UC San Diego Consent Requirements for Reliance on External IRBs

*When relying on an External IRB, if UC San Diego will be consenting subjects, the IRB approved template should be updated to include our UC San Diego required language and requirements as outlined in this document.*

*When submitting for Clearance to a commercial IRB (Advarra/WCG IRB), ensure the submitter’s user account and/or application indicates that the submitter and/or the research is affiliated with UC San Diego. The commercial IRB has our institutional language on file and can create a site-specific UCSD version with our required language or you can opt to create the site-specific UCSD version.*

*When submitting for Clearance to a non-commercial IRB or you prefer to create a site-specific UCSD version to submit to the commercial IRB, the research team should include the IRB approved Informed consent template with UC San Diego required language added via the Track Changes feature in Word.*

*Refer to the Kuali administrative registration application’s Supporting Information section for a list of documents required for the reliance application. For detailed information about the reliance review process, please visit the Reliance webpage at* [*https://irb.ucsd.edu/researchers/reliancesgeneral.html#Review-Process*](https://irb.ucsd.edu/researchers/reliancesgeneral.html#Review-Process) *or email us at* *irbrely@ucsd.edu*

**Header:** Identify University of California San Diego as the research institution.

**Gender Inclusive Language: Consent language should not assume the reader’s gender and should be inclusive of all gender identities.**

**Exception:** If a study is focused on participants of specific gender identity (e.g., as an inclusion criterion), it may be appropriate to use gender specific language.

**Risks: Include the following when research involves radiation (subject to modification by Radiation Safety):**

Risks of Radiation Exposure: During your participation in this research study, you will be exposed to radiation from scheduled imaging scans. The total exposure resulting from these imaging studies is calculated to be approximately xxxx millisieverts (mSv). This amount is [more/less/equal (choose one)] than you would receive from one year of natural exposure in the San Diego area, which is approximately 1.6 mSv. Cumulative exposure from radiation may increase your risk of developing certain types of cancer in the future.

The principal investigator for this research study has determined and verified that [all/most/some/none (choose one)] of the imaging scans prescribed for this study would be performed as part of the standard medical care required to adequately monitor your current illness. [Investigator may be specific here by listing the scans that are considered standard of care if applicable or deemed to be useful information for the research participant. In addition, non-radiation producing imaging alternatives should be included here if described in the research plan.] If you are especially concerned about radiation exposure, or you have had many x-rays and/or imaging scans already, you should discuss this with the study doctor [optional: “, Dr. [PI Name]”] or your regular doctor.

**Reproductive Risks Language: These sections tend to have gender specific language. Remove all gender specific language and replace with gender neutral language to align with UC policy. The UCSD IRB typically uses “person able to become pregnant” instead of “woman/women of childbearing potential” and “person able to cause a pregnancy” instead of “men/able to father a child.”**

**Genetic Testing: Include the following if the study involves genetic testing to align to CalGINA requirements:**

Risks of Genetic Testing:  Federal and State laws generally protect your genetic information in the following ways: a) Health insurance companies and group health plans may not request your genetic information from this research. b) Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. c) Employers with 5 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that these laws **do not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**Costs: Insert the cost statement appropriate to how procedures will be billed (subject to modification by Coverage Analysis):**

**If there are no events billed to the participant and/or their insurance, use the following:**

There will be no cost to you for participating in this study [However, if there are costs associated to participation, these should be stated (i.e., parking, costs associated with drug/device/procedure) and that the subject or the subject’s insurer will be responsible for the cost, as appropriate.]. You and/or your health plan/insurance company will need to pay for all costs of [As appropriate, add: “caring for” Or “preventing” Or “treating”] your condition while in this study.

**If this study involves events billed to the participant and/or their insurance, use the following:**

The study drug/device/procedure will be supplied at no cost while you take part in this study. The cost of getting the study drug/device/procedure ready [is also provided at no cost/is not paid by the study sponsor so you or your health plan/insurance company may have to pay for this.] **[If applicable:]** The cost of giving the study drug/device/procedure to you [is also provided at no cost/is not paid by the study sponsor so you or your health plan/insurance company may have to pay for this.]

It is possible that the study drug/device/procedure may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

You and/or your health plan/insurance company will need to pay for all of the other costs of [caring for/preventing/treating] your condition while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no cost. Before you decide to be in the study, you should check with your health plan/insurance company to find out exactly what they will pay for. Examples of procedures and drugs that may be billed include the following: [please provide a list, as appropriate, and include costly approved drugs that will not be provided by the sponsor].

**Injury: For research that is greater than minimal risk, the following language must be used in place of any other language:**

*[Option A: If this is an industry-sponsored study, please use the following:]*

If you are injured as a result of being in this study, UC San Diego [and RCHSD – insert as applicable] will provide necessary medical treatment. The costs of the treatment may be covered by the University of California [and Rady Children’s Hospital San Diego – insert as applicable] or the study sponsor [insert name – if federally funded, can remove mention of study sponsor], or billed to you or your insurer just like other medical costs, depending on a number of factors. The University [and RCHSD – insert as applicable] and the sponsor do not normally provide any other form of compensation for injury. For more information about this, you may contact the UC San Diego Office of IRB Administration at 858-246-4777 or irb@ucsd.edu.

