

UCLA CONSENT FORM STANDARDS AND SAMPLE LANGUAGE

This guidance document provides:

1. **General Instructions** about how to prepare and format the consent form.
2. **Section by Section Instructions** about how to complete each section of the [UCLA Consent Form for Greater Than Minimal Risk Studies \(Biomedical Focus\) template](#). Keep this document readily available as you prepare the consent form.
3. **Suggested Language** for each section of the consent form template.
4. **UCLA Required Language** for all UCLA consent forms.

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General Instructions

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Suggested Consent Language for Genomic Studies

General Instructions

This Consent Form Standards document and the UCLA Consent Template for Greater than Minimal Risks Studies (Biomedical Focus) provide clear consent information to increase potential research participant understanding of research studies. Follow these general instructions to help facilitate better informed decision-making by participants:

- **Recommended Formatting:** Use reader-friendly formatting so the consent form looks easy to read.
 - Leave a 1-inch margin around the entire document.

- Leave ample white space between headings and paragraphs, but do *not* double space within paragraphs.
- Use subheadings, bullet lists and/or tables when appropriate.
- Use black Arial or similar font, preferably 12-point size, or larger when appropriate for the study population.
- **Required UCLA Formatting:**
 - **Footer:** Leave the footer of the consent form blank. The webIRB program will automatically insert the assigned protocol number and IRB approval period in the footer.
 - **Header:** Include page numbers (“Page X of Y” format). Also include any additional information (e.g., sponsor protocol number, version) as needed. A header is not necessary on the first page.
- **Required versus Suggested Language:** The sample language is *suggested language* for each section of the consent template, unless it is labeled as *required language* (e.g., use of specimens, treatment and compensation for injury.) Required language cannot be altered, but suggested language can be modified to best fit the research study.
- **Required versus Optional Sections of the Consent Document:** Each part of this standards document is required unless labeled as an **optional section** in red. Required sections must be in every consent form. Optional sections should be included as they apply to the research study.
- **Question and Answer Format:** The question and answer format is considered best practice for improving readability in consent forms. Write the consent form in conversational style, as if you were speaking to the reader.
 - **Section headings** should be in question format (see template) as if the participant were asking the question e.g., Are there any benefits if I participate?).
 - Answers should be in **second person** (“You” instead of “I”, as if the researcher were answering the questions). Also, use **active voice** (e.g., “the researchers will ask you to...” instead of “you will be asked to...”) whenever possible to engage the reader.
- **Reading level:** Write the consent form so it is understandable to a lay audience, e.g., 8th grade reading level; *USA Today* newspaper. The reading level of a document is more difficult if it contains long complex sentences. Whenever possible use words with three syllables or less, non-scientific/non-medical words, simple sentences and break up the text into short straightforward sections.
- **Parental permission/child assent forms:**
 - **Adolescents ages 13-17:** Create a single document addressed to the adolescent with signature lines for assent and parental permission. An exception to this would be when parents and adolescents are being asked to undergo different procedures, in which case two forms are needed.
 - **Children ages 7- 12:** Create two documents, one for parental permission and a separate simplified assent form for children. **Note:** Children are not required to

sign the assent form. In some circumstances children may not be able to sign the assent form, but investigators are required to document in the research record that child assent is obtained. See [guidance](#) for more details.

- **Genomic Research Studies:** [Genome.gov](#) is an excellent resource for creating genomic research consent forms. The UCLA genomic research section of this document also contains suggested language that meets consent form standards required by NIH GWAS policy for data submission to the dbGaP data repository.
- **Oncology Research Studies:** This standards document and the Consent Template for Greater than Minimal Risks Studies can be used for oncology research studies. A NCI-UCLA informed consent template for cancer treatment trials also is available on the [OHRPP website](#).

Section by Section Instructions

Main Heading (required section)

The following heading is required for all UCLA consent forms:

UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH

Study Title (required section)

- Include the **study title** on the consent form.
- If the official title is technical and difficult to understand, also **use a lay title** or shorter title that the research staff will use (**optional**).
- If a study has **more than one consent form**, label each form appropriately and use the same references within the IRB application (e.g., Consent for Main Study, Consent for Control Group, Parental Permission).

INTRODUCTION (required section)

- Use **an active statement** asking for participation in the research, rather than passive statements like “you have been asked” or “you are invited” to participate.
- Indicate **who is conducting the research** (name and degrees of the PI). You may list a co-investigator or other investigators here but the IRB does not require that all investigators be listed in the consent form—only in the IRB application. If it is likely that investigators may change frequently, do not include all the names.
- Provide **the name of the UCLA department/division** conducting the research.
- Explain to potential participants **why the research team is asking them to take part** in the study. Include a listing of **basic** inclusion/exclusion criteria if it will help potential participants decide about participation (e.g., you are between the ages of 18 and 40). **Do not** discuss detailed inclusion/exclusion criteria here.
- When preparing a consent form for parental permission **do not** use “you/your child” throughout the form. Instead, use “you” and insert a statement about parental permission and child assent within the introductory paragraph. For example:

- “The use of “You” in this consent form refers to your child as the potential research participant and you as the parent or legal guardian providing permission.”
- For studies involving children under the age of 7: “The researchers are asking you to allow your child to participate in this research study.”

Suggested statements:

- The research team is asking you to be in this study because...
 - You are a healthy person between the ages of 18 and 40.
 - You have tried to quit smoking in the past but have not been successful.
 - You are undergoing surgery and will be given a general anesthetic.
 - You have leukemia and other standard medical treatments have not been successful.
- You may be able to participate in this study if you [Complete this sentence or use a bulleted list of key inclusion criteria that potential participants will understand.]
- You may not be able to participate in this study if you [Complete this sentence or use a bulleted list of key exclusion criteria that participants will understand.]

