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

**UNIVERSITY OF CALIFORNIA, IRVINE**

**CONSENT FOR DONATION OF SOMATIC CELLS FOR HUMAN STEM CELL RESEARCH**

***[Title of Study]***

**Lead Researcher**

Name and Title

Department

Telephone number and e-mail address

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

**Other Researchers** *[If not applicable, please remove]*

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

**STUDY LOCATION(S):**

**STUDY SPONSOR(S):**

**SPONSOR MASTER PROTOCOL NUMBER:**

**In the instance of parental permission, “You” refers to “Your child.”** *[If not applicable, please remove]*

|  |
| --- |
| **SUMMARY OF KEY INFORMATION:****The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.*****Participation is Voluntary***You are being asked to participate in a research study involving the donation of somatic cells. Somatic cells make up most of the body’s tissues and organs such as the blood, brain, liver, or skin. Participation in this study is completely voluntary. Please read the information below and ask questions about anything that you do not understand before deciding if you want to participate. A researcher listed below will be available to answer your questions.***Study Purpose****[Include a brief yet complete summary (i.e., no more than 3 sentences) of the study purpose. A detailed description will follow below in a subsequent section.]* The purpose of this research study is to *[Complete this sentence]**Examples: to use cells from your [skin/blood/tissue type] donation to create stem cell lines. Human stem cells have unique properties that allow them to grow forever with no known limit and they can become all types of cell in the body, such as muscle cells, brain cells or heart cells. Cells will be used to study the basic biology of stem cells, of certain diseases and disorders, and study whether it is possible to transplant iPS cells or products of cells as a treatment for many diseases.****Study Procedures****[Include a brief yet complete summary (i.e., no more than 3 sentences) outlining study procedures. A detailed description will follow below in a subsequent section.]* *Example: … You will be asked to authorize us to obtain information about your medical history and to provide biological samples (skin, blood or hair). To obtain biological samples we will perform a skin punch biopsy, blood draw, or remove a few hairs from your head. Cells from all these tissues may be used to create iPS cells.****Expected Duration****[Include a brief statement (i.e. no more than 3 sentences) of the time commitment required]* Participation will last approximately…      hours/ weeks/ months and will include…       visits. *Example: … Your involvement in this particular study will consist of 1-3 clinic visits and will take up to 3 hours.****Risks of Participation****[Include a brief summary of the* ***main risks*** *(i.e., no more than 3 sentences) for participants on this study. A detailed description will follow below in a subsequent section.]* The more notable risks of participation include…     .*Example: … The skin biopsy may cause bruising, swelling, pain, bleeding, infection, or scarring. Drawing blood may cause temporary pain, bruising, bleeding, swelling, dizziness, and on rare instances fainting or infection. Also, there is a slight risk that your private medical information could be shared with individuals who are not members of the study team.* ***Benefits to Participants***Derived cells or cell products are not intended to provide direct medical benefit to you, except in the case of autologous donation.The possible benefits you may experience from the procedures described in this study include… *(Complete this sentence)* *[If no direct benefit to the subject is anticipated, delete the above statement and insert –* You will not directly benefit from participation in this study.] ***Benefits to Others or Society****[Include a brief statement (i.e., no more than 3 sentences) about possible benefits to science or society]* ***Alternative Procedures or Treatments***There are no alternative treatments or procedures available. The only alternative is not to participate in this study.***The following definitions may help you understand the purpose of this study:*** *(Keep all of the definitions that apply to this study. Add others study design elements as necessary to aid understanding.)** **Cell Line:** A group of cells that can live and divide outside of the body; these cells can be frozen for storage for an indefinite period of time and can be used for future research.
* **Somatic Cells:** Any cell in the body except gametes (eggs or sperm). Skin cells and blood cells are types of somatic cells.
 |

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

***The following definitions may help you understand the purpose of this study:*** *(Keep all of the definitions that apply to this study. Add others study design elements as necessary to aid understanding.)*

* **Autologous** **donation:** the donation (such as a transplant) is made bya person for their own use.
* **Cell Line:** A group of cells that can live and divide outside of the body; these cells can be frozen for storage for an indefinite period of time and can be used for future research.
* **Somatic Cells:** Any cell in the body except gametes (eggs or sperm). Skin cells are a type of somatic cells.

***Stem Cell Development***

The purpose of this research is to develop human stem cell lines from the somatic cells you have provided. Human stem cells have the unique combination of capacities to divide with no known limit and to develop into most of the different types of cells of the body. These stem cell lines will be used for basic science experimentation and may be used at some future time for human transplantation research. *If appropriate add:* The donated somatic cells can be genetically manipulated so that they behave like stem cells. The cells after genetic manipulation are called “induced pluripotent stem (iPS) cells”.

