**CONSENT TO PARTICIPATE IN RESEARCH**

UCSC Study #: {Cayuse Human Ethics Study number}

Study Title: {Title of the Cayuse Human Ethics Study}

***Introduction:***

You are invited to take part in a research study being conducted by {Name of PI/Faculty Sponsor, and Student Investigator if applicable} from the department of {enter department as listed in the Cayuse Human Ethics Study} at the University of California, Santa Cruz. Before you decide whether or not to participate in the study, you should read this form and ask questions if there is anything that you do not understand. There will be about {fill in the total number of expected subjects to be enrolled} participants in this study.

***Purpose:***

The purpose of the study is {Describe the nature and purpose of the research, using layperson’s language}.

***What you will do in the study?***

If you decide to take part in this study, you will: {Describe what will happen to the subject; what type of information will be sought; state what portions, if any, are considered experimental, using layperson’s language}.

{If the study involves surveys, then include the following}

You will complete an {online} survey. The survey will ask about {insert topic of questions}.

{If the study involves interviews, then include the following.}

You will participate in an interview with a member of the study team. In the interview you will be asked about {insert topic of questions}.

{If the study involves focus groups, then include the following.}

You will participate in a focus group with other study participants. In the focus group you will be asked questions about {insert topic of questions}.

{If the study involves audio/video-recording, then include the following}

As part of this project, {an/a audio/video-}recording will be made of you during your participation. You have the right to request that the recording be stopped or erased in full or in part at any time. In any use of the {audio/video-}recording, you will not be identified by name. Please note below the uses of the recordings to which you are consenting.

{Delete any uses that are **not** appropriate for this study}

1. The {audio/video-}recording {will/can} be used by the investigators in this research study.

2. The {audio/video-}recording {will/can} be {reviewed by/shown to} subjects in other studies.

3. The {audio/video-}recording {will/can} be used for scientific publications.

4. The {audio/video-}recording {will/can} be {reviewed/shown} at meetings of scientists interested in the study of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ {fill in specific area of study}.

5. The {audio/video-}recording {will/can} be {reviewed/shown} in classrooms {by/to} students.

6. The {audio/video-}recording {will/can} be {reviewed/shown} in public presentations to non-scientific groups.

7. The {audio/video-}recording {will/can} be used on television and/or radio.

{If participants must agree to audio/video-recording in order to participate, then include the following}

If you do not consent to such use of the recording you should not participate in this study.

***Time Required*:**

Your participation will take about {enter time}.

***Risks or Discomforts:***

{Explain any risks or discomfort - including psychological discomfort - that might reasonably be expected to happen}

{If there is there a potential for boredom, fatigue or emotional distress, describe these risks and study procedures that will be done to minimize risks}

{If there is there a potential for subjects to experience risks related to the political, social or economic context in which they live, describe these risks and study procedures that will be done to minimize risks}

{If identifiable information is collected, include}

There is a risk that your identifiable information could be accidentally disclosed; however, the researchers are taking measures to protect your data.

{If the study involves a Certificate of Confidentiality, include}

***NIH Certificate of Confidentiality:***

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, {except as explained below}.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

{If investigators intend to make voluntary disclosure about information obtained in the research such as child abuse, or intent to hurt self or others, include}

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of {list what will be reported, such as child abuse and neglect, or harm to self or others}.

***What benefits can be reasonably expected?***

{Describe benefits to the subjects and/or others (society in general)}

{If no direct benefit to subjects, include}

Although there will be no direct benefit to you for taking part in this study, the study investigators may learn more about {description}.

***What happens if you change your mind about participating?***

If you decide that you no longer wish to continue in this study, you will be requested to: {fill in requirements for orderly termination of study participation e.g., final examination, return devices, etc.}.

You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

***Can you be withdrawn from the study without your consent?***

You may be withdrawn from the study if you do not follow the instructions given you by the study investigators.

{If applicable, include}

You may also be withdrawn from the study for the following reasons: {insert numbered list of reasons why a subject may be withdrawn from the study}.

***Confidentiality:***

{Describe how the confidentiality of records that identify the subject will be maintained}

{If the study will involve subject identifiable information, include}

The information that you give in the study will be handled confidentially. Identifiable research data will be encrypted and password protected. You will not be identified in any report or publication of this study.

{If the study will be anonymous, include}

The information that you give in the study will be anonymous. Your name will not be collected or linked to your answers.

{If it is possible to deduce the participant’s identity through their responses, include}

Because of the nature of the study information being collected, it may be possible for someone to deduce your identity. However, there will be no attempt to do so and your information will be reported in a way that will not identify you. You will not be identified in any report or publication of this study.

{If the study data will be coded with a link to identifiers retained by investigators, include}

Your responses will be assigned a code number. The list connecting your name to this code will be kept in an encrypted and password protected file. Only the study investigators will have access to the file. When the study is completed and the data have been analyzed, the list linking identifiable information to the study data will be destroyed.

{If the study data will be collected over the internet, include}

While the study investigators follow procedures to maintain your confidentiality, as with any internet activity, we cannot guarantee confidentiality of interception of data sent via the Internet by any third parties.

{If the study involves audio/video-recording, include}

With your permission, the {interview/discussion} will be {audio/video-}recorded so that an accurate transcript can be made. Once the transcription is complete, the recordings will be erased. Your name will not be in the transcript or study notes.

{If the study involves focus groups, include}

Even though we will tell all participants in the study that the comments made during the {group interviews/focus group} should be kept confidential, it is possible that participants may repeat comments outside the group.

{If the study involves information that legally must be reported to government agencies, include}

Your part in this study is confidential within legal limits. The study investigators will protect your privacy unless they are required by law to report information to city, state or federal authorities, or to give information to a court of law. Otherwise, none of the information will identify you by name. All study records will be {Describe how records are to be maintained}.

{If the study is subject to FDA regulations, include}

The Food and Drug Administration (FDA) may inspect your study records.

{If the study meets the definition of a [clinical trial](https://grants.nih.gov/policy/clinical-trials/definition.htm), include}

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov), as required by U.S. Law. This website will not include information that can identify you and will include a summary of the results. You can search this website at any time.

***Clinically Relevant Research Results:***

{If the study involves potentially clinically relevant research results, include} You {will/will not} receive any clinically relevant results discovered about you and/or the general subject population.

***Whole Genome Sequencing****:*

{If the study involves whole genome sequencing, include}

This study will look at your entire DNA using a method called whole genome DNA sequencing, to determine the order of the letters, or genetic code.

{Also review the [Model Consent Content for Whole Genome, Exome and Other Whole Genomic-Related Analysis](https://cdp.cancer.gov/resources/elsi/docs/Model_Consent_Genomic_Sequencing.docx) and use appropriate (based on study procedures) template language}

***Data Sharing:***

{If the study is subject to the NIH [Data Management and Sharing Policy](https://sharing.nih.gov/data-management-and-sharing-policy), include the following}

This study is collecting data and biospecimens from you. We would like to make your data and biospecimens available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Our goal is to make more research possible. We plan to keep your data and biospecimens **for [Insert time frame as indicated in the study protocol]**.

Your data and biospecimens may be shared with researchers around the world. However, the decision to share your data and biospecimens is controlled by **[indicate which entity has control]**. To get your data and biospecimens, future researchers must seek approval from **[indicate which entity has control]**. The researchers must agree not to try to identify you.

* **Option #1: If the data and biospecimens are coded and can be linked back to the identity of the participant:**
We will protect the confidentiality of your information to the extent possible. Your data and biospecimens will be coded to protect your identity before they are shared with other researchers. **[indicate which entity has the code key]** will have a code key that can be used to link to your identifying information. The code key will be securely stored.
* **Option #2: If the data and biospecimens cannot be easily linked back to the identity of the participant:**
Your name and identifying information will be removed from any data and biospecimens you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data and biospecimens.