WHY IS THIS STUDY BEING DONE? (required section)

- Discuss **the purpose of the study** in lay terms and include a statement that explains why the study is research (e.g., this study will test how an experimental drug works and whether it is safe.)
- Include a statement that the **study involves research**. This is particularly important for clinical studies because the relationship between patient-physician is different than that between subject-researcher.
- If the study involves **investigational test articles** (i.e., drugs or devices that are not FDA-approved), include this information in the consent. As appropriate, include a statement that a purpose of the study includes evaluation of the safety and efficacy of the test article.
 - Refer to the drug or device as “experimental” or “investigational” and explain why it is being used in the study. Do not use the term “new.”
 - Avoid statements that indicate test articles are safe or statements that the safety has been established in other studies when the purpose of the study includes the determination of safety.
 - Studies that involve an evaluation of safety and efficacy should not make claims of effectiveness.
- **Include definitions** for specific research design features (e.g., double-blind, randomization, placebo-controlled, dose escalation) if these will help participants understand the study.
- **Name the study sponsor**—use the same information as in the application.

Suggested clinical trial purpose statements:

For Phase I drug studies:

- The purpose of this research study is to test the safety and possible harms of

drug **XX** when it is given to humans at different dose levels. The researchers want to find out what effects (good and bad) drug **XX** has on you and your condition.

For Phase II drug studies:

- The purpose of this research study is to see if drug **XX** has any benefits at dose levels thought to be acceptable in earlier studies. The researchers want to find out what effects (good and bad) drug **XX** has on you and your condition.

For Phase III drug studies:

- The purpose of this research study is to see if drug **XX** is safe and effective for the treatment of your condition. The researchers want to confirm the right dose levels of drug **XX** and find out what effects (good and bad) drug **XX** has on you and your condition.

Suggested statements for unapproved drugs and devices, procedures:

- **XXX** is an investigational drug that has not yet been approved by the Food and Drug Administration (FDA). The safety and usefulness of the drug is being tested in this study.
- **XXX** is being compared to a standard drug, **XXX** that has already been approved by the Food and Drug Administration (FDA). The researchers are interested in learning which drug is more helpful in treating your condition.
- **Procedure XXX** is being compared to the standard procedure **XXX**. The researchers are interested in learning which procedure is more useful in treating your condition.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY? (optional section)

- State the **accrual goal** of the study and where appropriate discuss study cohorts.
- For multi-center studies, indicate accrual numbers for the entire study and for enrollment at UCLA; be consistent with the protocol.

Suggested statement:

- **XX** people will be asked to take part in this study at UCLA. **XX** people will be asked to participate nationwide.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY? (required section)

Guidelines for all consents:

- If **screening procedures** are involved, note these first and identify them as tests that will determine whether or not the person can continue in the study.
- Explain the **study design** to participants. Define complex design terms. Explain any procedures relating solely to research (e.g., randomization, placebo control) to the participants.
- Include **a description of the procedures** involved in the study and an explanation of which procedures are considered investigational and why.

- Procedures do not necessarily need to include specific names of standard lab tests (e.g., CBC, CMP, lipid panel, UA), but participants should know the type of specimen required for testing and the general purpose of the testing (e.g., “A blood sample will be taken from your arm to perform standard lab testing to make sure you do not have a low red blood cell count.”)
- Procedures do not necessarily need to include specific names of common psychological tests (e.g., BDI-II, MMSE, MCMI-III, MACI, QOLI), but participants should know the general purpose of the testing and how long the testing will take (e.g., “A standard test will be used to measure how you are feeling and your current level of depression. The test should take about 30 minutes to complete.”)
- Explain **how participation in the study differs from standard treatment** (if applicable).
- **List each procedure** in the order in which it will occur. Discuss each in a separate paragraph. Use subheadings as appropriate for complex studies, e.g., Screening, Visit 1, Visit 2, etc.
- **Describe randomization** to study groups as a study procedure. Explain the probability of assignment to a given group or condition. See suggested statement below.
- **Define terms** which might not be familiar to the average person the first time they are mentioned or replace them with a lay term – see the [PRISM Readability Tool Kit](#) for suggestions.
- As applicable, note the amount of time for each procedure and number of times each procedure will be performed.
- Specify the **amounts of blood** or tissue to be taken for study purposes using lay equivalents (e.g., teaspoons, ounces) for metric terms.
- Include **medical record review** as a study procedure when protected health information is created, accessed or disclosed for the study.
- **Use a study chart**, diagram, calendar, schedule, etc. as a possible addition to the narrative explanation of study procedures.
- For device studies, you may wish to **include simple diagrams** or pictures in the consent.

Guidance for studies that involve conventional (standard of care) medical procedures:

Make clear in the consent form whether procedures are being done for clinical reasons or for study purposes, including whether the procedures are being done *more often* because of the study. Use the following guidelines to determine the extent to which standard procedures and their associated risks need to be described in consent forms:

- If the standard procedure is not explicitly required by the study protocol, the consent form need not describe that procedure or its risks.
- If the standard procedure is a *main focus* of the study (e.g., one or more arms of a randomized study is standard) or is *explicitly required by the study protocol*, the consent form must include a full description of the procedure and its risks.

Suggested simple screening or procedure statements:

- A number of standard lab tests will be performed using your blood sample to make sure you can participate in this study.

- A number of standard psychological tests will be performed to measure how your brain processes information.

Suggested statements for describing study designs:

Randomized Studies:

- Randomization is a procedure used to assign research participants by chance to a study group in a clinical trial. It is used to make sure study results are not influenced by the selection of participants in one group as compared to another. In this study, you have a **XX** chance of being assigned to one group or another.
- Randomization means that you are assigned to a group by chance (like a flip of a coin). A computer program will place you in one of the groups. Neither you nor the researchers can choose the group you will be in. You will have an [equal/one in three/etc.] chance of being placed in any group. You will be randomized into one of the study groups described below.
 - If you are in Group 1: Explain what will happen for this group with clear indication of which interventions depart from routine care.]
 - If you are in Group 2: [Explain what will happen for this group with clear indication of which interventions depart from routine care.]
 - [For studies with more than two groups, an explanatory paragraph containing the same type of information should be included for each group.]

Blinded Studies:

- Double-blind means that neither you nor the researcher(s) conducting the study will know which treatment you are receiving. However, in the case of an emergency, the research team can quickly find out to what study group you are assigned.
- Single-blind means that you will not know which treatment you are receiving.

Placebo-controlled Studies:

- Placebo-controlled means that the one group will get a placebo. A placebo looks like the investigational drug but it includes no active ingredients. If you are in the group that receives placebo, your condition will go without active treatment for **XX** weeks.

