**UC Davis and UC Davis Health**

**Consent to Participate in Research**

***This document includes directions in red type. You must delete the red type after you follow the directions. It also includes yellow-highlighted type. Yellow-highlighted type indicates language that you should look at carefully and choose whether to leave it in or delete it. Please remove all red type and yellow highlight before submitting this consent document to the IRB.***

**Title of study:**

**Principal Investigator:**

***[Include only if the research includes skin penetration such as a blood draw]***

**(Experimental Subject's Bill of Rights)**

**Someone will explain this research study to you, including:**

* **The nature and purpose of the research study.**
* **The procedures to be followed.**
* **Any common or important discomforts and risks.**
* **Any benefits you might expect.**
* **Whether or not you take part is up to you.**
* **You can choose without force, fraud, deceit, duress, coercion, or undue influence.**
* **You can choose not to take part.**
* **You can agree to take part now and later change your mind.**
* **Whatever you decide it will not be held against you.**
* **You can ask all the questions you want before you decide.**
* ***[Delete if the consent process will not include obtaining signatures on the consent document.]*If you agree to take part, you will be given a signed and dated copy of this document.**
* ***[Delete if the consent process includes obtaining signatures on the consent document.]* If you agree to take part, you will be given a copy of this document.**

**Introduction and Purpose**

You are being invited to join a research study.

The purpose of this study is to see if

If you agree to be in this research, you will be asked to give ***[enter the type of sample(s) that will be collected. If blood samples are collected, enter the amount of blood you will collect in teaspoons or tablespoons.]*** for this research.This form will call the samples we collect from you “specimens.”

***[Delete if not applicable]***If you agree to take part, the study team will also collect information about you from your medical record at UC Davis Health***[Include other facilities where health information may be collected]****.* You will be asked to sign a separate HIPAA authorization form to allow us to collect information from your medical records. This information will become part of the research data.

**Here are some issues to think about before you decide whether to join this research:**

***[Delete the highlighted references to “biospecimens” if not applicable to this study]***

We will use your biospecimens and information to conduct this study.Leftover biospecimens and data collected for this research may also be used for future research studies. We will not share any personally identifiable information. Our goal is to make more research possible. These studies may be done by researchers at this institution or other institutions, including commercial entities. Data may be placed in one or more external scientific databases for access and use. Biospecimens may be placed in research repositories. We will not ask you for additional permission to share de-identified information or biospecimens*.*

You will/will not receive the results of any of the tests run on your specimens.***[If subjects will receive results, describe the results subjects will receive and the procedures you will follow to provide the information. Please note that there are restrictions on the information that can be provided to individuals when the tests performed on their specimens are considered investigational or the tests are not being performed at a CLIA-certified laboratory.]***

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.

Being in research is completely voluntary. You can choose to take part now and change your mind in the future. Whatever you decide, there will be no penalty to you or loss of benefits to which you are otherwise entitled. ***[Include if the specimens and information will be directly or indirectly identifiable]***If you decide to have your specimens and information removed from the research, contact the research team and ask to have your biospecimens and information removed from the study. No new research will be conducted with your specimens and information after you contact the research team.

You will not receive any direct benefit if you take part in this study. We hope this research will ***[describe benefits to society/ scientific knowledge as applicable]****.*

The physical risks of this research are minimal. ***[Delete if not applicable]***You might feel minor discomfort and there is a slight risk of infection when blood is collected from you.

Genetic and Genomic Research

Researchers might/will/will not use your specimens for genetic or genomic testing.

***[Delete the next four paragraphs if “will not” is selected above]***

Genetic testing involves examining DNA in the cells of the bio-specimen. DNA is the chemical database that carries instructions for your body's functions. Genetic testing can reveal changes (mutations) in your genes. Mutations can cause illness or disease. Genetic testing can also provide important information for diagnosing, treating and preventing illness.

Genomic sequencing is different from genetic testing. Genomic sequencing involves a process for analyzing a sample of DNA. Everyone has a unique genome that is made up of the DNA in all of a person's genes. Genomic sequencing is a complex test that can help identify genetic mutations that may relate to diseases and may help scientists determine how the body may react to a drug developed to treat a disease.

Allowing your specimens to be used for genetic testing and genomic sequencing involves some risk. For example, you might receive unwanted information of a personal and sensitive nature -such as paternity information- if the results of the research are returned to you. You might also learn that you are at risk for developing a disease. Information learned from this type of testing may also extend to your relatives. There is a risk that this sensitive information about you and your family might be accessed by individuals who do not have a right to access it; however, we will take the steps described below to prevent inappropriate access from happening.

