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

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

|  |  |
| --- | --- |
| **Sponsor / Study Title:** | **Sponsor Name / “Protocol Title”** |
| **Protocol Number:** | **Protocol Number** |
| **Principal Investigator:****(Study Doctor)** | **«PiFullName»** |
| **Telephone:** | **«IcfPhoneNumber»** |
| **Additional Contact(s):****(Study Staff)** | **«AdditionalStaffMemberContacts»** |
| **Address:** | **«PiLocations»** |

**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.

**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.

**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 a female and has had her menses (her period) she will have some of her *[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.

***Compensation***

*[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.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

*[Keep the statement that applies to this study and revise as applicable; remove other options]*

*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 billed 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 study drug at no cost while you take part in the study. [The next sentence should be included if appropriate: You and/or your health plan/insurance will be billed to cover the cost of the infusion/injection of the study drug.]  It is possible that the study drug 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 billed 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 study drug at no cost while you take part in the study. [The next sentence should be included if appropriate: You and/or your health plan/insurance will be billed 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. You and /or your health plan/insurance will need to pay for this routine care. You will also be billed 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 study doctor if you believe that you have been injured because of taking part in this study.  You can tell the study doctor 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 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.

You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing and dating this consent document*.*

*[For COVID related studies, the following injury language is to be inserted instead]*

It is important that you promptly tell the study doctor if you believe that you have been injured because of taking part in this study.  You can tell the study doctor 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, 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 949-824-6068 or 949-824-2125. 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](https://nam02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https%3A%2Fwww.hrsa.gov%2Fcicp%2Fabout%2Findex.html__%3B!!OLgoXmg!E7teSu7R5qJDG4tlA3bbxRdS-cy7gUQ72OFXdVtz0aOr787MgH1haU-PKQbKdLcS%24&data=02%7C01%7Candrew.saunders%40advarra.com%7C99d8f8f5b57a46dae84b08d7e329b025%7C3807a1e105a6467ab24e33a23eba91f4%7C0%7C0%7C637227640517301797&sdata=IBQ%2BuBTi8ycPCyEkSyyZy92FWcEyFUrMxBoIEhE2V0A%3D&reserved=0) 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.

You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing and dating this consent document.

###### ***[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.

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

The research team, authorized UCI personnel, the study sponsor *[If not applicable, please remove]*, the Institutional Review Board, 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

*[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.

***ClinicalTrials.gov*** [*Per FDA, this language will be required for clinical trials approved by the IRB on or after March 7, 2012. Although the language is optional for new studies approved before that date, sponsor may request the language. This language must be included verbatim.*]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.

***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.

**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.

***Genetics*** [Required if the study involves genetic testing, access to genetic information, or whole genome sequencing]

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>

*[Add the following language to the end of Advarra’s WHOM TO CONTACT ABOUT THIS STUDY section:]*

You may also contact UCI’s Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or by writing us at 160 Aldrich Hall, Irvine, CA 92697.

**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.

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 the UC HIPAA Research Authorization form for the use of your PHI.**

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

***[UCI Agrees to keep signature lines from Sponsor, but please use UCI Witness block.]***

***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 (for example, high risk and/or invasive research procedures).

Note: The witness must be impartial (for example, 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**

**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 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.

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During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects.  If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact Advarra IRB at the address, phone, number, or email address listed in the WHOM TO CONTACT section of the informed consent form.

Please reference the following number when contacting the Study Subject Adviser: Pro000XXXXX.

*You may also contact UCI’s Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at* *IRB@research.uci.edu* *or by writing us at* *160 Aldrich Hall, Irvine, CA 92697.*