**UCI-SPECIFIC 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. *SUBJECT INJURY LANGUAGE:*

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

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

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 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 billed to you or your insurer just like other medical costs, depending on a number of factors. The University does 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. *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**

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**Witness Signature Date**

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

**Printed Name of Witness**

**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.

***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 160 Aldrich Hall, Irvine, CA 92697-7600.