Dose Escalation Studies:

- Dose escalation means that participants enrolling early in the study will be given relatively low doses of the study drug and that if the low doses appear to be safe, participants enrolling later will receive higher doses. [*If, appropriate to inform subjects where they are in the dosing scheme.*]
- The purpose of this research is to find the best way to give an experimental drug and how much of it can be given safely. In this study, an experimental drug is given to a small number of people. The study starts by giving a very low dose of **XX**, and then the dose is slowly increased as other people enter the trial. [*If appropriate, indicate whether dose escalation is by cohorts or if*

individuals will receive escalating doses.]

Dose Titration Studies:

- The purpose of this research is to find the best way to give an experimental drug and how much of it can be given safely. In this study, the experimental drug will be given at a very low dose, and then it will be slowly increased to determine an effective dose of **XX**. The dose can be increased by giving more at one time or by giving the same dose more often.

HOW LONG WILL I BE IN THIS STUDY? (required section)

- Explain ***the duration of the study*** or how long the study will last. This will help participants decide if they have the time to participate.
- When appropriate, state that the study involves ***long-term follow-up*** by specifying the timeframes and requirements for long-term participation.

Suggested study duration statements:

Short-term, simple studies:

- You will be in this study for **XX** days.
- Your participation in this study will last ____.
- Participation in this study will require about **XX** hours of your time.
- This study will require approximately **XX** hours of your time for each study visit. There will be a total of **XX** study visits over six months.
- You will be in the [*insert clinic/center name*] for a total of **XX** days.

Long-term, complex studies:

- If you agree to participate in this study you will [*describe the research intervention, e.g., you will take drug XX for XX months/weeks/until a certain event occurs*]. After you complete [*drug XX, procedure YY*] the researchers will ask you to visit the office for follow-up exams every **XX** months for **XX** years.

WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT? (required section)

- ***Risks and discomforts include*** physical, psychological, social and economic harm.
- ***Explain the risks*** and/or possible side effects and discomforts ***of procedures*** relating solely to research.
- ***Explain the risks of the tests*** required in the study protocol, especially for tests that carry significant risk of morbidity/mortality themselves.
- ***Explain the risks associated with each drug separately***; however, for a given drug list the associated risks ***once*** and not multiple times by treatment arm. Explain any risks associated with combination drug regimens.
- ***Organize and describe risks*** according to their probability or severity of occurrence (e.g., likely, less likely, and rare but serious.)
- ***Provide the consequences of risks***; that is, whenever possible, describe how the risks and side effects will make the participant feel. For example, explain "anemia" as follows: "Loss of red blood cells, also called anemia, can cause tiredness, weakness and shortness of breath."

- **Describe the precautions to prevent risks from occurring** when appropriate. Also describe what will be done if they occur.

Guidelines for explaining certain risks associated with procedures performed for research:

- **Blood draw risks:** Standard wording notes temporary discomfort from the needle stick, bruising and, rarely, infection and fainting. If more than one unit of blood is to be drawn within an 8-week period, a medically appropriate precaution concerning subsequent blood donation is required.
- **Radiation risks:** The IRB recognizes that the risk from small amounts of radiation exposure is extremely difficult to describe in terms that are meaningful to the average layperson. While comparisons to chest x-rays are often used, most lay people have no way of estimating the risks of exposure from chest X-rays either, even though they are probably familiar with the procedure itself. Use a simple statement that alerts participants to the risk of the radiation exposure and advises him/her to speak with the researcher if there are further concerns about this exposure. The UCLA Medical Radiation Safety Committee (MRSC) or Radioactive Drug Research Committee (RDRC) will provide investigators with radiation dosimetry and calculation of the absorbed dose in matter and tissue resulting from the exposure to indirect and direct ionizing radiation.
- **CT scan risks:** Describe radiation risks from CT scans in the same way as those from x-rays. As with MRI, note the possibility of claustrophobia or discomfort from being in the CT scanner. In addition, include risks and discomforts of contrast agents and sedation if appropriate.
- **MRI risks:** Warn subjects that because the MRI machine acts like a large magnet, they must not have any metal on or in their bodies. This precaution is needed to prevent any resulting injury. Also note that subjects will be in a tight confined space and may be bothered by feelings of claustrophobia. They may also be bothered by the loud clanging noise during the MRI scan. Since the risks to a fetus from MRI are unknown, state that pregnant women may not participate in studies involving MRI procedures.
- **Reproductive risks:** Include among the screening procedures any pregnancy testing done for study purposes. If men or women are advised to use birth control or avoid pregnancy before, during, or after the study, describe these precautions among the study procedures. As appropriate, identify any required or acceptable methods of birth control and describe the risks to pregnant mothers, fetuses, and/or fertility of subjects.
- **Unknown risks:** For studies involving investigational agents, or experimental doses or combinations of drugs and/or treatments, tell subjects that there may be risks associated with the drug/treatment that are as yet unknown, but that the researcher will advise them if any new information becomes available that might affect their desire to participate in the study.

Suggested statements for routine risks/discomforts:

- **Risks associated with common cancer drugs:** The JCCC Office of Regulatory Compliance (ORC) has a document available on their [extranet site](#) that includes risk language for common cancer drugs. **Note:** A user name and password is required

to access the site. Contact the JCCC ORC for more information: (310) 794-8742.