***Future Research:***

**{**If the study involves collecting identifiable data/biospecimens, include **one** of the following statements}

Your information or biospecimens will not be used or distributed for future research studies.

{OR}

Your information or biospecimens, with all identifying information removed, may be used for future research without your additional consent.

**{**If the study may involve the use of identifiable data/biospecimens in future research, include.}

With your permission, study investigators may use your identifiable information/biospecimens for future research studies that {Describe how the identifiable information will be used and how confidentiality will be protected}.

***Commercial Profits:***

{If the study involves collection of biospecimens, include. If not applicable, remove}

Specimens collected from you for this study and/or information derived from your specimens will become the property of the University of California or a third party designated by the University. The information/specimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or other compensation from products developed using the information/specimens.

***Alternatives:***

{If applicable, list any alternatives available to the subject for obtaining the same benefit without participating in research – e.g., alternative assignments worth the same academic credit for comparable effort. If not applicable, remove}

***Compensation:***

{If the study involves subject compensation for participation, include. If none is available, state so}

You will receive {$X or/ X credits)} for participating in this study.

***Are there any costs associated with participating in this study?***

There will be no cost to you for participating in this study. {If there are costs associated with participation, these should be stated (i.e., parking costs)}

***What if you are injured as a direct result of being in this study?***

{If the study involves greater than minimal risk, explain whether any medical or other treatment is available if injury occurs, and who to contact; including} If this study causes you any injury, you should write or call {names} at {phone number}.

***Voluntary Participation:***

Your participation is completely voluntary; you are free to change your mind at any time and quit the study.

{If study involves surveys, include}

You may skip any questions you do not wish to answer. Whatever you decide will in no way {include appropriate language: penalize you, affect your grade, affect your status as a student} or result in loss of benefits or services to which you are otherwise entitled.

{If study involves interviews/focus groups, include}

You can withdraw at any time by simply leaving the {interview/focus group}. You are free to not respond to any question(s) you do not wish to answer. Whatever you decide will in no way {include appropriate language: penalize you, affect your grade, affect your status as a student} or result in loss of benefits or services to which you are otherwise entitled.

{If payment or course credit is being offered, include}

You will still receive full {payment or credit, as applicable} for the study.

-OR-

You will receive partial {payment or credit, as applicable} for the study. {Add details of pro-rating here}

***Rights and Concerns:***

If you have questions about this research study, please contact {investigator’s name, research title, campus address, phone number, and email address}. You may also contact the faculty member supervising this research: {Principal Investigator’s name, title, campus address, phone number, and email address}. If you have any questions regarding your rights as a research participant, please contact the University of California Santa Cruz, Office of Research Compliance Administration at 831-459-1473 or orca@ucsc.edu.

***Signature:***

Signing this document means that information in this form was provided to you and that you voluntarily agree to participate in the research described above.

{A checklist can be used if appropriate but is not required}

☐ You agree to be {audio/video-}recorded.

☐ You agree to allow the study investigators to keep your {identifiable or de-identified} data to be used in future research studies as described above.

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Signature of Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Typed/printed Name

***Please sign both consent forms, keeping one for yourself.***

***A witness signature is required on this consent form only if:***

*(Check which of the following applies. If no witness signature is required, this witness signature section may be completely removed.)*

☐ The subject has decision-making capacity, but cannot read, write, talk or is blind.

☐ The IRB specifically mandated a witness signature for this study.

The witness must be impartial (i.e., not a member of the subject’s family, not a member of the study team).

For the witness: Information in this form was provided to the subject or legally authorized representative (LAR) and the subject or LAR voluntarily agreed to participate in the research described above.

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Witness Signature Date

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Printed Name of Witness