***IMPORTANT: ALL SECTIONS ARE REQUIRED UNLESS OTHERWISE NOTED. BEFORE FINALIZING & UPLOADING THIS DOCUMENT, REMOVE: THIS SECTION, ALL [RED INSTRUCTIONAL TEXT] AND BLUE EXAMPLES.***

**UNIVERSITY OF CALIFORNIA, IRVINE**

**CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT**

***[Title of Study]***

**Lead Researcher**

Name and Title

Department

Telephone number and e-mail address

24-Hour Telephone Number/Pager *[Required for medical studies and clinical investigators]*

**Other Researchers** *[For minimal risk research, this is not required; please remove]*

*[List only those researchers qualified to finalize the informed consent process]*

**STUDY LOCATION(S):**

**STUDY SPONSOR(S):**

**SPONSOR MASTER PROTOCOL NUMBER:**

**In the instance of parental permission, “You” refers to “Your child.”**

*[If not applicable, please remove]*

|  |
| --- |
| **SUMMARY OF KEY INFORMATION:**  **The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.**  ***Participation is Voluntary***  You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed above will be available to answer your questions.  ***Study Purpose***  *[Include a brief yet complete summary (i.e., no more than 3 sentences) of the study purpose. A detailed description will follow below in a subsequent section.]*  The purpose of this research study is to *[Complete this sentence]*  *Examples: to find out which type of blood pressure medication has fewer side effects.*  ***Study Procedures***  *[Include a brief yet complete summary (i.e., no more than 3 sentences) outlining study procedures. A detailed description will follow below in a subsequent section.]*  *Example: …completion of a daily diary of health symptoms. We will also request access to your medical record to review and record the medications you are taking for blood pressure, dates of treatment and previously reported side effects related to your current medication.*  ***Expected Duration***  *[Include a brief statement (i.e. no more than 3 sentences) of the time commitment required]*  Participation will last approximately…      hours/ weeks/ months and will include…       visits.  *Example: …1 hour per day of time to complete the daily diary for a total of 30 calendar days. There will be 2 study visits which should take no more than 1 hour in total.*  ***Risks of Participation***  *[Include a brief summary of the* ***main risks*** *(i.e., no more than 3 sentences) for participants on this study. A detailed description will follow below in a subsequent section.]*  The more notable risks of participation include…     .  *Example: …boredom or fatigue in completing the diary each day. Also, should there be a breach in confidentiality of your data, there is a slight risk that your private medical information could be shared with individuals who are not members of the study team.*  ***Benefits to Participants***  *[Include a brief statement of the benefits to the participant, choose one of the following statements and remove the other options.]*  *[Option 1: If possible benefit to the subject is anticipated]* Taking part in this study may or may not make your health better. While researchers hope *[procedures/ drugs/ interventions/ devices]* will be *[more effective/have fewer side effects]* than the standard (usual) treatment, there is no proof of this yet.  *[Option 2: If subject is randomized:]* If you are in the group that receives *[XXX]* and it proves to treat your condition *[more effectively/with fewer side effects than standard therapy/placebo]*, you may benefit from participating in the study, but this cannot be guaranteed.  *[Option 3: If no direct benefit to the subject is anticipated]* You will not directly benefit from participation in this study.  ***Benefits to Others or Society***  *[Include a brief statement (i.e., no more than 3 sentences) about possible benefits to science or society] Example: a decrease in the number of children injured in car accidents*  This study will help researchers learn more about*[procedures/ drugs/ interventions/ devices]*, and it is hoped that this information will help in the treatment of future patients with *[. . . /conditions like yours]*.  ***Alternative Procedures or Treatments***  *[Include a brief statement of the alternatives, choose one of the following statements and remove the other option.]*  *[Option 1]* If you decide not to participate, or if you withdraw from this study before it is completed, your other choices may include:   * Getting no treatment * Getting standard treatment for your condition without being in a study. * Getting a different experimental treatment/taking part in another study. * *[Additional bullets should include, when appropriate, alternative specific procedures or treatments.]*   *[Option 2: If no alternatives]* There are no alternative treatments or procedures available. The only alternative is not to participate in this study. |

**WHY IS THIS RESEARCH STUDY BEING DONE?**

The purpose of this research study is to *[Complete this statement in one or two sentences – use lay language] Examples: …*find out which type of blood pressure medication has fewer side effects; …test the safety of an experimental drug. We also want to find out what effects, good and/or bad, it has on you and your [specify condition/other as applicable to study].

*[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. For studies involving investigational drugs or devices, the name of* ***investigational drug(s) or device(s)*** *must be noted and named. The name by which the drug or device is referred to in this section should be used consistently throughout the consent form.* **NOTE:** *Refer to an investigational drug or device as "investigational" or "experimental" rather than "new," since "new" can suggest that something is automatically better.]*

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

*[State the enrollment 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 UCI; be consistent with the protocol.]*Approximately       participants will take part in the research at UCI. A total of       participants will be asked to participate across all study sites.

**AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?**

Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

*[List only the inclusion/exclusion requirements subjects would be easily able to identify, including age, gender, behavior (e.g., smoking) health status, disease status]*

***Inclusion Requirements***

You can participate in this study if you *[Complete this sentence or use a bulleted list of inclusion criteria – use* ***lay******language****] Examples: are at least 18 years of age or older; have been clinically diagnosed with depression.*

***Exclusion Requirements***

You cannot participate in this study if you *[Complete this sentence or use a bulleted list of exclusion criteria - use* ***lay******language****] Example: are taking high blood pressure medications.*

**HOW LONG WILL THE STUDY GO ON?**

***Short-term/simple study:*** This study includes [*XX visits*] and takes about *[XX hours]* over a period of *[XX days/weeks]*.

***Long-term/complex study:*** You will take *[specify drugs or interventions]* for *[months, weeks/until a certain event].* After you are finished taking *[drugs or interventions]*, the researchers will ask you to visit the office for follow-up exams for at least *[indicate time frames and requirements of follow-up. When appropriate, state that the study will involve long-term follow-up and specify time frames and requirements of long-term follow-up.] For example, "The researchers would like to keep track of your medical condition for the rest of your life. They would like to do this by calling you on the telephone once a year to see how you are doing. Keeping in touch with you and checking on your condition every year helps them look at the long-term effects of the study.*

**WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?**

*Before you can participate in the main part of the study...*

You will need to have “screening” exams, tests or procedures. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include *[Complete this sentence or use a bulleted list - use* ***lay******language****]*

*During the main part of the study...*

If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following procedures and tests done. The main study tests and procedures include…

1. *[Explain the research procedures in chronological order –, main study procedures, and follow-up procedures. Include the expected duration of each procedure, or each visit and the procedures to be completed at the visit. Use lay language.*
2. *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 biospecimen 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.”)*
3. *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.”)*
4. *Specify the amounts of blood or tissue to be taken for study purposes using a lay equivalent (e.g., tablespoon, teaspoon).*
5. *Include medical record review as a study procedure when protected health information is created, accessed or disclosed for the study.*
6. *It is* ***strongly recommended*** *that you provide a table of visits, tests and procedures. Tables may be easier for the subject to understand and may help to shorten long repeated paragraphs throughout the consent document.*
7. ***For studies that involve routine (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:*

* 1. *If the standard procedure is not explicitly required by the study protocol, the consent form need not describe that procedure or its risks.*
  2. *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.]*

1. *For studies that involve* ***Whole Genome Sequencing (WGS):*** *Make clear in the consent form that WGS will be included as a research procedure.*
   1. *Include a description of WGS such as; WGS is the sequencing of a human germline or somatic biospecimen with the intent to generate the complete DNA sequence of that biospecimen.*

*After you complete the main part of the study* *[stop receiving [drugs or interventions]...*

*[Explain the follow-up tests, procedures, exams, etc. required, including the timing of each and how they relate to standard care (e.g., they are different from standard care; or they are part of standard care but are being performed more often than usual or being tested for the study. Define the length of follow-up. [If not applicable, please remove.]*

**RETURN OF RESULTS** *[Required if the study will produce clinically relevant research results. If not applicable, please remove.]*

*[Explain the possibility that subjects may or may not receive research results. This section is meant to pertain to all clinically relevant research results, including general or aggregate research findings and individual research results.] Example: You will / will not be provided any research related clinically relevant information that may pertain to your health.*

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?

*[When applicable, include a sub-heading to indicate risks associated with the investigational drug, device or procedure, and then provide another sub-heading to indicate risks related to other procedures involved with the study.]*

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. The researchers may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking *[drugs/interventions].* In some cases, side effects can be serious, long lasting, or may never go away. *[The next sentence should be included if appropriate:* There is also a risk of death*.]*

You should talk to the research team about any side effects you experience while taking part in the study.

Risks and side effects related to the *[procedures, drugs, interventions, and devices]* include those which are:

*[Categorize the risks by likelihood and severity of the risk occurring. Use percentages if known. Consider all types of risks – psychological, social, economic, legal and physical. Also include risks such as a breach of confidentiality and those risks related to the use of placebo. For risks related to radiation exposure, all protocols involving radiation exposure to normal subjects, and/or to clinical subjects when the exposure is not considered standard-of-care, must be referred to the UCI Radiation Safety Committee (RSC) for review.]*

Likely

Less Likely

Rare but serious

*[If appropriate to the study, include the following risk statement(s)– remove or revise as applicable]*

**Randomization:** You will be assigned to a study group by chance (like a coin flip) rather than by a medical decision made by the researchers. The treatment you receive may prove to be less effective or to have more side effects than the other study group(s), or than standard treatments available for your condition.

**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:** 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.

**Blood draw:** Removing blood by a needle may cause temporary pain, bruising, bleeding, swelling, dizziness, and on rare instances fainting or infection.

**Exercise testing**: The exercise test 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 discomforts:** Some of the procedures may cause embarrassment or anxiety, or the questions the researchers ask you may be upsetting or make you uncomfortable. If you do not wish to answer a question, you can skip it and go to the next question. If you do not wish to participate you can stop.

**HIV / Hepatitis / Covid-19 testing:** Being tested may make you feel nervous or anxious about the test results. Receiving positive results may make you very upset. If other people learn about your positive test results, you may 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 test results with your personal identifying information to the local health department.

**MRI:** 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. You may be bothered by feelings of claustrophobia when placed inside the MRI, or by lying in one position for a long time. In addition, loud noises occur during the study when the scanner is collecting measurements. These noises are beeping and hammering sounds and may bother you. Temporary hearing loss has been reported from this loud noise. This is why you will be asked to wear ear plugs.

