**UNIVERSITY OF CALIFORNIA, IRVINE**

**RESEARCH SUBJECT INFORMATION AND CONSENT FORM**

Standard Headings – PLUS

**SUB-INVESTIGATOR(S):** UCI requires sub-investigators to be listed on the consent form

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

Add the following text as the pre-amble to the consent form:

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 below will be available to answer your questions.

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

# **PROCEDURES**

WCG IRB approved study template or submitted text – plus

The site will include the number of study visits and how much time will be required of the subjects, per visit. Also indicate how long subjects will be in the study.

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

# **RISKS AND DISCOMFORTS:**

WCG IRB approved study template or submitted text – plus

NOTE: The following language MUST be submitted by the site if appropriate.

LIST ANY ADDITIONAL RISKS AS STIPULATED BY ANY OF THE FOLLOWING UCI REGULATORY COMMITTEES:

* Clinical Trials Protocol Review and Monitoring Committee (CTPRMC), required for all cancer trials
* Radiation Safety Committee (RSC) – see the required template language in the addendum at the end of this form
* Institutional Biosafety Committee (IBC)

The site will include if appropriate to the protocol when the study design involves scans (eg, MRI, X-ray, CT).

**Incidental finding:**

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.

The site will include if appropriate to the protocol when the study design involves randomization.

**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.

The site will include if appropriate to the protocol when the study design involves stopping drugs being used to treat a condition.

**Washout period:** During this study the medication you normally use for your condition will/may be stopped for up to [ 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.

The site will include if appropriate to the protocol when the study design involves use of a placebo.

**Placebo:** During this study there is a [Site to provide] 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 [Site to provide list]. The researchers will carefully monitor your condition. If your symptoms worsen and make you uncomfortable, you can withdraw from the study.

The site will include if appropriate to the protocol when the study design involves testing for HIV, Hepatitis B or C, or Covid-19 testing.

**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.

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

# **PAYMENT FOR PARTICIPATION**

WCG IRB approved study template or submitted text - If not paying subjects, the consent form should state so.

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

# **CONFIDENTIALITY:**

DO NOT INCLUDE WCG IRB HIPAA LANGUAGE IN ANY SECTION OF THE CONSENT FORM ADD THE FOLLOWING LANGUAGE IN A “CONFIDENTIALITY” SECTION:

Information from this study will be given to the sponsor. “Sponsor” includes any persons or companies which are contracted by the sponsor to have access to the research information during and after the study.

The information will also be given to the U.S. Food and Drug Administration (FDA). It may be given to governmental agencies in other countries where the study drug may be considered for approval.

Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

* the research team
* authorized UCI personnel
* the sponsor

and may be looked at and/or copied for research or regulatory purposes by:

* the FDA
* Department of Health and Human Services (DHHS) agencies;
* governmental agencies in other countries;
* the University of California; and the Western Copernicus Group (WCG) IRB, Inc.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. If the results of this study are made public at meetings or in scientific journal articles, information that identifies you will not be used.

**Medical Care**

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.

The site will include if appropriate to the protocol

**Certificate of Confidentiality**

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. With this Certificate, the study team 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.

[The site will include only if applicable]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,[The site will state 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.].

[The site will include 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].

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

# **COMPENSATION FOR INJURY**

The wording of this section cannot be altered and no other wording related to injury may be added to this section or anywhere else in the consent form, except as instructed in the body of this text. 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.

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 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) 824-6068 or (949) 824-2125 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 949-824-8170. 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](https://www.hrsa.gov/cicp/about/index.html%20or%20call%201-855-266-2427).

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.

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

# **COSTS**

The site will submit one of the following options as appropriate to the research:

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.

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 - 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 – mixed 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.

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

The following language should immediately follow the Voluntary Participation/Withdrawal text:

# **OTHER ISSUES TO CONSIDER WHEN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY**

If there is “Source of Funding”, include that text here.

# **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 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.

Include the following text only if the research involves cancer:

UCI’s NCI-Designated Cancer Center or the Study Sponsor also 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.

# **Investigator Financial Conflict Of Interest**

Include disclosures as required by WCG IRB and the UCI Conflict of Interest Oversight Committee (COIOC) as stipulated in the COIOC memo to be included, as applicable, with each WCG IRB submission.

The site will include one of the following statements if the study involves collection of specimens:

# **Use of Research Specimens**

Option 1 - If specimens will be discarded

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

OR

Option 2 - If specimens will be retained by UCI

Any specimens (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the University of California, Irvine (UCI). Once you provide the specimens you may not have access to them. Use of the specimens could 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 products or other products that may be developed from the use of your specimens.

OR

Options 3 - If specimens will be provided to an outside entity, such as the study sponsor

Any specimens (e.g., tissue, blood, urine) obtained for the purposes of this study will be provided to the Sponsor of this study [, sponsor name - optional]. Once you provide the specimens you may not have access to them. Use of the specimens could 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.