- **Statement about treating side effects:** The researchers will observe you carefully for any harmful side effects. Although the experimental [drug/device](#) has been well-tested in laboratory and animal studies, the side effects in people are not completely known at this time. You will be followed closely by the study doctor for the entire time you are a part of this study. If you experience any side effects from the study, the researchers will provide you with the treatment that has the best chance of taking care of the side effects. If you experience any side effects related to the study [drug/device](#) that continue at the end of study, we will continue to follow-up with you until these effects stabilize or resolve.
- **Risks associated with randomization:** You will be assigned to a study group at random (by chance). Your assignment is based on chance (like a coin flip) rather than a medical decision made by the researchers. The study group you are assigned to might not be the group you would prefer to be in. It might also prove to be less effective or have more side effects than the other study groups(s), or standard treatments available for your condition.
- **Risks associated with withdrawing from current medication (washout period):** During this study the medication you normally use for your condition will/may be stopped for up to [[XX days/weeks/months](#)]. You will/may receive no medication, or medication at a dose which may not help your condition. As a result, you will/may have an increase in symptoms including [XX](#).
- **Placebo risks:** During this study there is a [XX](#) chance that you will receive a placebo. This could lengthen the amount of time before you receive a treatment that may be effective. During this time you may experience worsening of your condition, including increased symptoms such as [XX](#). The researchers will carefully monitor your condition. If your symptoms worsen and make you uncomfortable, you can withdraw from the study.
- **HIV testing risks:** Being tested for HIV can make you feel nervous or anxious about the test results. A positive test indicates that you are infected with the HIV virus, but no one knows for certain when, if ever, you will get AIDS or a related condition. Receiving positive results may make you very upset. If other people learn about your positive test results, there might be a risk that you could be treated unfairly or badly, and even have trouble obtaining insurance or employment. To the extent permitted by law, the researchers will keep your test results confidential and will not release them to anyone without your written permission. If you test positive, California law requires health care providers and clinical laboratories to report the HIV test results with your personal identifying information to the local health department.
- **Blood draw risks:** Drawing blood may cause temporary pain from the needle stick, bruising or swelling at the site, and rarely, infection or fainting.
- **Exercise testing risks:** The exercise test(s) may cause muscle soreness, dizziness, or shortness of breath. In rare instances, exercise tests may cause chest pain, tightness, or a change in vital signs.
- **Psychological risks:** Some of the questions the researchers ask you may be

upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.

- **Standard of Care (SOC) Radiation Exposure Risks:** Since the radiation procedures used in this study are all standard of care, the amount of radiation you will receive is the same as that for similar patients who are not participating in this study. Therefore, you will not be exposed to any additional radiation for participation in this study.
- **Non-SOC Radiation Exposure Risks:** You are exposed to radiation on a daily basis, both from natural (sun and earth) and manmade sources. The estimated radiation dose that you will receive as a participant for this type of research has been compared to the limits allowed for a radiation worker. This limit is low and is not expected to be harmful. The person obtaining your consent can answer any questions you have, and provide detailed written information about the amount of radiation resulting from this study.
- **Radiation Exposure Risk Statement for Studies Requiring Radioactive Drug Research Committee (RDRC) Review:** You are exposed to radiation on a daily basis, both from natural (sun and earth) and manmade sources. In addition to the radiation that you may be exposed to as part of your clinical care, you may potentially receive [[describe e.g., XXX PET CT scans](#)] in a year while participating in this study.

The US Food and Drug Administration (FDA) has set radiation limits for participants for this type of research. The dose you will receive in this study is low and below these limits and is not expected to be harmful. The person obtaining your consent can answer any questions you have, and provide detailed written information about the amount of radiation resulting from this study. Please inform your researcher if you have been exposed to radiation as a result of any other research studies.

- **CT scan risks:** CT scans involve the risks of radiation (see above). In addition, if contrast material (iodine dye) is used, there is a slight risk of developing an allergic reaction, which may cause symptoms ranging from mild itching or a rash to severe difficulty breathing, shock, or rarely, death. The contrast material may also cause kidney problems, especially if you are dehydrated or have poor kidney function. The study doctors will ask you about any allergies or related conditions before the procedure. If you have any of these problems, you may not be allowed to have a CT scan [[or continue in the study](#)].

Having a CT scan may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia when placed inside the CT scanner, or by lying in one position for a long time. If contrast material is used, you may feel discomfort when it is injected [[given by XXX](#)]. You may feel warm and flushed and get a metallic taste in your mouth. Rarely, the contrast material may cause nausea, vomiting or a headache. [[List other risks as appropriate to the method by which contrast agent is administered](#)]. [[If sedation may be used, discuss risks of sedation here](#)].

- **PET Scan - General Risk Statement:** PET scans involve the risks of radiation (see above). If you have had a PET scan or have been exposed to radiation while participating in other research during the past year, you should inform the researcher(s). This will enable the researcher(s) to determine your total radiation exposure and make sure it does not exceed accepted safety guidelines. If you participate in future studies that involve the use of X-rays or radioisotopes, you should discuss the safety guidelines for radiation exposure with the researcher who is performing the study.

- **Clinical MRI risks:** The MRI procedure uses a powerful magnetic field to generate detailed images of the body. The magnet could move objects within your body that contain metal, such as implants, clips and pacemakers. Tell the doctor if you have any metal items within your body.

MRI scanning is painless but you might experience discomfort in the machine. In particular, loud beeping and hammering noises occur during the study when the scanner is collecting measurements. You also may be bothered by feelings of claustrophobia when placed inside the MRI, or by lying in one position for a long time. You might also experience stimulation of the nerves in your body, which feels like a gentle tap or sensation of mild electric shock. [\[If appropriate, also discuss the risks of sedation here\].](#)

Because the risks to a fetus from MRI are unknown, you cannot participate in this study if you are pregnant.

- **Injection of Gadolinium during Clinical MRI:** Gadolinium, a substance given during the MRI examination, will be given by injection into a vein in your arm. This may cause some minor pain, and may cause some bruising near the area of injection. Gadolinium may also cause headache, nausea, and vomiting. Rarely, it may cause dizziness, rash, itching, or a numb or tingling feeling in the hands or feet, or an allergic reaction. Medical personnel will be available to treat any of these problems if they should occur.
- **Nephrogenic Systemic Fibrosis Risk Associated with Gadolinium:** Some people who have had MRIs with gadolinium-based contrast agent gadodiamide have experienced a serious reaction called nephrogenic systemic fibrosis (NSF). NSF is a condition where people develop large areas of hardened skin with lesions called plaques and papules with or without skin discoloration. In some cases, NSF could lead to physical disability and may involve not only the skin, but also the liver, lungs, muscles and heart. The typical patient in whom this has occurred is middle-aged and has end-stage kidney disease.
- **Known reproductive risks:** You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. Therefore, you need to use effective birth control while on this study. [\[As appropriate, specify what methods of birth control are required or acceptable and discuss how long to use them.\]](#)
- **Unknown Risks to Women of Child Bearing Potential and Pregnant Women:** The effects of **XXX** on fertility or a fetus are not known. For this reason, if you believe that you are pregnant or have a chance of becoming pregnant you should

not participate in this study. A [blood / urine] pregnancy test will be performed before the start of study procedures. If you are pregnant, you will not be allowed to participate in the study. If you do participate in this study, you must use a medically effective form of birth control before entering the study, while participating in the study, and for at least XXX after stopping the study. If you become pregnant during the study, tell the researchers right away.