In addition to taking the steps described in this document to protect the privacy of your genetic information, there is a Federal law called the Genetic Information Nondiscrimination Act (GINA) that prohibits employers and health insurers from discriminating against you because of your genetic information. Another Federal law called the Affordable Care Act (ACA) prevents health insurers from denying insurance to people with pre-existing conditions, including genetic conditions. A California state law called CalGINA increases the protections of the Federal GINA law by also protecting you from being discriminated against because of your genetic information by emergency medical services, housing agencies, businesses, lenders, or state-funded activities or programs.

**Confidentiality**

As with all research, there is a chance that confidentiality could be compromised. To minimize the risks of breach of confidentiality, we will not include any information that directly identifies you on the specimens and information we collect, and on the data resulting from the research. ***[Delete if not applicable]***Instead, we will record a code on the specimen and information, and we will keep a link between the code and your identity in a different location.***[If the bio-specimen and information will include identifiers, provide in the protocol justification for retaining the identifiers and describe in both the protocol and this consent document the data security measures you will take to protect the subjects’ confidentiality (e.g. encryption, password protection, storage, limited access to study records]***

People from UC Davis who oversee and monitor research to see if it is done properly may look at the information we collect about you. ***[Delete if not federally funded]*** Regulatory agencies who oversee research may also access your data during audits or other monitoring activities.

***[Include for all studies that include, as part of their protocol, any clinical intervention, including the invasion of any research participant (control or subject) body cavity (e.g. blood draw) when such an intervention takes place within a UC Davis Health licensed facility. Otherwise, delete.]***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 research records.

***[Delete if not applicable]*** This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. For example, the information collected in this research cannot be used as evidence in a proceeding unless you consent to this use. Information, documents, or biospecimens protected by this CoC cannot be disclosed to anyone else who is not connected with the research, except:

* To a federal agency sponsoring this research when information is needed for auditing or program evaluations;
* To meet the requirements of the U.S. FDA;
* If a federal, state or local law requires disclosure such as a requirement to report a communicable disease;
* If information about you must be disclosed to prevent serious harm to yourself or others such as child abuse, elder abuse or spousal abuse;
* If you consent to the disclosure, including for your medical treatment, to an insurer or employer to obtain information about you; or
* If it is used for other scientific research, as allowed by federal regulations protecting research subjects.

This CoC also does not prevent you or a family member from voluntarily releasing information about yourself and your involvement in this research.

**Compensation**

***[Describe any payment or other types of compensation. Specify method and timing of payment. Please note that compensation through a raffle is acceptable only if all potential subjects are provided with a method for entering the raffle regardless of whether they participate in the study.]***

***[OR, if there will be no payment/compensation:]***

There will be no compensation for your participation in this study.

**Questions**

If you have any questions about this research, or you believe that you’ve been injured or harmed as a participant of this research, please contact the investigator at ***[phone number]*** or ***[email address]****.*

If you have any questions about your rights or treatment as a research participant in this study, please contact the UC Davis, Institutional Review Board by phone: 916-703-9158 or by email: HS-IRBEducation@ucdavis.edu.

***[Delete if not applicable]*****If you agree to take part in the research****please *[give instructions, e.g., “print a copy of this page to keep for future reference, then click on the “Accept” button below.”]***

***[Delete if not applicable]*****Signature Block for Capable Adult**

|  |
| --- |
| Your signature documents your permission to take part in this research. |
|  |  |  |
| Signature of subject |  | Date |
|  |  |
| Printed name of subject |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |

***[Delete if not applicable]*****Signature Block for Adult Unable to Consent**

|  |
| --- |
| Your signature documents your permission for the named subject to take part in this research. |
|  |  |  |
| Printed name of subject |  |  |
|  |  |  |
| Signature of legally authorized representative |  | Date |
|  |  |
| Printed name of legally authorized representative |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

***[Add the following block if you will document assent of the subject.]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 |

 ***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |

***[Delete if not applicable]* Signature Block for Children**

|  |
| --- |
| Your signature documents your permission for the named child to take part in this research. |
|  |  |
| Printed name of child |
|  |  |  |
| Signature of parent or individual legally authorized to consent to the child’s general medical care |  | Date |
|  | * Parent
* Individual legally authorized to consent to the child’s general medical care (See note below)
 |
| Printed name of parent or individual legally authorized to consent to the child’s general medical care |
| **Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise. |
|  |  |  |
| Signature of parent |  | Date |
|  |  |
| Printed name of parent |
| If signature of second parent not obtained, indicate why: (select one) |
| * The IRB determined that the permission of one parent is sufficient. ***[Delete if the IRB did not make this determination]***
* Second parent is deceased
* Second parent is unknown
 | * Second parent is incompetent
* Second parent is not reasonably available
* Only one parent has legal responsibility for the care and custody of the child
 |

***[Add the following block if you will document assent of children]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
* Waived by the IRB because the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.
 |

 ***[Add the following block to all consents]***

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining consent and assent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

 ***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |