# When do I use this document?

This document should be used when you have a sponsor’s/external IRB’s informed consent form (ICF) to double check that the form contains the required language for University of Southern California.

# How do I use this document?

1. Review all the sections in the ICF from the sponsor/external IRB.
2. Review all the sections in this document.
3. Next, you will create the ICF that will be submitted to the USC IRB by cutting and pasting information from this document into the sponsor/external IRB’s ICF.
4. The text in the blue font are the instructions. The text in black font may be text that is needed for the sponsor/external ICF.
5. **You *must* use tracked changes with MS Word. This is required. This helps the IRB team clearly identify the changes and additions to the informed consent form.**
6. Please read the following tips below to help you.

# Please note: It is *not* required to revise the sponsor/external IRB section titles to match USC titles as presented in this document.

# Tips:

1. Insert the name and address of your institution and department in the header of the document or print the document on your institution/department letterhead. The name and address must appear on at least the first page of the consent form.
2. Ensure the principal investigator’s name, department, and 24-hour telephone number appears at the beginning of the consent form. The 24-hour telephone number is required for greater than minimal risk studies. The number must be a USC phone number answered by a live person 24 hours a day.
3. Ensure the form includes a version date and page numbers.
4. Fill in any blanks on the Sponsor/External IRB Informed consent form template to provide information relevant to the local site (i.e., local study team contact information).
5. Remove text or language that does not apply to the local site (i.e., testing/sub studies done at select sites that will not be done at USC).
6. Remove or revise language that does not comply with federal regulations, California law, HIPAA, and USC policy.
7. \*\*Comply with the additional instructions for specific informed consent sections.
8. Formatting (not required for studies that have been ceded to an external IRB):

* Use a font size of 12 or larger.
* Add a one-inch right margin to accommodate the IRB stamp.

***The USC IRB may require that additional language be inserted to be compliant with state law and institutional policies.***

## 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 Note.** 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 Note.** The language in the Subject’s Bill of Rights may not be modified.

If the research is NOT a medical experiment, then the Experimental Subject’s Bill of Rights page is not required on the consent form. [Please review policy statement regarding the Experimental Subject’s Bill of Rights.](https://hrpp.usc.edu/policies/informed-consent-requirements/)

\*\*\*\*\*Below is the text required if the Experimental Subject’s Bill of Rights is needed\*\*\*\*

**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: \_\_\_\_\_\_\_\_\_\_\_\_

# Key Information

* This section will be required for federally sponsored research.
* “Key Information” that is included in the study sponsor’s template will be accepted as written and requires no alteration by the study team or IRB.
* “Key Information” [(45 CFR 46.116(a)(5)(i) )](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46#p-46.116(a)(5)(i)) as defined by the Common Rule federal regulations is not required in the ICF for FDA-regulated/industry-sponsored studies at this time.

# Introduction

Please see the language in the sponsor’s or external IRB’s template to identify funding if applicable.

# Procedures

If you are testing for any reportable communicable diseases (such as HIV, hepatitis, tuberculosis, and sexually transmitted diseases), add the following language:

This research requires testing for [insert HIV, hepatitis, other]. If you test positive, California law requires that we report your results to the local health department. If you test positive, we will refer you to a health care provider for medical care.

# Risk and Discomforts

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.

## USC Center for Imaging Acquisition (CIA) MRI Risks and Discomforts [Include if procedure is performed for medical research]

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

TheMRI 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 [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 Contrast Injection Risk and Discomforts [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.

## Benefits

Use the language in the sponsor’s or external IRB’s template.

## Privacy and Confidentiality

California law requires that the HIPAA form be separate from the consent. Remove any HIPAA language that already appears in the separate USC HIPAA Research Authorization Form. If not already stated in the sponsor’s or external IRB’s consent, add the following statement:

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.

Note if applicable: Your personal doctor(s) may find out or be told about your participation in this research study.

## Alternatives or Other Options

Use the language in the sponsor’s or external IRB’s template.Please do not modify this section from sponsor.

## Payments/Compensation

The payment language in the informed consent must be consistent with the language at iStar #25.2. Specify the form of compensation (e.g., gift certificate, meal voucher, parking voucher, 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.

If participants will not be paid or receive other forms of compensation, please include.

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

Include the following paragraph if participants will receive payments for taking part in the study.

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.

Include for research that targets military personnel where subjects will be paid, otherwise delete.

Military personnel should check with their supervisor before accepting payment for participation in this research.

Include for research that targets military personnel who are a targeted population, where subjects will be paid, otherwise delete.

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

Include for research that targets Federal employees who are a targeted population, where subjects will be paid, otherwise delete.

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

## Cost

Depending on the type of study funding, either the USC Clinical Trials Office or the Department of Contracts and Grants will provide the final cost language as applicable.

## Injury [This section may be deleted for most expedited applications]

For funded full board medical studies: The USC Clinical Trials Office or the Department of Contracts and Grants will provide the final injury language.

For full board social behavioral studies: Language for this section will depend upon the nature of the study, funding, and risk determination.

## Potential Conflict of Interest

Add the language below if USC investigator(s) or USC has a conflict of interest. Do not include conflicts of interest from other institutions.

[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).

## Contact Information

The contact information for the external IRB must appear if applicable. The USC IRB contact information may also be included for USC participants to contact the USC IRB.

## USC IRB Contact Information

*Telephone: 323-442-0114*

*Email: hrpp@usc.edu*

## Agreement

The addition of signature lines for witness, parent/guardian, and legally authorized representative should be consistent with the external IRB approval letter.