- **Unknown risks to infants:** The side effects of XXX on infants are also not known, therefore if you are currently breastfeeding you cannot participate in this study.
- **Loss of confidentiality:** As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening (see “How will my information be kept confidential?” section below).
- **Unknown Risks:** The experimental drug may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

ARE THERE ANY BENEFITS IF I PARTICIPATE? (required section)

- Clearly **describe all expected benefits**. Do not overstate the benefits.
Note: Federal regulation does not allow the provision of free drugs or medical procedures (including increased monitoring) to be described as a benefit.
- **If there is no anticipated direct benefit** to the participant from the study, state this at the beginning of the section.
- Describe any potential direct benefits to the participant first, followed by **potential general benefits** (e.g., to the group of patients to which the individual belongs, or to medical knowledge).

Suggested statements:

- You will not directly benefit from participation in this study. (**Note:** *This statement cannot be used if participants will be billed for research-related procedures.*)
- There will be no direct benefit to you from participating in this study. However, this study will help the researchers learn more about [procedure/drug/intervention/ device]. Hopefully this information will help in the treatment of future patients with [disease /condition] like yours. (**Note:** *Do not use this statement if participants will be billed for research-related procedures.*)
- You may benefit from this study if you are assigned to the study group that receives [XXX] and [XXX] proves to be beneficial.
- The study will test whether [XXX] improves your condition. However, you personally may not benefit from taking part in this study.
- Taking part in this study may or may not improve your health. While doctors hope [procedure/ drug/ intervention/ device] will be [more effective/have fewer side effects] than standard (usual) treatments, there is no proof of this yet.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

(required section)

- Describe the **alternatives to participation** in the study.
 - Inform participants of the range of options available to them, especially for studies that involve medical interventions.
 - For studies that do not involve medical interventions, it is acceptable to say that the alternative is not to participate in the study.
- Include applicable information on alternative procedures or courses of treatment that may be advantageous to the participant if he/she refuses to participate or withdraws from the study (e.g., treatment without being in a research study; participating in another study; getting no treatment.)

Suggested statement for alternative treatments or procedures:

Example #1:

You may wish to talk with your treating physician about your choices before deciding if you will take part in this study. If you decide not to participate in this study, your other choices may include:

- Receiving no treatment at this time.
- Receiving the same drug being used in this study but not being in this study [only if available and easily prescribed].
- Receiving standard treatment for your condition without being in a study.
- Taking part in another study.

Example #2: [For studies involving end-stage diseases, add the following paragraph as an additional bullet.]

- Receiving comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by your disease. It does not treat the disease directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Example #3:

- There are no alternative treatments or procedures available. The only alternative is not to participate in this study.

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY? (optional section)

- Inform participants of **circumstances** under which their participation may be terminated by the investigator without their consent, if applicable.
- Inform participants of any procedures for **safe and orderly withdrawal** from the study if they withdraw or are removed from the study.
- Inform participants that the study might also be **ended by the researchers or the study sponsor**.

Withdrawal from FDA-regulated clinical trials:

- Inform participants if they withdraw from an FDA-regulated clinical trial, the data collected about them up to the point of withdrawal will remain part of the study database and may not be removed. See [FDA Guidance](#) for more details.

- Participants may withdraw from the interventional portion of a study and consent to allow for continued follow-up and/or further data collections are outlined below:
 - A separate, UCLA IRB-approved consent document is required for this limited participation activity if such a situation is not described in the original informed consent.
 - The consent form clearly must distinguish between study-related interventions and continued follow-up of associated clinical outcome information (e.g., lab results, review of medical records).
 - If a participant **does not consent to continued follow-up** of associated clinical outcome information, their medical records or other confidential records cannot be accessed to obtain any **new information** about the participant.

Suggested Withdrawal Statements:

- The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers or the study sponsor might also decide to stop the study at any time.
- If you decide to stop being in the study, or are removed from the study, or the study is stopped, the researcher will ask you to... [\[complete this sentence. For example, return for a final close-out visit or evaluation, return unused study medication, complete an exit telephone interview.\]](#)
- **Add to FDA-regulated clinical trials:** If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about you up to that point will remain part of the study and may not be removed from the study database.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL? (required section)

- Inform participants of the extent to which the researchers intend to maintain confidentiality of records that identify them. Specifically:
 - How data, records, specimens containing private or personal information will be collected and used for the study.
 - What methods are in place to code or de-identify information.
 - How data, records, specimens will be stored, and who will have access to them (including how they will be shared for future research.)
- Indicate what regulatory or other agencies might have access to the research records (e.g., the FDA, sponsoring company, authorized UCLA representatives).
- Suggested consent statements below can be combined into paragraphs and all options provided should be considered.
- Data collection and storage procedures need to be in compliance with the [OHRPP Data Security Guidelines](#).

Guidance:

- **Do not guarantee complete confidentiality:** An inherent risk of participating in research is a loss of privacy and the potential for a breach in confidentiality. There is no legal privilege between the researcher and participant as there is between physician and patient or counselor and client. Thus, a guarantee of “complete” or “strictest” confidentiality should not be given or implied.
- **A separate UC HIPAA research authorization form is required:** Due to the complexities of HIPAA and California Medical Information Act (CMIA), and the University of California’s status as a hybrid covered entity, a separate UC Research Authorization form is used to comply with all applicable laws concerning access, use and disclosure of medical health information for research.
Note: Do not add additional information about the use of protected health information in the consent form. The UC HIPAA research authorization form cannot be altered.
- **Protection from forced disclosure of research data and records:** Researchers may wish to obtain a Certificate of Confidentiality (COC) for studies that involve illegal activities or collect sensitive information, that if disclosed, could have adverse consequences for participants or damage their financial standing, employability, insurability, or reputation. COCs allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. For studies where a COC will not be obtained, participants should be informed about a loss of privacy if records are subpoenaed.
- **Use, storage, access and sharing of data and specimens:** Data statements below may also include information about specimens, as appropriate. In all cases participants need to be informed about the confidentiality provisions in place for collection, storage, use and sharing of data and specimens.

