review this information. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

The University of Southern California’s Institutional Review Board (IRB) and Human Research Protection Program (HRPP) may review your records. Organizations that may also inspect and copy your information include list all applicable organizations that may have access to the subject’s records including the Food and Drug Administration (FDA), the sponsor, or the funding agency.

**Delete if not applicable.** Employees who provide medical care or who handle billing and payment at USC may review your research records and medical records, if necessary, to conduct the research.

**Delete if not applicable.** The Department of Defense (DOD) or Federal representatives may also access research records for the purpose of protecting human subjects.

**Delete if not applicable.** Officials of the U.S. Army Research Protections Office and the Army Research Laboratory’s Human Research Protection Program are permitted by law to inspect the records obtained in this study to ensure compliance with laws and regulations covering experiments using human subjects.

**Include if a HIPAA authorization is required, otherwise delete**. Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA Authorization document. You will be asked to sign a separate HIPAA Authorization for Research form authorizing the access, use, creation, and disclosure of your health information.

Include if you are conducting a focus group. Otherwise delete. Given the nature of focus groups, complete confidentiality cannot be guaranteed. As a participant you should only share information that you are comfortable with others knowing. Researchers are not able to control how information is shared outside the focus group.

## The paragraph titled Future use of data and/or specimens is required if your study is funded by the *NIH or if you explicitly plan to share materials* (data or biospecimens) after the conclusion of this specific research project.

Future use of data and/or specimens

This study is collecting data and/or biospecimens from you. We will make your data and/or biospecimens available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Our goal is to make more research possible. We plan to keep your data and/or biospecimens indefinitely. All data will be transferred securely. If you are not comfortable with this, you should not participate in this study.

## The paragraph titled Possible Future use of data and/or specimens is required in all other cases

Possible Future use of data and/or specimens

Your data will be maintained confidentially and may be shared with other researchers. The research may be about similar or unrelated topics to this study. Our goal is to make more research possible. We plan to keep your data and/or specimens indefinitely. If shared, data will be transferred securely. If you are not comfortable with this, you should not participate in this study.

**Delete if not applicable.** If this research will involve American Indian/Alaskan Native (AI/AN), Native Hawaiian, and/or Indigenous communities this language must be included.

Your data and/or specimens collected as part of this research will not be used or distributed for future research studies without your explicit written permission and the written permission from your tribe/community.

**Delete if not applicable.** If this research is regulated by the FDA or meets the NIH definition of a clinical trial this language must be included.

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

**Delete if not applicable.** If this research involves minors this language must be included. The investigators are required to report certain cases with the potential of serious harm to you, or others, such as suicidality or child abuse, to the appropriate authorities.

**Delete if not applicable.** If this research has received NIH funding this language must be included. 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.

**Delete if not applicable.** If this research will be requesting a Certificate of Confidentiality this language must be included. A Certificate of Confidentiality has been requested from the National Institutes of Health. If obtained, this means that 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.

**Delete if not applicable.** If this research will be using Amazon MTurk, Qualtrics, SurveyMonkey, etc. to recruit participants for survey responses, this language must be included. This study will use Fill in name of company here. To understand the privacy and confidentiality limitations associated with using Fill in name of company here we strongly advise you to familiarize yourself with Company’s name, with a link to their privacy policy here privacy policy. USC has no jurisdiction or oversight of how data are used or shared on third party applications.

Alternatives Required for all research studies.

This section aligns to section 28.3 in iStar.

If you have checked “Not Participating” in section 28.3 in iStar the following statement is required.

An alternative would be to not participate in this study.

If you have checked *any other option* in iStar section 28.3, you are required to describe alternatives to participation. Please review the options below.

**Delete if not applicable.** Insert if the study is recruiting from a subject pool. If you joined the student subject pool, your alternative may be to participate in another study or to write a paper. Please contact the Subject Pool Coordinator for further information.

**Delete if not applicable.** Insert if the study is conducted in a classroom. An alternative would be to participate in a non-research activity comparable in time and effort.

Describe appropriate therapeutic, diagnostic, or preventive procedures that will be offered to participants if they decide not to participate in the study.

There may be alternative(s) to participating in this study. These include list the alternatives. The risks and benefits will be explained to you.

-or-

An alternative would be not to take part in this study and continue with your current care.

Payments/Compensation Required for all research studies.

**The following information is instructional information for investigators.** The payment language in the informed consent must be consistent with the language at iStar section 25.2. Specify the form of compensation (e.g., gift certificate, meal voucher, parking voucher, academic credit and travel expenses). Compensation cannot be withheld until the participant completes the entire study. Payment should be provided after each study visit. Compensation can be prorated if participants do not complete all study visits.