The stem cells lines that are developed will be used to study… *(Complete this sentence and include an explanation of what cells are being used and why. Examples include “to develop a stem cell line that will allow researchers to study Huntington’s disease in a human model system, and provide a cell model to screen new drugs for treatment.”*

***Focus of this Specific Study***

This is a research study because… *(Complete this sentence, assuring that all procedures are clearly identified and defined)*

*Sample language:*

* *Your [embryo(s) or gametes] will allow researchers to develop a stem cell line to screen new drugs for treatment of spinal cord injuries.*
* *We hope to learn… (State what the study is designed to discover or establish).*

Subjects who agree to participate will… *(Briefly describe the study design including the assignment of subjects to different study groups.)*

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

*[State the enrollment goal of the study and where appropriate discuss study cohorts. For multi-center studies, indicate accrual numbers for the entire study and for enrollment at UCI; be consistent with the protocol.]*Approximately       participants will take part in the research at UCI. A total of       participants will be asked to participate across all study sites.

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

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

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

***Inclusion Requirements***

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

***Exclusion Requirements DO NOT LIST THE CONVERSE OF THE INCLUSION CRITERIA***

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

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

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

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

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

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

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

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

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

*(Provide a detailed explanation of the research procedures in chronological order; include the expected duration of each procedure or each visit and the procedures to be completed at the visit. You may provide a visit schedule, chart, or calendar to assist the participant. Explain where the work will be conducted, the types of experiments that will be performed, whether new cell lines will be established, how they will be established, and how they will be used. Indicate that the cells may multiply indefinitely.) Example language:*

* *We will ask for a skin sample from you. The skin sample is obtained by a process called a “punch biopsy”. In this procedure, a small area of skin on the thigh or arm is cleaned and injected with xylocaine, a local anesthetic. When the skin is numb, a small round blade of three millimeters (one-eighth of an inch) in diameter is pressed into the skin, creating a circular cut approximately one eighth of an inch deep. This round piece of skin is then removed, pressure is applied to stop any bleeding and the resulting hole in the skin is covered with a sterile bandage. In some cases one or two stitches are required. The biopsy takes about ten minutes to perform, including time for cleaning and preparation. We will only ask for one punch biopsy.*

*If samples will be sent out of UCI for analysis or other purposes, include the statement: Your samples will be sent outside of UCI for… (Provide an explanation of where the sample will be sent and why).*

*Genetic Reprogramming (e.g. which is used when creating induced Pluripotent Stem Cells or iPS) is when certain genes are put into your somatic cells to study how the cells can be changed, or reprogrammed, into embryonic-like cells.*

*Stem cell lines may be made from the method described above. Cells multiply by dividing in two, and the genetic material is replicated every time a cell divides. It is possible that these lines, which can live indefinitely, may contain all or part of your DNA.*

*Any cell lines created may be kept for many years and may be used in further studies, by researchers at UCI or other research institutions outside of UCI, which cannot be predicted at the present time. They may include research that involves genetic manipulation.*

*It is possible that derived cells or cell products may be placed into humans or animals. There are no restrictions on the ultimate recipients of these derived cells or cell products, except in the case of autologous donations.*

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

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

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

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

The possible risks and/or discomforts associated with the procedures described in this study include: *(Categorize the risks by severity and the likelihood of the risk occurring. A bulleted list may be used. Make sure to consider all types of risks – psychological, social, economic, legal and physical.)*

*Examples of risks/discomforts include:*

* *Skin biopsy may cause bruising, swelling, pain, bleeding, infection, or scarring. If you have a biopsy, it is important that you follow skin care instructions that are given to you; otherwise, it is possible that you may develop a skin infection.*
* *Blood draw may produce pain, bruising, bleeding, swelling, dizziness, or rarely, fainting or infection*
* *Psychological discomforts such as* embarrassment, anxiety, or distress.
* *Breach of confidentiality -* While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it.

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

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

**Unknown Risks:** There may be risks to being in this study that we don't know about now. You will be informed of any changes in the way the study will be done and any additional identified risks to which you may be exposed.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

***Compensation***

You will not be compensated for your participation in this research study.

***Reimbursement***

You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

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

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]*

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 the study sponsor *[sponsor name]*, or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury.  For more information about this, you may call UCI Human Research Protections (949) 824-8170 or by e-mail at IRB@research.uci.edu

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

***Biospecimens/Tissue***

If you decide to donate your somatic cells you may withdraw your consent **up to 30 days** from the time this informed consent is signed. The derivation process will not begin until after the 30 day wait period. However, somatic cells cannot be returned; the only alternative is to discard them. **After 30 days the donation is irrevocable**. To withdraw your consent during the 30 day wait period, you must do so in writing to [*name individual here*], University of California Irvine, [*provide address and phone number here*].

***Information/Data***

*[When researchers will access medical records]* If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

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

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

***Subject Identifiable Data***

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

Identifiable information collected about you will be removed at the end of the 30 day wait period.

