**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:**

**Investigator:**

**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 (complete a survey/questionnaire/participate in an interview). You will be asked questions about     . It will take about       to complete the (survey/questionnaire/interview/focus group),

***[Delete if not applicable]*** The interview will be audiotaped/videotaped and transcribed, but your name will not be included on the transcription.

There is no direct benefit to you from taking part in this study. We hope that the research will ***[describe benefits to society/ scientific knowledge as applicable]****.*

The risks of this research are minimal. Some of the questions might make you feel uncomfortable or upset. You do not have to answer any of the questions you do not want to answer.

**Confidentiality**

As with all research, there is a chance that confidentiality could be compromised; however, we are taking precautions to minimize this risk. Your responses to the survey and interview questions will not/will include information that identifies you. This identifiable information will be handled as confidentially as possible. However, individuals from UC Davis who oversee research may access your data during audits or other monitoring activities.

To minimize the risks of breach of confidentiality, we will       ***[Explain data security measures to be taken, e.g., coding, encryption, password protection, storage, limited access to study records, destruction of video or audio recordings after transcription, and/or destruction of code key after data is collected/matched, etc.]***

***[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*.*

***[Certificate of Confidentiality: If this research is funded by the NIH, you must include this language. If you have submitted or plan to submit an application for a Certificate of Confidentially, you must include this language.]***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.

***[Include the following paragraph if the research may involve topics or subject matter that may represent risks to participants in foreign countries. Of particular concern would be data, subject to intercept or loss of confidentiality collected by electronic means, otherwise delete]***

This research study may address topics that could be illegal or socially sensitive where you live. If discussing the topics addressed in this study will represent a possible hazard to you, your family, or your acquaintances’ freedom, reputation, or social standing please consider these additional risks of participation when deciding whether to take part in this research study. ***[Include if applicable]***In addition, the use of electronic means of communication (e.g. the internet, e-mail, text messages, faxes, and social networking) may not be secure, private, or confidential in your community.

**Compensation**

***[Include information on payment or other types of compensation, as applicable. Specify the method and timing of payment or compensation, e.g., "To thank you for participating in this study, you will receive (e.g., a $20 gift card for \_\_\_\_\_\_\_\_”) mailed to you within \_\_ weeks after you complete the survey." or “You will receive $\_\_\_\_\_ of Amazon credit after you complete the survey”.***

***Please note:***

* ***MTurk is acceptable when conducting human subjects research if the data collected is non-sensitive. UC Davis IRB Administration will not allow the use of Mechanical Turk if the data collected could reasonably place the subjects at risk of criminal or civil liability or damaging to the subjects’ financial standing, employability, or reputation, or is covered by HIPAA.***
* ***If class extra credit is offered as compensation for student research participants, then those who choose to not participate will be offered an equivalent assignment/opportunity for extra credit.***
* ***If compensation is provided through a raffle, all potential subjects must be provided with a method for entering the raffle regardless of whether they participate in the study.]***

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

You will not be paid for taking part in this study.

**Rights**

***Taking part in research is completely voluntary***. You are free to decline to take part in the project. You can decline to answer any questions and you can stop taking part in the project at any time. Whether or not you choose to take part, or answer any question, or stop taking part in the project, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

**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.

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