If non-military government employees are a targeted population and the research is conducted during their working hours, they cannot be compensated for their participation in a research study. Please contact [USC’s Office of Government Relations](https://dornsife.usc.edu/college-business-office/) for additional information. If non-military, non-government employees *and* government employees are eligible to participate in the same study, the compensation section must include a statement that Government employees cannot be compensated in addition to a statement describing the compensation for the non-government employees.

If *on duty* DoD employees, including contractors are eligible to participate, any payment for participation occurring while participants are on duty must be limited to payment for blood donation and cannot be greater than $50 per blood sample.

**Delete if not applicable.** If participants will not be paid or receive other forms of compensation, this language must be included.

You will not be compensated for your participation in this research.

**Delete if not applicable.** If participants will receive payments for taking part in the study, this language must be included.

Payments for research participation are considered taxable income and participants may be required to pay taxes on this income. If participants are paid $600 or more in total within a calendar year for participation in one or more research studies, the University will report this as income to the IRS and participants may receive an Internal Revenue Service (IRS) Form 1099. This does not include any payments you receive to pay you back for expenses like parking fees.

**Delete if not applicable.** If participants are military personnel, and taking place using DoD resources, where participants will be paid, this language must be included.

Military personnel should check with their Commanding Officer/supervisor/HR Department before accepting payment for participation in this research.

**Delete if not applicable.** If participants are Federal employees who will be paid, this language must be included.

Federal employees should check with their supervisor and/or HR Department before accepting payment for participation in this research.

**Delete if not applicable.** If participants are students who will receive academic course credit for their participation, this language must be included and any conditions, such as being member of the SONA pool, detailed.

USC students will be offered course credit for their participation in the amount of [specify] \_\_\_\_\_\_.

Possible Commercial Products

**Delete if not applicable.** Include only if you intend to collect tissue and/or body fluid samples as part of the research and a commercial product may be developed from this research.

All tissue and fluid samples are important to this research study. Your sample will be owned by insert the University of Southern California, another university, or a private company. The use of your data and biospecimens may lead to new tests, drugs, devices, or other products or services with commercial value. These products or services could be patented and licensed. If a commercial product is developed from this research project, the commercial product will be owned by insert the University of Southern California or its designee, another university, or a private company. You will not profit financially from such a product. There are no plans to provide any payment to you should this occur.

**Delete if not applicable.** Include only if you plan to create a cell line from the research specimens. Cells from your body may be used to start a cell line. A cell line is one that will grow in the laboratory. It may be of commercial value. There is no plan for you to receive payment for any commercial products that are developed.

Cost

**Delete if not applicable.** The Cost information must be consistent with iStar section 25.1. After you select an option on iStar 25.1, text will auto-populate in section 25.1A. *Copy and paste* that text here in the ‘cost’ section. Carefully review the cut and paste text and follow any additional instructions.

Injury This section is required for Full board studies.

**The following information is instructional information for investigators.** All studies will require one of the paragraphs below. Carefully review all paragraphs and choose the applicable statement.

**Delete if not applicable. For full board studies only** When filling out the iStar application in section 25.3 select an option. After you select an option, text will auto populate (25.3.A) within iStar. Copy and paste that text here.

**Delete if not applicable.** For industry funded full board medical studies USCs Clinical Trials Office will provide the final injury language.

Non-industry sponsored studies that use the Clinical Trials Unit (CTU) must include the specific CTU injury language. You are participating in this study under the supervision of Dr. insert study doctor’s name. Some or all the study procedures will be performed on the USC Clinical Trials Unit (CTU) or by staff of the CTU at a location designated earlier in this consent form. If you get hurt or sick from participating in the study, you will be offered treatment for the injury. Who will pay for the treatment depends on how and where it will occur. If the injury is from the study drug or procedures performed or directed by Dr. insert study doctor’s name or their staff, explain the policy and if applicable, the sponsor’s responsibility. If you get hurt from a procedure performed by one of the CTU staff that was not under the direction of Dr. insert study doctor’s name, the CTU Advisory Committee will review your case and decide whether to pay for part or all of that care. The CTU will not provide any other money for the injury.

**Delete if not applicable.** Include the following language for research sponsored by the Department of Defense (DoD) or a DoD specific component (e.g., US Army Medical Research)

For DoD-affiliated personnel that are research participants, for the duration of the study, you may be eligible for health care services for research-related injuries at a military treatment facility. This eligibility for health care services extends beyond your participation in the study to [please include the timeline that the COHRP provided] after the study has ended. The University of Southern California does not provide any monetary compensation for injury.

**Delete if not applicable.** Required unless your study meets one of the options above.

The University of Southern California does not provide any monetary compensation for injury. If you are injured as a direct result of research procedures, you will receive medical treatment; however, you or your insurance will be responsible for the cost.

Potential Conflict of Interest Delete if not applicable.