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

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

***Biospecimen and Data Storage*** *[Describe how the data will be maintained.]*

Examples include:

* The *[indicate cell type and/or tissue]* and resulting cell lines will be maintained in a secure location at UCI. Only authorized individuals will have access to it.
* The research data will be stored electronically on a secure [computer or network] with encryption [and password] protection.
* The research data will be stored on a laptop computer that has encryption software [and is password protected]
* *Other privacy options:*

***Biospecimen and Data Retention*** *[Explain how long the research data will be maintained. Choose the longest option that applies and remove the other options.]*

* The *[indicate cell type and/or tissue]* and resulting cell lines will be kept for approximately \_\_ years.
* The *[indicate cell type and/or tissue]* and resulting cell lines may be frozen for an undefined period of time.
* The *indicate cell type and/or tissue]* and resulting cell lines will be maintain in a repository indefinitely. Other researchers may have access to the de-identified stem cell line for future research.
* The *indicate cell type and/or tissue]* and resulting cell lines will be kept for at least 6 years because the study involves Personal Health Information.
* The researchers intend to keep the resulting cell lines for seven years after all children enrolled in the study reach the age of majority (age 18 in California).
* The researchers intend to store your research data and/or biospecimens in a repository indefinitely. The researchers may continue to use and share your information and information obtained from analyses of your biospecimens indefinitely. Also the use and sharing of your identifiable biospecimens will continue until the specimens are gone.

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

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

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

***Future Research******Use***

Your tissue, cells or other materials derived from these tissues may be used by other researchers at UCI or by researchers at institutions outside of UCI in future studies, which are currently undefined. They may include research that involves genetic manipulation. However, the tissue, cells or other materials will not contain any identifiable information about you (for example it will not include your name, social security or medical record number).

It is possible that derived cells or cell products may be placed into humans or animals. There can be no restrictions placed on the ultimate recipients of these derived cells or cell products, except in the case where the donation is intended for autologous transplantation (where you, the donor, would also be the recipient).

The results of the study of your samples will be used for research purposes and tissue derivatives may also be used in human therapies.

Your information and biospecimens may be used for future research still to be planned. Possible future research studies may include, for example:

*[Add information here about any applicable possible future research that may be conducted. Examples are provided below.]*

* *Studying the causes and progression of different diseases and conditions*
* *Whole genome sequencing (meaning that your entire personal genetic code will be identified)*
* *Research that creates cell lines by growing cells from your biospecimens in a laboratory – including cells that can be used to create different types of tissue*
* *Research about drug abuse and alcoholism diagnosis and treatment*
* *Research about mental health diagnosis and treatment*
* *Research about developmental disabilities*

You will not be informed about any of the specific research studies that might be conducted with your information and biospecimens. This means that your information and biospecimens could be used in research in which you might not have chosen to participate (i.e. without your additional consent).

***Future Research Use***

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

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

*[OR]*

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

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

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

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

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

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

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

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

As part of the study, the researcher may do genetic testing or access genetic information. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may also include genetically modifying cells that are derived from your tissues to better understand how genes function. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications, and responses to treatment.

*[Standard Template]*

In the event of an unexpected breach of confidentiality, a federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about you. In California, state law (CalGINA) requires that employers with 5 or more employees may not use your genetic information, obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, these laws do not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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

*[Alternative language for research that involves individuals who have a diagnosis and/or are being treated for a genetic disease or disorder]*

In the event of an unexpected breach of confidentiality, a federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about you. In California, state law (CalGINA) requires that employers with 5 or more employees may not use your genetic information, obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

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

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

***Use of Biospecimens***

All of the *[indicate cell type and/or tissue]* obtained for the purposes described in this consent form will become the property of the University of California, Irvine (UCI). **After 30 days the donation is irrevocable**. These materials 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.

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

Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

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

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

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

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

***Investigator Financial Conflict of Interest***

*[If the study involves a clinical investigation or there could be the appearance of a conflict of interest, one of the following statements is required]*

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

 *OR*

[A member of the study team or their spouse or dependent child(ren)—list people here] has a disclosable financial interest in [the Sponsor company or other related entity—list here]. The nature of this financial interest and the design of the study have been reviewed by the UCI Conflict of Interest Oversight Committee, and this committee has determined that the investigator’s financial interests will not compromise the quality or reliability of the study. Furthermore, the UCI Institutional Review Board has determined that the investigator’s financial interests will not adversely affect your safety and welfare.

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

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

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

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

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

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

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

If, during the 30 day wait period, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

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

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

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

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 **Subject Signature Date**

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 **Printed Name of Subject**

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

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

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

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

*­­­­­­­­­­­­*

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

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

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

**Signature of Person Obtaining Informed Consent Date**

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

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

­­­­­­­­­­­­­­­ **Printed Name of Person Obtaining Informed Consent**

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

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

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

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

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

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

 research procedures).

**For the witness:**

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

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

**Witness Signature Date**

*Note: Refer to Human Research Policy # 35 for implementation of a witness signature.*

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

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

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI’s Human Research Protections unit in the Office of Research by calling (949) 824-8170 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at **160 Aldrich Hall, Irvine, CA 92697-7600.**