**Radiation:** *[For additional examples of radiation language for total dose of more than 1 rem see the last page of the consent form.]*

*[Use language for* ***x-ray, DXA, or CT scans*** *(i.e., machine-produced radiation)* ***if the total dose*** *to one individual (across entire study) is* ***less than 1 rem]****.*

During this study you will have *[insert total number of scans across the entire study]* *[insert type of scan; e.g., x-ray, DXA, or CT]* scans of your *[insert name of body part(s) to be imaged]*. These scans are *[or “this scan is,” as appropriate]* solely for the purpose of this research and you would not have these scan(s) if you decide not to participate in this research study. A *[insert type of scan; e.g., x-ray, DXA or CT scan]* scan uses radiation to create pictures of the structures inside the body. The total radiation dose that you will receive from *[insert total number of scans]* scan(s) of this type is about *[insert total effective dose (e.g.,* 20 millirem)*]*. A millirem is a unit used to quantify radiation dose. Typically persons in the U.S. receive a radiation dose of about 310 millirem per year from natural sources of radiation, including from the sun, air, water and soils. Therefore your total radiation dose will be about the same as *[XX]* extra *[insert number of equivalent days, months or years]* of natural background radiation.

There is no known health effects associated with this amount of radiation exposure, and no radiation remains in the body after the scan. If you are especially concerned about radiation exposure, you should discuss this with the researcher listed at the top of this form.

*[Insert if Iodinated contrast used during CT scans]*

“Iodine-containing contrast “dye” will be injected into your vein.  This increases the ability of the CT scan to show certain tissues in the body.  Side effects may include a mild headache, nausea, or burning at the injection site. Some people are allergic to the contrast, experiencing hives and itchy eyes, or very rarely, a bee-sting type of severe allergic reaction (anaphylactic shock). Use of iodine contrast may also cause an injury to the kidneys that is usually reversible, but can be more severe if you have kidney disease or diabetes. Before you are given this dye, please share any history you have of allergies, asthma, diabetes, heart disease or kidney disease.”

*[Insert if a Gadolinium-based contrast will be used during MRI scans]*

Gadolinium contrast “dye” will be injected into your vein.  This increases the ability of the MRI scan to show certain tissues in the brain or elsewhere in the body.

The contrast agent used during the MRI scans is a Gadolinium-based contrast agent (GBCA).  Gadolinium is retained for months or years in several organs. The highest concentrations (nanomoles per gram of tissue) have been identified in the bone, followed by other organs (e.g. brain, skin, kidney, liver, and spleen). The duration of retention also varies by tissue and is longest in bone. Consequences of gadolinium retention in the brain have not been established.

While clinical consequences of gadolinium retention have not been established in patients with normal renal function, certain patients might be at higher risk. These include patients requiring multiple lifetime doses, pregnant, pediatric patients, and patients with inflammatory conditions. *Note: Typically, pregnant patients are not given gadolinium.*

**Common Risk:**

You may experience a temporary metallic-like taste in your mouth when the agent is injected.

**Rare Risk:**

You may experience a “burning” sensation, pain or discomfort at the site of the contrast infusion.

You may experience bleeding or bruising at the site of the contrast infusion.

Both of these risks are fairly rare.

**Very Rare, Serious Risks**

Side effects include a mild headache, nausea, or burning at the infusion site. Some people are allergic to gadolinium, experiencing hives and itchy eyes, or very rarely, a bee-sting type of severe allergic reaction (anaphylactic shock).

In rare cases you may experience infections at the needle site. Infusing the contrast agent into your arm is done with sterile equipment, but germs on the skin may enter through the skin around the IV, causing swelling, redness, pain and fever.

Pathologic and clinical consequences of GBCA administration and retention in skin and other organs have been established in patients with impaired renal function. There are rare reports of pathologic skin changes *in patients with normal renal function. Adverse events involving multiple organ systems have been reported in patients with normal renal function without an established causal link to gadolinium retention*.

Use of gadolinium may be linked to an *extremely rare* but sometimes fatal condition (nephrogenic systemic fibrosis or NSF) *in people with severe chronic kidney disease or acute kidney problems*. Therefore, before you are given this dye your risk factors for kidney disease will be reviewed.

*[Use language for a* ***nuclear medicine scan*** *if the total dose to one individual (across entire study) is* ***less than 1 rem****.]*

During this study you will have *[XX]* *[insert number and type of scan; e.g., bone scan, thyroid scan, PET scan including body part to be imaged]*  using a radioactive drug to produce an image of your *[insert body part to be imaged]*. The drug is injected *[insert route of administration; e.g., it may be ingested]* in your body, and then after *[XX]* hours *[insert time based on specific nuclear medicine protocol]*, you will have a scan of your *[insert actual body part; e.g., your whole body, thyroid, or heart]* using a “gamma camera” that detects the radiation inside you, and creates a picture of structures inside your body. This scan is solely for the purpose of this research, and you would not have this scan if you decide not to participate in this research study. The total radiation dose you will receive from one scan is about 0.1 rem *[put in actual total effective dose]*. For comparison, persons in the United States receive a radiation dose of about 0.31 rem every year from natural sources of radiation, including from the sun, air, water, and soils, so the radiation exposure from one scan is equivalent to about four extra months *[put in actual number of equivalent days, months or years]* of natural background radiation.