Suggested Confidentiality Statements for All Consents:

- The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.
- The researchers will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known. This signed consent form will be stored in a locked file that will be accessible only to a very small number of authorized people involved in this project. The research team will carefully follow the coding, storage, and data sharing plan explained below.

Combine one of the above suggested statements with the relevant suggested statements below to create simple paragraphs to describe data use, storage, access and sharing:

Describing identifiers linked to data and records:

- No identifiable information about you will be kept with the research data.
- [All/some](#) identifiable information about you will be replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.
- [All/some](#) identifiable information about you will be kept with the research data.

Describing storage of data and records:

- [All/some](#) research data and records will be maintained in a secure location at UCLA. Only authorized individuals will have access to it.
- [All/some](#) research data and records will be stored on a laptop computer that is [\[describe protection and/or has encryption software.\]](#)
- [All/some](#) research data and records will be stored electronically on a secure [\[computer or network\]](#) with [\[encryption and/or password\]](#) protection.

Describing routine access to study data and records (suggested for all consents):

- The research team, authorized UCLA personnel, the study sponsor ([remove if not applicable](#)), and regulatory agencies such as the Food and Drug Administration (FDA), may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

Describing retention of data and records:

- The researchers intend to keep the research data and records until the research is published and/or presented.
- The researchers intend to keep the research data and records for approximately ___ years.
- The researchers intend to keep the research data and records indefinitely for future research.
- The researchers intend to keep the research data and records in a repository indefinitely. Other researchers will have access to the data for future research.
- The researchers intend to keep the research data and records until analysis of the information is completed.
- In the future, data collected for this study may be shared with other researchers for other studies that are unknown at this time. Any data shared with other researchers, will not include your name or other personal identifying information.

Certificate of Confidentiality statements:

- **Example #1 (NIH example):**
To help the researchers protect your privacy, they have obtained a Certificate of Confidentiality from the [National Institutes of Health/Food and Drug Administration](#). With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold the information.

- **Example #2:**

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the [National Institutes of Health/Food and Drug Administration](#). With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Exceptions:

- The researchers are required by law to disclose information about incidents such as child abuse or the intent to hurt yourself or others.
- The Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.
- A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you without your consent. In addition,

- **Mandated child or elder abuse reporting:** Under California law, the privilege of confidentiality does not extend to information about sexual or physical abuse of a [\[child/elderly/dependent adult.\]](#) If any member of the research team has or is given such information, he or she is required to report it to the authorities. The obligation to report includes alleged or reasonably suspected abuse as well as known abuse. [\[As appropriate, provide descriptions and examples of the types of information which would be reported.\]](#)

Suggested language for giving participants choices about future use of data and specimens [\[Note: Use only the choices that are appropriate for this study\]:](#)

USE OF DATA AND SPECIMENS FOR FUTURE RESEARCH

1. My data and/or specimens may be kept for use in future research to learn about, prevent or treat other health-related problems (for example: diabetes, Alzheimer's disease, or heart disease).

YES	NO
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2. Additional tissue [and/or blood] may be taken for this research, as described in the What Will Happen If I Agree... section above.

YES	NO
-----	----

CONTACT FOR FUTURE RESEARCH

UCLA researchers may contact me in the future to ask me to take part in other research studies.

YES	NO
-----	----

ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY? (optional section; required if participants will incur costs)

- Inform participants about **any additional costs** that may result from participation in the study.
Note: Do **not** provide an actual dollar amount for the costs.
Do identify which study procedures will result in additional costs.
- If there are **no additional** costs for participation, state this in the consent form.
- As appropriate, inform the participants of any additional costs they will incur such as **parking fees** or transportation that will not be reimbursed...
- **Do not discuss research related injury costs in this section.** See the section below, “What Happens if I believe I am injured because I took part in this study?” for UC required language for treatment and compensation for research-related injury.
- **Sponsor covered items and services:** The costs section may be specific about items and services that will be covered by a Sponsor, e.g., study medication.
Note: Sponsor-initiated clinical trials are to be fully funded by the sponsor and such costs should not be billed to third party medical insurance, unless such billing is permissible per State and Federal law. Insurance billing cannot be a condition for Sponsor payment.
- **Insurance coverage and participation in research studies:** Include a statement informing subjects that because they are participating in a research study, insurance providers may not cover all costs.
- **For NCI-funded studies:** Provide participants with the website address and phone number of the National Cancer Institute (NCI) that offers more information on clinical trials and insurance coverage. See <http://www.cancer.gov/clinicaltrials/education/insurance-coverage> for details.
- **Financial counseling and cost estimates:** Participants should be informed that financial counseling and itemized cost estimates are available upon request. Investigators can contact UCLA Patient Financial Services for a list of estimated costs. Contact Bina Sehmi, (310) 794-1130 or HospitalCashPricing@mednet.ucla.edu

Suggested statements:

UCLA standard insurance billing language:

Note: *Use of this statement is required for almost all studies, as it allows UCLA to bill for research related costs permissible under Medicare billing rules.*

- You or your insurer will be billed for the costs of any standard medical care you receive during your participation in the study and you will be responsible for any associated co-payments and deductibles. There is a possibility that your medical insurance company may not cover these costs because you are in a research study. If this happens you might have unexpected expenses from being in this study, such as the costs associated with treating side effects. Financial counseling and itemized cost estimates are available upon request.
- The study sponsor will supply and pay for the cost of supplying and administering the study drug and the extra related laboratory tests. However, you and your insurer will be billed for the costs of all other study procedures as these are considered standard of care. [Continue with above language.]

NCI clinical trial information about insurance coverage:

- For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at <http://cancer.gov/clinicaltrials/understanding/insurance-coverage>. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site. Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

WILL I BE PAID FOR MY PARTICIPATION? (optional section; required if participants will be paid or reimbursed)

- If participants will be paid for participation or reimbursed for costs (e.g., parking), describe in detail the type of payment, amount, and terms of payment or reimbursement.
- Payment for participation and cost reimbursement should be commensurate to the participants' time and the inconvenience of being a research subject.
- The payment section of the consent form should indicate:
 - The total dollar amount that participants will be paid and any relevant information such as pro-rating if a person does not complete the study, or bonus payments at the end of the study.
Note: Participants should not be required to complete the entire study in order to be paid, and any bonuses for study completion should be modest.
 - How payment will be made (e.g., in cash, by check).
Note: If payments are made by check, participants will need to provide the researcher with an address and social security number.
 - When participants will be paid (e.g., immediately after the interview, approximately six weeks after individual completion of the study). Include a payment schedule, if appropriate.
 - Whether participants need to submit receipts in order to be reimbursed.
 - Whether participants need to provide their home address and social security number to receive payment, if applicable.