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

The site will include when the study involves genetic testing or access to genetic information

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>

**OR**

The site will include this 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>

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

# **QUESTIONS**

This language replaces WCG IRB sponsor template language:

Contact the research team listed at the top of this form during office hours for any of the following reasons:

* if you have any questions about your participation in this study,
* if you feel you have had a research-related injury or a reaction to the study drug, or
* if you have questions, concerns or complaints about the research

Call the 24-hour number also listed on the top of this form at any time to report a research-related injury or a health concern possibly related to the study drug.

If you have questions about your rights as a research subject or if you have questions, concerns, input, or complaints about the research, you may contact:

WCG IRB

1019 39th Avenue SE, Suite 120

Puyallup, Washington 98374-2115

Telephone: 1-855-818-2289

E-mail: researchquestions@wcgirb.com

WCG IRB is a group of people who perform independent review of research.

WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

# **CONSENT**

This language replaces WCG IRB sponsor template language:

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 “Research 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.

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

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

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

**Subject Signature Date**

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

**Printed Name of Subject**

Include the following LAR/Parent signature lines if approved by the Board for the study

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

Legally Authorized Representative or Parent/Guardian Date

Signature

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

Printed Name of Legally Authorized Representative or Parent/Guardian

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

Relationship to Subject

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

Parent/Guardian Signature (if necessary) Date

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

Printed Name of Parent/Guardian (if necessary)

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

Relationship to Subject

Include in all consent forms.

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

**Signature of Person Obtaining Informed Consent Date**

(Individual must be listed on Page 1 of this consent)

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

**Printed Name of Person Obtaining Informed Consent**

**Pre-board: Include the following Note to Board with your redline.**

Note to Board: Please do not alter the language in this Witness statement. It has been approved by the EPC as is, and is required verbatim by the institution.

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

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).

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

**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**

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

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

**Printed Name of Witness**

**BILL OF RIGHTS**

Begin this section after a page break.

**UNIVERSITY OF CALIFORNIA, IRVINE**

**Research 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 is 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.

-------------------------------------------------------

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

I can also contact the WCG IRB, Inc. which helps protect research study participants. I can reach the WCG IRB, Inc by calling 855-818-2289 from 8:00 AM to 5:00 PM, Monday to Friday. If I call this office and do not speak English or Spanish, I should have someone available who can interpret for me. I may also write to WCG IRB, Inc., 1019 39th Avenue SE Suite 120, Puyallup, WA 98374-2115. To get a copy of the bill of rights I may contact the research team or go to [**https://research.uci.edu/wp-content/uploads/experimental-subjects-b-o-r.docx**](https://research.uci.edu/wp-content/uploads/experimental-subjects-b-o-r.docx)

The appropriate language will be submitted by the site:

**RADIATION RISK LANGUAGE AS DETERMINED BY UCI RSC:**

[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 Gadolinium contrast used during CT or MRI scans]

Gadolinium contrast “dye” will be injected into your vein. This increases the ability of the CT or MRI scan to show certain tissues in the brain or elsewhere in the body. Side effects include a mild headache, nausea, or burning at the injection 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). Use of gadolinium may be linked to a 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 [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.

[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 **between 1 - 5 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 [XX] rem [insert total effective dose (e.g., 2 rem)]. A rem is a unit used to quantify radiation dose. Typically, persons in the U.S. receive a radiation dose of about 0.31 rem 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 short-term health effects associated with this amount of radiation exposure, and no radiation remains in the body after the scan. 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 about radiation exposure, you should discuss this with the researcher listed at the top of this form.

[Use language for a **nuclear medicine scan** if total dose to one individual (across entire study) is **between 1 and 5 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 [XX] rem [insert 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 [XX] extra [insert 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 24 - 48 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 first [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.

[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 **greater than 5 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] 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 [XX] rem [insert total effective dose]. A rem is a unit used to quantify radiation dose. Typically, persons in the U.S. receive a radiation dose of about 0.31 rem every 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 short-term health effects associated with this amount of radiation exposure, and no radiation remains in the body after the scan. The primary risk from radiation exposure at this level is the potential for a very small increased risk of future cancer. The average adult in the United States has about a 42% lifetime risk of having cancer (that is, about 42 out of 100 people will have cancer in their life). An exposure of [XX] rem [insert total effective dose], may increase that risk to about XX% [insert increased risk]. If you are especially concerned about radiation exposure, you should discuss this with the researcher listed at the top of this form.

[Use language for a **nuclear medicine scan** if total dose to one individual (across entire study) is **greater than 5 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 [XX] 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 [XX] extra [insert 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 first [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. The average adult in the United States has about a 42% lifetime risk of having cancer (that is, about 42 out of 100 people will have cancer in their life). An exposure of [XX] rem [insert total effective dose], may increase that risk to about XX% [insert increased risk]. If you are especially concerned about radiation exposure, you should discuss this with the researcher listed at the top of this form.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*