After the scan, you will still have some radioactivity retained in the body, which will go completely away in the following *[XX]* hours *[insert time based on isotope and scan]*. The risk to others is very low, but you may cause sensitive radiation detectors used for security to alarm in the *[XX]* hours *[insert time based on isotope and scan]* after the scan. There is no known short-term health effects associated with this amount of radiation exposure. The primary risk from radiation exposure at this level is the potential for a very small increased risk of future cancer. If you are especially concerned with radiation exposure, you should discuss this with the study doctor.

**Incidental finding:** *[Required for scans (e.g., MRI, X-ray, CT, NM, US)(Revise as applicable)]*

In this study, you will have a *[specify the type of scan].* This scan is for research purposes only. The purpose of the scan is to look for *[specify]*. This is not a whole-body scan. The scan will be done of your *[specify the body part]* only.Whenever imaging of this type takes place, there is a chance that the imaging will show something in addition to what the research study is designed to find. We refer to any finding that is in addition to the purpose of the research study as an “unexpected finding.” Because we are not in a position to determine what significance, if any, there is to an unexpected finding, if there is an unexpected finding, the finding will be shared with you along with a copy of the imaging to take to your primary care physician for further review.  If you do not have a primary care physician, ask the research team for a list of current UCI primary care providers.

**Unknown risks:** *[Required if this research is a medical intervention, or a clinical investigation with investigational drug, biological product or device; or risk profile of research intervention is not well known]*

There may be risks related to the research that we don't know about yet. However, you will be informed of any additional risks to which you may be exposed, and any changes that are made to the study, as a result of any newly-identified risks.

**Reproductive Risks:** *[Required if the study intervention could harm a pregnancy or baby fed with lactated milk. All of the following statements in this section may be modified as applicable.]*

This study *[specify: experimental procedure, investigational treatment, experimental drug]* may harm a developing pregnancy or a baby fed with lactated milk. The risks associated with *[specify: known reproductive and/or breastmilk risks based on animal or human experiences].*

* If you are pregnant or feeding a baby with your lactated milk, you cannot take part in this study.
* If you think you may be pregnant, you should not volunteer for this study.
* You must not become pregnant (or get someone pregnant) while on this study.
* If you are able to become pregnant, you must have a pregnancy test before you begin the study.
* If you are someone who is able to become pregnant or someone who can make someone pregnant, you must use effective birth control while on this study.
* **If you or your partner does become pregnant while you are on this study, you must contact the researchers immediately.**

**Contraception Requirements for Participants Able to Become Pregnant**

If you are able to get pregnant, you must avoid becoming pregnant while you are in this study. You must use one *[or more]* of the following acceptable methods of birth control while you are in this study until *[insert how long]:*

* *[Insert acceptable/recommended methods of birth control in bullets or chart. For your reference, birth control options in order of effectiveness are listed here. Insert those that are appropriate for this study:*
  + *Highly effective: copper or hormonal intrauterine device (IUD), hormonal implant, tubal ligation*
  + *Moderately effective: Hormonal pill, patch, ring, or injection*
  + *Least effective: condom, withdrawal, fertility awareness methods]*

**Contraception Requirements for Participants Able to Cause a Pregnancy**

If you are able to get another person pregnant, you and/or your partner must use one *[or more]* of the following acceptable methods of birth control while on this study until *[insert how long]*:

*[insert acceptable/recommended methods of birth control in bullets or chart. For your reference, birth control options in order of effectiveness are listed here:*

* + *Highly effective: copper or hormonal intrauterine device (IUD), hormonal implant, tubal ligation, vasectomy*
  + *Moderately effective: Hormonal pill, patch, ring, or injection*
  + *Least effective: condom, withdrawal, fertility awareness methods]*

**Pregnancy Testing in Minors:** *[Required if the form is to obtain parental permission and the study includes pregnancy testing in minors.]*

If your child is able to get pregnant, your child will have some *[specify: blood and/or urine]* collected at different times in the study for the purposes of pregnancy testing. Per California Law, pregnancy test results will be provided to you only with permission from your child.

**Your study doctor will discuss further with you additional contraception requirements not otherwise specified above. In addition, your study doctor can answer any questions should you feel unsure if you, your parter or your child are able to get pregnant or cause a pregnancy.**

**Whole Genome Sequencing (WGS):** *[Required if WGS will be included as a research procedure.]*

*Example: WGS generates an extremely large amount of information about people, including factors that will contribute to their future medical conditions. It can provide insight into the health of individuals and their biological family. It is possible that WGS data gathered for one purpose could reveal important information, perhaps unanticipated and unplanned for, years later.*

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

*[Keep all statements that apply to this study and remove/revise as applicable]*

***Compensation***

*[If subjects will be compensated for multiple visits]* You will be paid $ *[Enter type of payment and amount/value]* at specified time points over the course of the study. There are *[Enter # of study sessions]* visits. Total compensation for participation in the entire study is $ *[Enter total compensation for completion of the study]*. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits and/or procedures that you have completed.

*[If subjects will be compensated for one session]* You will receive *[Enter type of compensation and amount/value]* for your participation in this study. *Example: a $50 gift card to a local merchant*

*[If subjects will receive payments in excess of $600 per calendar]* The IRS requires UCI to report compensation in excess of $600 per calendar year. Since you may receive compensation in excess of $600 per calendar year, your name and social security number will be collected and released to the UCI Office of Accounting to process the Form 1099-Misc for Internal Revenue Service (IRS) tax-reporting purposes.