- Payments for research participation are considered taxable income. If subjects are paid more than \$600 total in a calendar year for participation in research studies, the University will report this as income to the IRS.

Suggested payment statements:

No payment or reimbursement:

- You will not be paid for your participation in this research study. You will not be reimbursed for any out-of-pocket expenses, such as parking or transportation fees.

Reimbursement for out-of-pocket expenses:

- You will be reimbursed for the following expenses [complete this sentence, e.g., parking.] In order to be reimbursed, please be sure and save your receipts so that you can provide these to the research staff.

Identity of participant required for payment:

- Personal information about you, including your name, address, and social security number, will be released to the UCLA Accounting Office for the purpose of payment.
- For payments of \$600 or more - use the statement above and add, "...and for tax reporting to the Internal Revenue Service (IRS)."

WHAT OTHER THINGS SHOULD I CONSIDER BEFORE PARTICIPATION?

(optional section; required section if specimens are collected and/or there are researcher financial interests)

Use of Specimens:

- Include *one* of the following three statements in all consent forms that collect specimens for research.
Note: These statements should not be altered with the exception of specifying the type of specimen collected.
- Any specimens shared with outside entities must be de-identified or coded.

UC Required Statements:

If specimens will be kept by UCLA:

- Any specimens (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the University of California. Once you provide the specimens you will not have access to them. The University may share your specimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of UCLA. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

If specimens will be provided to an outside entity, such as the study sponsor or national group:

- Any specimens (e.g., tissue, blood, urine) obtained for the purposes of this study will be provided to [the Sponsor of this study (company name optional) or the name of the national group]. These specimens will not include information that identifies you directly. Once you provide the specimens you will not have access to them. The specimens will be used for research and such use may result in discoveries that could become the basis for new products or therapeutic agents. In some instances, these discoveries may be of potential commercial value. You will not receive any money or other benefits derived from such a product.

If specimens will be discarded:

- Any specimens (e.g., tissue, blood, urine) obtained for routine lab testing will be discarded or destroyed once they have been used for the purposes described in the protocol.

Researcher Financial Interests in this Study

- If a member of the study team has a personal financial interest in the outside entity funding the study or other personal financial interests in entities that might reasonably be affected by the research, include a financial interest statement.

Suggested Financial Interest Statements:

- [Insert researcher's name with financial interest] has a personal financial interest in the company sponsoring this study [insert sponsor name]. Specifically, [researcher(s) name] is receiving [identify the financial interest, e.g., salary/payment for consulting, owns stock, holds a patent, serves on the Board of Directors]. A UCLA committee has reviewed these financial interests to help prevent them from affecting the quality and reliability of this study.
- See also <http://www.ucop.edu/raohome/cgmemos/11-04.pdf> for additional examples of standard language.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY? (required section)

- Provide the name of a person and the telephone number if participants want to contact the study team:
 - For answers to questions about the research itself
 - To be able to express concerns

Note: Do not provide a long list of numbers for the participant to call.
- For greater than minimal risk studies, provide a 24-hour contact number (e.g., UCLA page operator) in this section.
- Provide information about how to contact the UCLA Office of the Human Research Protection Program.

Note: The statement below should be used for all consent documents.
- **Clinical Trials:** If the consent form is for a study that meets the [NIH definition](#) of an “Applicable Clinical Trial,” the statement provided below must be added to the consent.

Note: FDA asserts that the reference to the clinicaltrials.gov website allows participants to ascertain the nature, scope, and progress of a registered applicable clinical trial, thus reassuring the participant that participation in a trial contributes to the advancement of medical knowledge.

Suggested Statements:

- **The Research Team:**
You may contact [insert name] at [insert phone number] with any questions or concerns about the research or your participation in this study.
- **UCLA Office of the Human Research Protection Program (OHRPP):**
If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UCLA OHRPP by phone: (310) 825-5344; by email: mirb@research.ucla.edu or U.S. mail: UCLA OHRPP, 11000 Kinross Ave., Suite 211, Box 951694, Los Angeles, CA 90095-1694.
Note: Use Telephone: (310) 825-7122; email: gcirb@research.ucla.edu for General Campus studies.

Required statement for “Applicable Clinical Trials” – see [NIH definition](#).

Note: This statement cannot be altered, per federal regulation:

- **Public Information about this Study:**
ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. 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.

WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY? (required section)

- **Required UC treatment and compensation injury statement:** Below is the UC standard treatment and compensation injury statement.
Note: This statement cannot be altered. If sponsors ask that the wording of this statement be altered, even if only very slightly, they should be advised that any change in the wording will delay, if not prevent approval of the consent form.
- **Working with sponsors:** Sponsoring companies often request different wording for the treatment and compensation for injury policy statement, minor changes to the UC statement, or conditions for when the sponsor will pay for injury. **Such requests cannot be honored.** The wording of the statement was formulated with the advice of UC legal counsel with the intent of adhering to the requirements of federal regulations and UC’s subject injury policy. The sponsor may include its name in the UCLA statement as written below, or the sponsor may remain silent on this point, in which case the reference to the sponsor should be omitted from the statement. The clinical trial contract language specifies under what conditions and process a Sponsor has a duty

to reimburse the University for the costs the University incurs in meeting its obligation to participants.

- **MMSEA 111 Language:** Section 111 of the Medicare, Medicaid and S-CHIP Extension Act, referred to as “MMSEA 111”, requires liability insurers to report on certain payments made to or on behalf of Medicare beneficiaries in order to facilitate enforcement of the Medicare Secondary Payer rules. Such reports are required by law, may be a prerequisite to securing payment from sponsors for diagnosis or treatment of complications or injuries caused by a patient’s participation in research, and qualify as coordination of benefits activities. Occasionally, sponsors request that information about this requirement be added to the consent form. Please use the required UC treatment and compensation injury statement below that includes information about MMSEA 111.