If you receive Medicare benefits, the sponsor, [insert Sponsor name] is required by law to report payments made to you for treatment, complications, and injuries that arise from this study. Information will be provided to the Centers of Medicare and Medicaid Services and its agents and/or contractors for this purpose. UC San Diego will provide the Sponsor with your name, date of event and health identification number (if not available, then Social Security number) only for Medicare beneficiaries that have had a study related injury for which the sponsor has issued reimbursement to the University.

[**Do not Include this language**] **Note:** Commercial companies sponsoring research often request their own language be used for subject injury or harm clause wording or that minor changes be made to this wording. Such requests cannot be honored. The wording was formulated with the intent of adhering to the requirements of federal regulations and University of California policy and conveying the basic, necessary information to the subject.

*[Option B: If this a grant-sponsored or PI-initiated study, please use the following:]*

If you are injured as a direct result of participation in this research, the University of California [and RCHSD – insert as applicable] will provide any medical care you need to treat those injuries. The University [and RCHSD – insert as applicable] will not provide any other form of compensation to you if you are injured. You may call the Office of IRB Administration at 858-246-4777 or irb@ucsd.edu for more information about this, to inquire about your rights as a research participant, or to report research-related problems.

The following additional language may be added for all **ACTG studies** only:

The study sponsor, the U.S. National Institutes of Health (NIH) does not have a mechanism to provide direct compensation for research related injury.

**Specimen Sharing/Value: The following language must be used. Similar sponsor language should be replaced:**

Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

**HIPAA: If information will be accessed, used, created, or disclosed, study teams are required to use the standalone University of California and Rady Children’s** [if applicable] **authorization form to cover both HIPAA and state law. Remove any HIPAA authorization language from the consent and include the following statement:**

You will be asked to sign and date a separate form authorizing access, use, creation, or disclosure of health information about you.

**Confidentiality: Add the following in the list of who has access to individual information:**

Members of the research team and other staff or representatives of UC San Diego whose work is related to the research or to protecting your rights and safety.

**If study involves medical procedures or administration of agents at any UCSD facility, add:**

This consent form and some details of your study participation will be noted in your UC San Diego [or Rady Children’s Hospital San Diego – insert as applicable] medical record. If you do not currently have a UC San Diego Health record [or Rady Children’s Hospital San Diego record – insert as applicable], one will be developed for you. People involved with your medical care and insurance at UC San Diego or other organizations may become aware of these details. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your UC San Diego Health record [or RCHSD record – insert as applicable] until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.

**If study involves sensitive information/populations such as HIV, Hepatitis B and C, minors, LAR, controlled substances, genetic disease studies, addiction studies, add the following to the above paragraph:**

UC San Diego [and Rady Children’s - insert as applicable] participates in health information exchanges (HIEs) with multiple other health systems. Sharing your electronic Health Record (EHR) with other health systems is only allowed when they are involved in your medical care. Study details included in your EHR would also be shared. For more information about HIE, including how you can opt out of sharing, ask the study team.

**Contact: Add the following statement to the section describing contact information:**

You may also contact the UC San Diego Office of IRB Administration at 858-246-4777 or irb@ucsd.edu to inquire about your rights as a research subject or to report research-related problems.

**Experimental Participant’s Bill of Rights is required for research studies that are defined as a “**[**medical experiment**](https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=24174.)**”.** **Include the following language in the consent signature section** **and add the Experimental Participant’s Bill of Rights at end of the consent form.**

You will receive a copy of this consent document and a copy of the “Experimental Participant’s Bill of Rights” to keep.

**FOR UCSD/RCHSD STUDIES (in addition):**

1) Add mention of Rady Children’s Hospital San Diego in header

2) Add RCHSD bar code to the header

3) Add mention of RCHSD in injury language [as seen above]

4) Add mention of RCHSD in medical record/HIE statement [as seen above]

**Experimental Participant's Bill of Rights**

**Every individual asked to participate in a research study has the right to be:**

1. Informed about the nature and purpose of the study.
2. Provided an explanation of the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.
3. Given a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.
4. Informed about any benefits that would reasonably be expected from the participation in the study, if applicable.
5. Informed about any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.
6. Told of the types of medical treatment, if any, available if complications should arise.
7. Provided an opportunity to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.
8. Informed that individuals can refuse to participate in the research study. Participation is voluntary. Research participants may refuse to answer any question or discontinue their involvement at any time without penalty or loss of benefits to which they might otherwise be entitled. Their decision will not affect their right to receive the care they would receive if they were not in the experiment.
9. Provided a copy of the signed and dated written consent form and a copy of this form.
10. Given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

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If you have any concerns or questions regarding the research study contact the researchers listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research participant, please contact:

* UC San Diego Office of IRB Administration at irb@ucsd.edu or 858-246-4777