**INSTITUTIONAL LANGUAGE TO BE INCLUDED IN NCI CIRB APPROVED CONSENT FORM**

**THE LANGUAGE IN GREEN WILL BE CUSTOMIZED ON STUDY-BY-STUDY BASIS.**

**THE LANGUAGE IN RED IS INSTRUCTIONAL.**

1. ***RESEARCH PARTICIPANT ENROLLMENT:***

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

Approximately       people will take part in the research at UCI. A total of       people will participate across all study locations.

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

*[There are multiple options for risks associated with radiation exposure depending on type of procedure and amount of radiation exposure – see Additional Language To Be Used As Appropriate section]*

1. *SUBJECT INJURY LANGUAGE:*

**What happens if I am injured or hurt because I took part in this study?**

***Note: This statement must be used without changes.***

If you feel you have been injured as a result of being in this study it is important that you tell the study doctor. 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

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

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

1. ***ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?***

***UCI Investigator Financial Conflict of Interest***

*[If a study team member has a disclosable financial interest per the UCI Conflict of Interest Oversight Committee (COIOC), COIOC will develop specific language detailing the financial interest as well as include this specific paragraph]*

The nature of this financial interest and the design of the study have been reviewed by the UCI Conflict of Interest Oversight Committee (COIOC). The COIOC has determined that the researcher’s financial interests are appropriately managed as to avoid  compromising the quality or reliability of the study and furthermore, the Institutional Review Board has determined that appropriate safeguards are in place to avoid adversely affecting your safety and welfare.

*OR*

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

***Use of Research Participant Specimens (Moore Clause)***

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

*[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.

*[If specimens will be kept 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. Once you provide the specimens you will not have access to them. The University may share your specimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of UCI. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

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

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

***Genetic Testing***

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

A Federal law, called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and employers of 15 or more persons to discriminate against you based on your genetic information. This means that they may not use your genetic information when making decisions regarding insurability. GINA does not, however, protect against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. If you would like more information about GINA go to: <http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf>.

1. *RESEARCH PARTICIPANT RIGHTS:*

What are my rights in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no 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 study doctor.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

If you have any concerns 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) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 5171 California Avenue, Suite 150, Irvine, CA 92697.

1. ***UCI SIGNATURE LINES***

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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***

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

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

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**Signature of Person Obtaining Informed Consent Date**

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

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­­­­­­­­­­­­­­­ **Printed Name of Person Obtaining Informed Consent**

***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.

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**Witness Signature Date**

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

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**Printed Name of Witness**

1. ***CALIFORNIA EXPERIMENTAL SUBJECT’S BILL OF RIGHTS***

**THE UNIVERSITY OF CALIFORNIA, IRVINE (UCI)**

**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 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 research team listed on the first page of the consent. If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints 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) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 5171 California Avenue, Suite 150, Irvine, CA 92697.

1. **ADDITIONAL LANGUAGE TO BE USED AS APPROPRIATE:**

**Radiation Risks:**

*[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 are 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.

*[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 are 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 are 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* ***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 are 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******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 are 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 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 are 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.