**GDPR NOTICE & CONSENT FOR COLLECTION AND USE OF STUDY DATA**

UCSC Study #: [Cayuse Human Ethics Study umber]

Study Title: [Title of the Cayuse Human Ethics Study]

This research study will collect data about you that can identify you, referred to as Study Data. The General Data Protection Regulation (“GDPR”) requires investigators to provide this Notice to you when we collect and use Study Data about people who reside in a State that belongs to the European Union or in the European Economic Area. If you reside in the European Union or European Economic Area during your participation in the Study, your Study Data will be protected by the GDPR, in addition to any other laws that might apply.

We will obtain and create Study Data directly from you or from [Insert the data sources, including repositories, collaborators, publicly available sources, etc.] so we can properly conduct this research study. As we conduct research procedures with your Study Data, new Study Data may be created.

The Study Team will collect and use the following types of Study Data for this research study [Delete any categories of information that you will not collect or create]:

* Contact Information
* Health information relating to [Describe health information collected/used]
* Your racial or ethnic origin
* Your political opinions
* Your religious or philosophical beliefs
* Your sexual orientation or beliefs
* Genetic data relating to [Describe genetic data collected/used]
* Information about your response to the research procedures
* [Insert categories of any additional data that you will collect]

[If applicable; otherwise, delete:] The Study Team will enter data about you and your health into a computer and a computer program will help the study team decide if you meet requirements to be in this study.

[If applicable; otherwise, delete:] The research study requires the Study Team to enter data about you and your health into a computer. A computer program will be used to assign you to one of the following specific study treatments [List study treatments]: If you sign this consent form, you are consenting to the use of this automated process to determine the treatment you receive. [Describe any other procedures that use an automated process to make decisions about the subject.]

Please initial one of the boxes below to indicate whether you consent to use of the automated processes described above.

\_\_\_ I agree

\_\_\_ I do not agree

This research study will keep your Study Data for [Insert the length of time the data will be maintained by the research – UC Santa Cruz requires the data to be maintained for at least 10 years following completion of the research] after this research study ends.

The following categories of individuals may receive Study Data collected or created about you [Delete any category that is not applicable]:

* Members of the Study Team so they properly conduct the research
* UC Santa Cruz staff will oversee the research study to see if it is conducted correctly and to protect your safety and rights
* The research sponsor who will monitor the study and analyze the data
* Agents of the sponsor who will assist the sponsor with data monitoring and analysis
* Representatives of the U.S. Office of Human Research Protections (OHRP) who oversee the research
* Representatives of the FDA who will use the data to determine whether a marketing application for the investigational [Drug/Device] can be approved
* Other investigators, so they can perform procedures required by this research
* Other investigators, including investigators in other countries, so they can conduct additional research on [Condition] and other, unrelated diseases and problems
* [List additional categories of individuals who may receive access to Personal Data and describe the reason for the disclosure.]

[If applicable; otherwise, delete:] The Study Team will transfer your Study Data to our research site in the United States. The United States does not have the same laws to protect your Study Data as States in the EU/EEA. However, the Study Team is committed to protecting the confidentiality of your Study Data. Additional information about the protections we will use is included in the consent document.

If you reside in the European Union or European Economic Area during your participation in the Study, the GDPR gives you rights relating to your Study Data, including the right to:

* Access, correct or withdraw your Study Data; however, the Study Team may need to keep Study Data as long as it is necessary to achieve the purpose of this research study
* Restrict the types of activities the Study Team can do with your Study Data
* Object to using your Study Data for specific types of activities
* Withdraw your consent to use your Study Data for the purposes outlined in the consent form and in this document (please understand that you may withdraw your consent to use new Study Data but Study Data already collected will continue to be used as outlined in the consent document and in this Notice)
* The Regents of the University of California, on behalf of UC Santa Cruz, is responsible for the use of your Study Data for this research. You can contact the UC Santa Cruz Privacy & Information Practices Office by phone at (831) 459-4003 or by email at privacy@ucsc.edu if you have questions about this Notice, complaints about the use of your Study Data, or if you want to make a request relating to the rights listed above.
* [If the data will be used for sponsored research or research authored by another research institution, where a non-UC investigator or non-UC institution is determining the data to be collected and scope of research, and UC is acting at the direction of the non-UC investigator or non-UC institution], insert name and contact information of sponsor/institution; sponsor/institution’s Data Protection Officer and Representative, if any, and their contact information; if no DPO or Representative, provide name and contact information of sponsor/institution privacy official.]