UC Treatment and Compensation for Injury Statement:

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed above.

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor [sponsor name], or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to mirb@research.ucla.edu.

Note: For General Campus studies use telephone: (310) 825-7122 and email: gcirb@research.ucla.edu.

UCLA Treatment and Compensation for Injury Statement (with MMSEA 111 Language):

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed above.

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor [sponsor name], or billed to you or your insurer just like other medical costs, depending on a number of factors. If the study sponsor covers these costs they will need to know some information about you like your name, date of birth, and Medicare Health Insurance Claim Number, or, if you do not have one, your Social Security Number. This information will be used to check to see if you receive Medicare, and, if you do, report the payment they make to Medicare. The study sponsor will not use this information for any other purpose. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to mirb@research.ucla.edu.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY? (required section)

- Inform all participants of the following:
 - **Participation is voluntary,**
 - **Refusal to participate** will involve no penalty or loss of benefits to which the subject is otherwise entitled, and
 - The **subject may discontinue participation** at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- Do not alter the UCLA standard statement.

UCLA voluntary participation statement:

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.
- If you decide to take part, you can leave the study at anytime.
- If you decide not to take part, you can still receives medical care from UCLA.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE? (required section)

- Documentation of informed consent requires a signature and date from the participant.
- Participant should receive as part of the consenting process:
 - A copy of the *signed* consent form,
 - Research Participant's Bill of Rights (required per CA statute for studies involving medical procedures) in a language understandable to the participant, and
 - A separate HIPAA Research Authorization form for studies that involve Protected Health Information (PHI) (required per UC policy).
- **The UCLA standard statement should not be altered.**

UCLA agreement to participate statement:

If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant's Bill of Rights to keep. [If Protected Health Information as defined by HIPAA will be accessed, used, created, or disclosed, add the following statement: You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.]

SIGNATURES (required section)

- The UCLA [Documentation of Informed Consent Guidance](#) should be reviewed to determine the required signature lines for the consent document.
- The participant must sign and date the consent form. Rare exceptions include blind or illiterate subjects and subjects unable to consent for themselves.

- Add any **additional signature lines** as applicable and approved by the IRB. For example, research involving children that research falls under [45CFR Part 46.406](#) or [21CFR 50.53](#) or [50.54](#) requires two parents/guardians to consent; research approved using surrogate consent requires a signature line for a legally-authorized representative (LAR). See [LAR-Surrogate Consent Guidance](#) for more information.
- The signature of the **person obtaining consent** indicates he/she has explained the research to the participant (or the legally-authorized representative when IRB approved,) answered any questions and the participant understands the information described in the document and freely consents to participate.

Suggested signature lines:

SIGNATURE OF THE PARTICIPANT

Name of Participant

Signature of Participant

Date

SIGNATURE OF THE PARENT/GUARDIAN [as appropriate]

Name of Parent/Guardian

Signature of Parent/Guardian

Date

Name of Parent/Guardian #2

Signature of Parent/Guardian #2

Date

SIGNATURE OF THE LEGALLY-AUTHORIZED REPRESENTATIVE [as appropriate]

Name of Legally-Authorized Representative

Signature of Legally-Authorized Representative

Date

SIGNATURE OF PERSON OBTAINING CONSENT

Name of Person Obtaining Consent	Contact Number
Signature of Person Obtaining Consent	Date

SUGGESTED CONSENT LANGUAGE FOR GENOMIC STUDIES

Note: These sample consent statements comply with NIH GWAS policy requirements. This is suggested wording only. Not all paragraphs will apply to your research.

Risks Associated with Loss of Privacy in Genomic Research:

- While neither the public nor the controlled-access databases developed for this project will contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.
- Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives. Therefore, your genetic information could potentially be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carry a genetic disease. There also may be other privacy risks that we have not foreseen.
- Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record.
- Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk. Although your name will not be with the sample, it will have other facts about you such as [insert specific details]. These facts are important because they will help us learn if the factors that cause [insert specific condition] to occur or get worse are the same or different based on these facts. Thus it is possible that study findings could one day help people of the same race, ethnic background, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.
- In the event of an unexpected breach of confidentiality, a federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health

insurance or employment discrimination based on genetic information obtained about you. In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Coding of Specimens and Medical Information:

- Your [[identify specimen\(s\) here](#)] and medical information will be labeled with a code. Only the researchers conducting this study will have the information that matches the code to traditional identifying information, such as your name, address, phone number, or social security number. The information that matches the code to your identifying information will be kept in a safeguarded database. Only very few, authorized people, who have specifically agreed to protect your identity, will have access to this database. All other researchers and personnel, including those who will be working with your samples and medical information, will not have access to any of this identifying information about you.

Storage and Release of Samples and Medical Information:

- Your coded [[identify specimen\(s\) here](#)] will be sent to a National Human Genome Research Institute (NHGRI) sequencing laboratory for detailed analysis. Remaining portions of your samples will be stored for an unlimited period of time for future use in research related to diseases or, perhaps, in other research projects. Information from analyses of your coded samples and your coded medical information will be put into databases along with information from the other research participants. These databases will be accessible by the Internet.
- Anonymous information from the analyses will be put in a completely public database, available to anyone on the Internet. Your coded medical information and information from more detailed analyses of your coded samples will be put in a controlled-access database. The information in this database will be available only to researchers who have received approval from a National Institutes of Health Data Access Committee. Note that traditional identifying information about you, such as your name, address, telephone number, or social security number, will NOT be put into either the public or controlled-access databases for this project.

Re-contacting Participants for Future Research:

- In the future, we may want to obtain additional samples or follow-up information about your health or medical care. Should this be needed, an authorized person from the UCLA research team will contact you to ask whether you would be interested in participating in this additional research.

Withdrawing of specimens and data by the research participant:

- If you want to withdraw from this project you can contact [[Insert Name & Contact Information](#)] at [[Insert Name of Institution](#)] and he/she will destroy any remaining specimens of yours that have been obtained for the study. In addition, it may be possible for [[him/her](#)] to destroy the link between you and your genetic and medical information. However, the samples and data generated from your specimens that have already been distributed to other research centers or placed in the research databases cannot be withdrawn.

