**UC Davis and UC Davis Health**

**Letter of Information**

**Title of study:**

**Investigator:**

**Introduction and Purpose**

You are being invited to join a research study. If you agree to be in this research, you will be asked to (describe research procedures). Your taking part in this research should take about (describe the length of time).

***Taking part in research is completely voluntary***. You are free to decline to take part in the project or you can stop taking part in the project at any time.

**Questions**

If you have any questions about this research, please feel free to contact the investigator at *[phone number]* or *[email address].*

*[For research involving deception or incomplete disclosure, include the following (or similar) statement, as appropriate. Otherwise, delete]*Research sometimes requires that information regarding its purpose not be shared with the research participants because its knowledge could impact the results of the research. Note that none of the aspects of the research being withheld are reasonably expected to affect your willingness to take part. While the tasks you will be asked to perform for this research have been explained, the full intent of the research will not be provided until the completion of the study. At that time you will have the opportunity to ask questions, including about the purpose of the study and the procedures used, *[add the next phrase if applicable]* and withdraw your data if you so choose.

*[Delete if not applicable]* When you take part in this research you will be (audio/video) recorded. The recording will be transcribed, but your name will not be included on the transcription.

*[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.

*[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. Otherwise, delete]*

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.