*[If subject compensation is processed through UCI Office of Accounting]* Personal information about you, including your name, address and social security number, will be released to the UCI Office of Accounting for the purpose of payment.

*[If subjects will not be compensated]* You will not be compensated for your participation in this research study.

***Reimbursement***

*[If reimbursement will be provided]* You will be refunded for expenses *[specify such as parking, transportation fees, etc.]* personallypaid for because of your participation in this study.  *[Insert condition for reimbursement e.g. receipt, up to how much, etc. This should be consistent with contract language and not conflict with the costs language below.]*

*[If no reimbursement will be provided]* You will not receive reimbursement for any out of pocket expenses, such as parking or transportation fees.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

*[Keep all statements that apply to this study and remove/revise as applicable]*

There is no cost to you *[specify: or your insurer/third party payer]* for your participation in this study. However, there may be out-of-pocket expenses such as parking and transportation fees.

*OR*

*[Option 1: Research Only - All research related costs are covered by the study (industry or investigator authored)]*

There is no cost to you or your insurer for your participation in this study. However, there may be out-of-pocket expenses such as parking and transportation fees. You and /or your health plan/insurance will be billed for the costs of any standard medical care you receive to diagnose and/or treat any medical condition(s) outside of this study. You will also be responsible for any deductibles or co-payments that would normally be associated with these standard medical costs.

*[Option 2: Routine Care Billable under Medicare Billing Rules for Non-Profit Sponsors (i.e., Federal-Sponsors (e.g., NCI, NIAID, NINDS and Foundations)]*

The (funding agency, cooperative group name) will supply the (name of investigational device/agent) at no cost while you take part in this study. *[The next sentence is required to be included when the administration of the investigational agent(s) will be billed to the subject and/or subject insurer):* You and/or your health plan/insurance will need to cover the cost of the infusion/injection of the study drug.*]* It is possible that the (name of investigational device/agent) may not continue to be supplied while you are on the study. If this occurs, the study doctor will talk to you about your options.

Most of the tests, procedures, and/or drugs provided to you are routinely used to treat your illness. You would receive these tests, procedures, and/or drugs even if you were not participating in this study. You and /or your health plan/insurance will need to pay for this routine care. You will also be responsible for any co-payments or deductibles required by your insurance. Some health plans/insurance companies will not pay the costs associated with these tests, procedures, and/or drugs. Financial counseling and itemized cost estimates are available upon request.

*[Option 3: Mixed Research and Routine Care (Industry-Sponsored – mix research and routine care)]*

The (study sponsor) will supply the (name of investigational device/agent) at no cost while you take part in this study. *[The next sentence is required to be included when the administration of the investigational agent(s) will be billed to the subject and/or subject insurer:* You and/or your health plan/insurance will need to cover the cost of the infusion/injection of the study drug.*]* Any additional research-related tests, procedures or visits will also be provided at no cost while you take part in this study. (OPTIONAL: insert bulleted diagnostic tests and procedures that are covered by the sponsor if applicable).

You and /or your health plan/insurance will be billed for the costs of any routine medical care you receive to diagnose and/or treat any medical condition(s) within the scope of this study [include the following for inpatient related studies (including your hospitalization due to your underlying medical condition). You and /or your health plan/insurance will need to pay for this routine care. You will also be responsible for any co-payments or deductibles required by your insurance. Some health plans/insurance companies will not pay the costs associated with these tests, procedures, and/or drugs. Financial counseling and itemized cost estimates are available upon request.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

*[This statement is required for all Full Committee research studies and for Expedited studies that are industry-sponsored.* ***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. If not applicable, please remove]*

*[****Working with sponsors:*** *Sponsors 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 UCI statement as written below, or the sponsor may remain silent on this point, in which case the reference to the sponsor should be removed from the statement. The clinical trial contract language specifies under what conditions and process a Sponsor has a duty to reimburse the University for any costs the University incurs in meeting its obligation to participants.]*

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 them at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI 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 UCI Human Research Protections (949) 824-8170 or by e-mail at [IRB@research.uci.edu](mailto:IRB@research.uci.edu)

###### ***[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 following required UC treatment and compensation injury statement that includes information about MMSEA 111 if it applies. Add the following statement to the paragraph above, where the highlighting appears:]***

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.

###### ***[If a study involves the use of drugs, biologics, diagnostics, devices, and vaccines used to treat, diagnose, cure, prevent, or mitigate COVID-19 and the product used is under an FDA-approved mechanism, please use this language:]***

###### If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor [sponsor name], depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at XXX-XXX-XXXX. The federal government also has a program that may provide compensation to you or your family if you experience serious physical injuries or death and these costs are not covered by other payors. To find out more about this “Countermeasures Injury Compensation Program” go to <https://www.hrsa.gov/cicp/about/index.html> or call 1-855-266-2427.

###### Due to the coronavirus public health crisis, the federal government has issued an order that may limit your right to sue and recover for losses if you are injured or harmed while participating in this COVID-19 clinical study. If the order applies, it limits your right to sue and recover for losses from the researchers, healthcare providers, any study sponsor or manufacturer or distributor involved with the study. However, the order does not limit your right to seek compensation for injuries that result from conduct or activities of the researchers, health care providers, study sponsors, manufacturers and distributors that is unrelated to the study.

**WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?**

*[Required if subjects may be terminated by researcher and/or if there are adverse consequences (physical, social, psychological, economic, or legal) of the subject’s withdrawal from the study]*

You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to *[Complete this sentence] Examples: return for a final close-out visit or evaluation; if you are interested in continuing long-term follow-up procedures; return unused study medication; complete an exit telephone interview.*

*[Include the following statements to Inform Subjects of Their Rights Related to Data Retention. If not applicable, please remove.]*

*[When research is subject to the FDA (regardless of whether or not HIPAA applies]* If you elect to withdraw or are withdrawn from this FDA-regulated research study, the data collected from your participation in this study must remain in the trial database in order for the study to be scientifically valid.

*[When research is subject to the HIPAA Privacy rule (AND not subject to FDA regulations]* If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

*[When research is not subject to the FDA or HIPAA regulations]* If you elect to withdraw or are withdrawn from this research study, the researchers will discuss with you what they intend to do with your study data. Researchers may choose to analyze the study data already collected or they may choose to exclude your data from the analysis of study data and destroy it, as per your request.

*[When private identifiable information or biospecimens are maintained for future research]* You are free to withdraw your consent to use your identifiable private information and biospecimen for future research at any time however there are some limitations. If you withdraw your consent, the researchers will not use your information or biospecimens in future research studies. However, any of your information or biospecimens already being used in a research study that began before your request to withdraw will continue to be used for that specific study. Also if information and biospecimens have already been provided to another researcher, institution, or company, it may not be possible to limit their continued and new uses.

**HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?**

***Subject Identifiable Data***

*[Explain whether subject identifiers will be linked to the research data. Choose one of the following statements and remove the other options.]*

Identifiable information collected about you will be removed at the end of data collection.

Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. *[Explain why personal identifiers will be retained.]*

Identifiable information collected about you will be kept with the research data. *[Explain why personal identifiers will be retained.]*

***Data Storage*** *[Describe how the data will be maintained. Keep and revise all statements that apply and remove the other options.]*

Research data will be maintained in paper format in a secure location at UCI.

Research data will be stored electronically on a laptop computer in an encrypted file *[and* *is password protected].*

Research data will be stored electronically on a secure [*computer or network*] in an encrypted file *[with password protection].*

The *[audio/video recordings]* that can identify youwill also be stored in a secure location; then transcribed and erased as soon as possible.

The *[audio/video recordings]* will also be stored in a secure location; then transcribed and erased at the end of the study.

The *[audio/video recordings]* will also be stored in a secure location and transcribed. The recordings will be retained with the other research data.

***Data Retention*** *[Explain how long the research data will be maintained. Choose the longest option that applies and remove the other options.] [NOTE: The following language applies regardless of whether or not HIPAA applies to this research. If research involves HIPAA: Protected Health Information (PHI) must be destroyed at the earliest opportunity, which may be sooner than the 10-year period. Notwithstanding PHI, research records must be retained as follows.]*

*[UC policy]* In accordance with UC Office of the President policy, information/biospecimens will be retained for 10 years after the end of the calendar year in which the research is completed, unless otherwise specified in the award agreement.

*[If the research is conducted under an IND or an IDE]* In accordance with UC Office of the President policy, information/biospecimens will be retained for 10 years after the end of the calendar year in which the research is completed, unless otherwise specified in the award agreement. In addition, this research involves the investigation of [FDA regulated](https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate) products. As such, information/biospecimens will be retained for two years after an approved marketing application. If approval is not received, the information/biospecimens will be kept for 2 years after the investigation is discontinued and the FDA is notified per [FDA sponsor requirements.](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4)

*[If the research involves a biorepository]* The researchers intend to store your research data and/or biospecimens in a repository indefinitely. The researchers may continue to use and share your information and information obtained from analyses of your biospecimens indefinitely. Also the use and sharing of your identifiable biospecimens will continue until the specimens are gone.

**WHO WILL HAVE ACCESS TO MY STUDY DATA?**

The research team, authorized UCI personnel, the study sponsor *[If not applicable, please remove]*, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

***Future Research Use***

[*Include one of the following statements. If you are unsure if data may be shared, choose Option 1 so you are not prevented from sharing de-identified study data with other researchers in the future:]*

*[Option 1:]* Researchers will use your *specimens and* information to conduct this study. Once the study is done using your *specimens and* information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

*[OR]*

*[Option 2*:] Researchers will use your *specimens and* information to conduct this study. Specimens and information gathered during this research study will only be used for this study. They will not be shared with other researchers.

***ClinicalTrials.gov*** *[Include these statements if this study is a clinical trial and will be registered on clinicaltrials.gov]* ClinicalTrials.gov is a Web site that provides information about clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law.  This Web site will not include information that can identify you.  At most, the Web site will include a summary of the results. You can search this Web site at any time.

***Clinical Trials Reporting Program*** *[Required for NCI funded research, choose one of the following statements and remove the other option.]*

*[Required for industry-sponsored cancer research studies. If not applicable, please remove]*

UCI’s NCI-Designated Cancer Center or the Sponsor registers National Cancer Institute (NCI)-supported clinical trials with NCI though their Clinical Trials Reporting Program (CTRP) to provide study related information. The data provided will not include information that can identify you.  NCI uses the data to manage and enhance the nation’s investment in cancer research.

