**Instructions for Use:**

1. The below sample informed consent language document provides examples of the language that must be included in research consent forms when UCSB researchers are using or collecting personal data of individuals located in the European Union (EU) or European Economic Area (EEA) as required by the General Data Protection Regulation (GDPR). ***Personal data is any information that can identify or be used to identify a person, and includes, but is not limited to name, date of birth, internet protocol address, ethnic or racial data, financial data or health-related data.***
2. Insert the below language into applicable sections of the informed consent document that is given to research participants who reside in the Economic European Area (EEA) or European Union (EU).
3. [*Blue*] text in brackets indicates instructional language that should be deleted.
4. Upload a copy of the informed consent document to your ORahs protocol application for review.
5. This sample consent applies to exempt and non-exempt research if personal data is collected from individuals residing in the EEA/EU.

**Sample Consent Language:**

**Procedures:**

*[Insert for research subject to the General Data Protection Regulation (GDPR)]* As part of this study, we will collect information about you that could identify you or be used to identify you. We refer to all such data as “Your Study Data.” Your Study Data will be processed, or used, for the purpose of conducting the study. *[Include if and as applicable:]* Your Study Data includes more sensitive personal information about you, including *[modify as appropriate to ensure you have identified all health-related, genetic or biometric data, as well as the other categories identified here:] .e.g., health-related data (e.g., information relating to the type of tumor you have, XYZ; your heart rate following treatment ABC); biometric data (e.g., your iris recognition, your DNA); genetic data (e.g., specific phenotypic or variant data); racial or ethnic data; data concerning your sex life or sexual orientation; political opinions or philosophical beliefs, and/or trade union membership.].* We refer to all such data as “Your Study Data.”

*[Include if you are obtaining personal data from a third party who is not the research subject and using the personal data in the study:]* We have obtained *[some/all]* of Your Study Data from *[identify the source/publicly accessible sources],* and this data includes *[identify the types of personal data obtained from a third party or public sources].*

*[Insert for research subject to GDPR. Otherwise delete.]* In addition to the length of time researchers intend to keep research data, including Your Study Data, UC will keep Your Study Data for ten years after the research, and any other research you agree to using Your Study Data, is completed.

The research team, authorized UCSB personnel, the study sponsor *[if not applicable, please remove],* and regulatory entities such as the Office of Human Research Protections (OHRP) may have access to your research data, including Your Study Data to protect your safety and welfare.

**Confidentiality:**

*[Add the following entire section below:]*

**Your Rights as a Research Participant under the EU/EEA General Data Protection Regulation (GDPR)**

In addition to being regulated by applicable U.S. laws, since you reside in the European Economic Area (EEA) during your participating in this study, your study data will be subject to the protections of the European Privacy Law, known as the General Data Protection Regulation (the “GDPR”). We will comply with the privacy and data protection laws that apply to you under the GDPR.

Any information you give today will only be used for research purposes. Your personal information may be released if required by law. Authorized representatives from the following organizations may review your research data for purposes for such as monitoring or managing the conduct of the study *[insert* *list of recipients and/or organizations that receive study data as part of this research below:]*

* UC Santa Barbara Institutional Review Board (a committee of individuals who reviewed this study),
* the research team, and faculty sponsor.

It is possible individuals may recognize you from published works.

We may conduct this study in the United States or in other countries where the laws do not protect your privacy to the same extent as the laws in the European Economic Area. However, we will comply with the privacy and data protection laws that apply to you if you are residing in the EEA during your participation in this study.

Since you reside in the European Economic Area during your participation in this Study, the European Privacy Law (GDPR) gives you certain rights with regards to Your Study Data. You have the right to request access to, rectification, or erasure of, your data.

There is no limit on the length of time we will keep your study data for this research because it may be analyzed for many years.

*[Insert the following if the University/investigator is receiving the data from another researcher or institution in the EEA/EU:]* We have entered into a data transfer agreement with *[DISCLOSER],* which includes standard contractual clauses approved by the European Commission and ensures an adequate protection for Your Study Data. You may obtain a copy of the standard contractual clauses by contacting the Principal Investigator *[OR ALTERNATIVELY, IDENTIFY A CONTACT PERSON IN YOUR RESEARCH ADMINISTRATION OFFICE AND INCLUDE NAME AND E-MAIL ADDRESS.]*

**Consent for Secondary Uses of Research Data:**

*[****CONSENT MUST BE AS SPECIFIC AS POSSIBLE FOR SECONDARY USES****. Include if consent will include consent for secondary research:]* In the sections below, you will be asked to consent to the donation of Your Study Data *[and and/or specimens]* for future research. Depending upon the future research uses of Your Study Data and/or specimens you agree to, Your Study Data may also be disclosed to researchers not affiliated with the study sponsor or with the study team.

*[Include a request for donation of the study data and if participant says “no” what will be done with the data:]* The below is a request for donation of Your Study Data *[insert brief description*]. If you choose not to donate your data, your data will only be used for the purposes you have given permission, as described in this consent.

\_ Yes \_ No: You may keep my data for future research related to [s*pecify types of potential research and types of institutions, e.g., UC, other universities, in a repository, etc. that may have access to the data and whether it is identifiable or de-identified*]. My study data will be *[specify how data will be stored, e.g., stored with an identification number or stored in a de-identified fashion]*

**Right to Refuse or Withdraw:**

Once again, your participation in this study is entirely voluntary you can refuse to participate at any given time. You will not be penalized by any institution or person .You may withdraw your consent at any time. If you withdraw your consent, this will not affect the lawfulness or our collecting and use of your Study Data up to the point in time that you withdraw your consent. If you do withdraw consent, we still may use your Study Data that does not identify you, because it has been stripped of identifiers and cannot be linked to you.

Campus Privacy Officer Information:

You have the right to request that we move, copy, or transfer your Study Data to another organization. The entity responsible for the use of your Study Data is: Regents of the University of California, on behalf of its Santa Barbara location. Contact *[UCSB Privacy Officer]* Compliance Officer at +1 (805) 893 - 7025 or *[insert UCSB Privacy Officer email].* Or write to the Policy Coordinator, University of California, Santa Barbara, Office of the Vice Chancellor for Admin Services, Santa Barbara, CA 93106-2033.