Insert name of investigator or study doctor has a financial interest in the company sponsoring this study. Briefly describe the financial interest. The nature of this conflict and the management of the conflict of interest have been reviewed by the USC Conflict of Interest Review Committee (CIRC).

New Information

**Delete if not applicable.** Required when studies involve 2 or more visits.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in the research.

Voluntary Participation Required for all studies.

It is your choice whether to participate. If you choose to participate, you may change your mind and leave the study at any time. If you decide not to participate, or choose to end your participation in this study, you will not be penalized or lose any benefits that you are otherwise entitled to.

**Delete if not applicable**. If this study is FDA regulated research, this language is required.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can continue to collect data from your records. If you agree, this data will be handled the same as the research data. No new information or samples will be collected about you or from you by the study team without your permission.

If withdrawal must be gradual for safety reasons, the study doctor or investigator will tell you. The study site may still, after your withdrawal, need to report any safety event that you may have experienced due to your participation to all entities involved in the study. Your personal information, including any identifiable information, that has already been collected up to the time of your withdrawal will be kept and used to guarantee the integrity of the study, to determine the safety effects, and to satisfy any legal or regulatory requirements.

Withdrawal from Study Instructions Delete if not applicable.

Include any specific withdrawal instructions.

Participant Termination Delete if not applicable.

Required when studies involve more than 2 visits.

You may be removed from this study without your consent for any of the following reasons: you do not follow the study doctor’s or investigator’s instructions, at the discretion of the study doctor or investigator or the sponsor, your condition gets worse, or the sponsor closes the study. If this happens, the study doctor or investigator will discuss other options with you.

Contact Information Required

If you have questions, concerns, complaints, or think the research has hurt you, talk to the study doctor or investigator at insert the name of principal investigator and contact information.

This research has been reviewed by the USC Institutional Review Board (IRB). The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. Contact the IRB if you have questions about your rights as a research participant or you have complaints about the research. You may contact the IRB at (323) 442-0114 or by email at hrpp@usc.edu.

Statement of Consent

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

Name of Research Participant Signature Date Signed

 (and Time\*)

**Legally Authorized Representative** Delete if not applicable.

Name of Legally Authorized Signature Date Signed

Representative (and Time**\***)

**Minor/Youth Participant** (Ages 14-17 years) Delete if not applicable.

If your child agrees to participate, have your child sign here.

Name of Child Child’s Signature Date Signed

 (and Time**\***)

Name of Parent Signature Date Signed

 (and Time**\***)

**⬜ Second parent/legal guardian is not available to sign because he/she/ze is deceased, unknown, incompetent, or not reasonably available, or only one parent has legal responsibility for the care and custody of the child (45 CFR 46.406).** Delete if not applicable.

Name of Second Parent Signature Date Signed

 (and Time**\***)

**Pregnant Women** Delete if not applicable.

Name of Father of Unborn Child Father’s Signature Date Signed

 (and Time**\***)

Include the following language for studies where it is foreseeable that a participant may lose capacity to consent. Delete if not applicable.

Loss of Capacity to Provide Consent

In order to make your wishes known in the event you lose the capacity to provide consent to take part in this study, please initial next to your choice:

\_\_\_\_\_\_YES, I wish to continue participating in the study if I lose the capacity to consent.

\_\_\_\_\_\_ NO, I do not wish to continue participating in the study if I lose the capacity to provide consent.

\_\_\_\_\_\_I DO NOT wish to make a decision at this time.

We will notify your Legally Authorized Representative of your choice if you are no longer able to provide consent to take part in the study.

If you lose the capacity to consent and you indicated above that either you wish to continue or you did not wish to make a decision, we will ask your Legally Authorized Representative if they will allow you to continue in the study. We will also ask for your assent to continue in the study. You will continue in the study if your Legally Authorized Representative approves your continued participation and you indicate verbally or nonverbally that you wish to continue.

Person Obtaining Consent

I have personally explained the research to the participant and/or the participant’s legally authorized representative using non-technical language. I have answered all the participant’s questions. I believe that the participant understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Signature Date Signed

Informed Consent (and Time\*)

Witness Delete if not applicable.

A Witness is Required When: (1) the participant cannot see, read, write, or physically sign the consent form, or (2) the Short Form method is used to obtain consent. In these situations, the witness must sign and date the consent form.
If no witness is needed, leave this signature line blank.

Name of Witness Signature Date Signed

*\* If a study procedure is done on the same day the informed consent is signed, the time and date are required. No study procedures may be done before the participant has signed the informed consent. Otherwise, delete the references to the time.*

If a waiver of signed consent is requested and justified in iStar, the signature sections above should be removed. The language below must be included. Otherwise delete.:

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. By indicating below, I am agreeing to take part in this study.

\_\_\_\_\_\_YES, I agree to participate in the study.