*[Required for non-industry-sponsored cancer research studies. If not applicable, please remove]*

UCI’s NCI-Designated Cancer Center or the Sponsor registers National Cancer Institute (NCI)-supported clinical trials with NCI though their Clinical Trials Reporting Program (CTRP) to provide study related information. The data provided will include the following identifiable information that may identify you: birth month/year and five-digit zip code.  NCI uses the data to manage and enhance the nation’s investment in cancer research.

***Certificate of Confidentiality*** *[*[*For NIH funded research that started or is ongoing on or after 12-13-16, if research is biomedical, behavioral, or clinical in nature and collects identifiable, sensitive information (including biospecimens)*](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html)*. Also for non-federally funded research, seeking a Certificate of Confidentiality. If not applicable, please remove]*

To help us protect your privacy, *[*we have obtained / are in the process of obtaining*]* a Certificate of Confidentiality from the National Institutes of Health (NIH) ) / FDA / <specify other federal entity>.. With this Certificate, researchers cannot be forced to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by *[sponsor name]* which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).  You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

*[If not applicable, please remove]* The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Researchers will voluntarily disclose information to prevent serious harm to you or to someone else including, *[State here the conditions under which voluntary disclosure would be made (e.g., Examples: child abuse, elder abuse, domestic violence or sexual assault). If no voluntary disclosures will be made, the researchers should so state.].*

*[If not applicable, please remove. Required if the researchers intend to disclose information covered by a Certificate, with the consent of the research participant.]* The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document *[restate what will be disclosed, such as including research data in the medical record].*

***Medical Care***

*[Required if the researcher is utilizing Oncore]*

If you agree to participate in this research study, a signed copy of this consent document and the privacy authorization form may be filed in your electronic medical record (EMR) and your study participation may be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment.

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 EMR 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 records. If necessary for your care, this information will be provided to you or your physician.

**ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?** *[If the considerations listed below are not applicable, please remove this heading]*

***Use of Biospecimens*** *[Required if the study involves collection of specimens]*

*[If biospecimens will be discarded]*

Biospecimens (such as blood, tissue, or saliva) collected for routine labs will be discarded or destroyed once they have been used for the purposes described in this consent.

*[If biospecimens and / or information derived therefrom will be collected from a research subject and used for research and / or development purposes]*

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.

***Genetics*** [Required if the study involves genetic testing or access to genetic information]

*[Standard Template]* 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 California, state law (CalGINA) requires that employers with 5 or more employees may not use your genetic information, obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, these laws do not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

If you would like more information about the federal GINA law go to: <http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf> or CalGINA: <http://www.leginfo.ca.gov/pub/11-12/bill/sen/sb_0551-0600/sb_559_bill_20110906_chaptered.pdf>

*[Alternative language for research that involves individuals who have a diagnosis and/or are being treated for a genetic disease or disorder]* 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 California, state law (CalGINA) requires that employers with 5 or more employees may not use your genetic information, obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not prohibit discrimination on the basis of an already manifest genetic disease or disorder.  This means if you have a diagnosis and/or are being treated for a genetic condition, a health insurer may use the information to determine eligibility or rates.  Also, GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

If you would like more information about the federal GINA law go to: <http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf> or CalGINA: <http://www.leginfo.ca.gov/pub/11-12/bill/sen/sb_0551-0600/sb_559_bill_20110906_chaptered.pdf>

***Investigator Financial Conflict of Interest*** *[Required if there could be the appearance of a conflict of interest. If not applicable, please remove. If a study team member has a disclosable financial interest the UCI Conflict of Interest Oversight Committee will develop specific language detailing the disclosable financial interest]*

*OR*

No one on the study team has a disclosable financial interest related to this research project.

***Future Contact*** *[Required if researchers intend to contact participants for future research. If not applicable, please remove.]*

The study team would like your permission to contact you for future research. Please initial your level of permission below:

\_\_\_\_\_\_ Yes, UCI researchers may contact me in the future to ask me to take part in other research studies.

\_\_\_\_\_\_ No, UCI researchers may **not** contact me in the future to ask me to take part in other research studies.

**WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?**

If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

*[If the study is a clinical investigation]* A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact the UCI Institutional Review Board by phone at (949) 824-8170, by e-mail at [IRB@research.uci.edu](mailto:IRB@research.uci.edu) or at 160 Aldrich Hall, Irvine, CA 92697-7600.

**What is an IRB?**  An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists.  The IRB’s role is to protect the rights and welfare of human subjects involved in research.  The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

**HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?**

You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached “Experimental Subject’s Bill of Rights” to keep. **Participation in this study is voluntary.**  You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

**Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate** **UC HIPAA Research Authorization form for the use of your PHI.**

***I agree to participate in the study.***

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**Subject Signature Date**

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**Printed Name of Subject**

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***Legally Authorized Representative/Guardian Signature Date***

*­­­­­­­­­­­­­­(Remove all LAR signature lines if Surrogate Consent / Parent Permission is not applicable)*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*­­­­­­­­­­­­­­­****Printed Name of Legally Authorized Representative/Guardian Relationship to Subject***

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

***Legally Authorized Representative/Guardian Signature Date***

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*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*­­­­­­­­­­­­­­­****Printed Name of Legally Authorized Representative/Guardian Relationship to Subject***

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**Signature of Person Obtaining Informed Consent Date**

*(For research that is greater than minimal risk, this individual must be listed on Page 1 of this consent)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

­­­­­­­­­­­­­­­ **Printed Name of Person Obtaining Informed Consent**

***A witness signature is required on this consent form only if: (Researchers: check which one applies)***

**IMPORTANT! If no witness signature is required, this witness signature section of the consent form may be left blank.**

Consent is obtained from the subject via the Short Form process, as approved by the IRB.

The subject has decision-making capacity, but cannot read, write, talk or is blind.

The subject’s guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.

The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive

research procedures).

**For the witness:**

I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Witness Signature Date**

Note: The witness must be impartial (i.e. not a member of the subject’s family, not a member of the study team).

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Printed Name of Witness**

**UNIVERSITY OF CALIFORNIA, IRVINE**

**Experimental Subject's Bill of Rights**

**The rights listed below are the right of every individual asked to participate in a research study. You have the right:**

1. To be told about the nature and purpose of the study.
2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures are different from what would be used in standard practice.
3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.
4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.
5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.
6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.
7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.
8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.
9. To receive a copy of the signed and dated written consent form and a copy of this form.
10. To be 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 you should contact the research team 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 subject, please contact the UCI’s Human Research Protections unit in the Office of Research by calling (949) 824-8170 Monday – Friday, 8 am – 5 pm; or by e-mail at [IRB@research.uci.edu](mailto:IRB@research.uci.edu); or by writing us at 160 Aldrich Hall, Irvine, CA 92697-7600.

*[Additional examples of radiation risk language that may be inserted in the consent, as applicable.]*

EXAMPLE: SINGLE RESEARCH RELATED CHEST X-RAY

In this study, you may have a chest x-ray. This x-ray is solely for the purpose of this research study. A chest x-ray exposes you to a small dose of radiation.

**The amount of radiation from one standard chest x-ray is about the same as you receive in 10 days from the natural radiation in our environment.**

EXAMPLE: SINGLE RESEARCH RELATED CT SCAN

In addition to any scans you may have as a part of your normal medical care, you may have 1 additional CT scan of your chest, abdomen and pelvis.  This scan is solely for the purpose of this research, and you would not have this additional scan if you do not enroll in this study.

CT uses radiation to see inside of your body.  The radiation from a single CT scan of your chest, abdomen and pelvis is about 20-25 millisievert (mSv) / 2.5 millirem (mrem).  An mSv or mrem is a measure of radiation dose.  The average person in the United States receives about 3 mSv / 0.3 mrem per year from natural sources of radiation in our soils, water and air.

**The total dose from 1 CT scan (of your chest, abdomen and pelvis) is equivalent to about 6-9 years of radiation exposure from natural sources.**

EXAMPLE: MULTIPLE NON-SOC CT SCANS

In addition to any scans you may have as a part of your normal medical care, during the first two years of this study, you may have 8 additional CT scans of your chest, abdomen and pelvis, and up to 5 additional CT scans of your head and neck.  These scans are solely for the purpose of this research, and you would not have these additional scans if you do not enroll in this study.

CT uses radiation to see inside of your body.  The radiation from a single CT scan of your chest, abdomen and pelvis is about 20-25 millisievert (mSv) / 2.5 millirem (mrem), and the radiation from a single CT scan of your head and neck is about 7 mSv / 0.7 mrem.  An mSv or mrem is a measure of radiation dose.  The average person in the United States receives about 3 mSv / 0.3 mrem per year from natural sources of radiation in our soils, water and air.

The total dose from 8 CT scans (of your chest, abdomen and pelvis), and 5 CT scans of your head and neck could deliver up to 195-215 mSv/ up to 21.5 mrem over two years. **It is equivalent to about 65-70 years of radiation exposure from natural sources.** **Radiation exposure at this level may be associated with an increased risk in cancer.**  For an average person in the U.S., with no history of cancer, a total dose of 195-215 mSv / up to 21.5 mrem may increase their risk of cancer from about 40% to about 42%.  There are many factors that contribute to an individual’s personal risk of a second future cancer, and your increased risk may be higher or lower than the average person.  You may wish to discuss radiation risk further with your study doctor or radiologist.

EXAMPLE: NUCLEAR MEDICINE BONE SCAN WITH Tc-99m

In addition to any scans you may have as a part of your normal medical care, you may have 1 additional nuclear medicine bone scan using a radioactive element, technetium-99m.  This scan is solely for the purpose of this research, and you would not have this additional scan if you do not enroll in this study.  Nuclear medicine uses radioactive material to take pictures inside of your body.  The radiation from a single nuclear medicine bone scan is about 4-5 millisievert (mSv) / up to 0.5 millirem (mrem).  An mSv or mrem is a measure of radiation dose.

The average person in the United States receives about 3 mSv / 0.3 mrem per year from natural sources of radiation in our soils, water and air.  **The total dose from 1 nuclear medicine bone scan is equivalent to about one and a half years of radiation exposure from natural sources.**

**After the bone scan, you will still have some radioactivity in the body, which will go completely away in the following 24 - 48 hours. The risk to others is very low, but you may cause sensitive radiation detectors used for security to alarm in the first 1 – 10 hours after the scan.**