*Informed Consent Template*

***California State University, Dominguez Hills***

***Consent to Participate in a Research Study***

**(Insert Title)**

### Before submission to the IRB, please remove all instructional language (written in blue) from the template.

INSTRUCTIONS: **The consent form should be written in the 2nd** person (e.g., “You are being asked to participate in a research study about…”); This is the written version of a conversation with each prospective study participant.

**Complex terms and concepts should be described or defined in lay language.** The consent form should be written at the appropriate reading level for your subjects and explain all necessary scientific and medical terms in a way that they can understand. They need to know what is being asked of them so that they can make an informed decision to participate in the study. Define all abbreviations the first time they are used.

Key Information**: [Explain each component of your research using a bulleted format using one sentence for each bullet point.]**

* The fact that consent is being sought for research and that participation is voluntary.
* The purpose of the research, expected duration of the prospective subject’s participation, and the procedures to be followed in the research.
* The reasonably foreseeable risks or discomforts to the prospective subject.
* The benefits to the prospective subject, to science, or to society that can be expected from the research.
* Appropriate alternative procedures or course of treatment, if any, that might be advantageous to the prospective subject.

Investigators: Provide the **name and academic degrees of all investigators** involved in the study, the department, institution, and phone number. If you are a student, include the name of the person supervising your research and indicate they are supervising the study.

**Indicate the faculty member who is the Principal Investigator first, include all degrees and title, and the CSUDH email and office phone.**

Unless students have one or more graduate degrees, no degrees are listed. Make sure to include each student’s Toro email and a phone number.

Example

Veronica Stearns, PhD, Assistant Professor, CSUDH, XX Department,

vstearns@csudh.edu or 310-243-xxxx.

John Smith, CSUDH student, jsmith324@toromail.csudh.edu or xxx-xxx-xxxx.

Purpose and Description of the Study: **Provide a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and the identification of any procedures which are experimental. Do not simply copy and paste information from your proposal**. Include the **number of subjects** being recruited and the **eligibility criteria** used to identify potential participants. **Indicate if your study is being funded and include the source of funding if applicable**. **Be concise and use a bulleted format if there are several study activities involved**. If there will be interviews or questionnaires, indicate the types of topics that will be covered.

If there will be a preliminary screening to determine eligibility, indicate what will happen to the information obtained during that screening.

Costs for Participation: If there are costs associated with participation specify in detail the extent of these costs and who is responsible to pay them. **If this is not applicable to the study, you do not have to include this section.**

Risks or Discomforts: **A description of any reasonably foreseeable risks or discomforts** to the subject. Studies may include risks that are not only physical, but psychological, social, or economic in nature**. Do not assume that there are no risks even if your research seems straightforward and harmless**. **Identify the risks or discomforts the subjects might encounter as a result of participation**. Outline the provisions you have made to minimize or eliminate them. For example, you may include the following statement: “Because of the personal nature of the questions that will be included on the questionnaire, you may reflect on unpleasant memories. If you begin to feel uncomfortable, you may discontinue participation at any time, and it will not affect your relationship with CSUDH, the researcher or any other person or organization involved in the study.”

Benefits of the Study: **A description of any benefits to the subject, science, and society which may reasonably be expected from the research**. If there are no benefits that the subject can expect, say so. For example, you may include the following statement: “There is no guarantee, however, that you will receive any benefits from participating in this study”. **Be careful to not overstate the benefits of the study.**

Alternative Procedures or Courses of Treatment: A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. For biomedical studies, be sure to identify appropriate alternative procedures or courses of treatment that might be available or advantageous to the subjects. For socio-behavioral studies, you can state that the alternative is not to participate.

Confidentiality: A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Indicate how the data will be stored and maintained. All study data must be password-protected and stored and maintained on an IT-approved platform. If video or audio tapes are used to record study information, describe how they will be used, who will have access to them, and how long they will be stored or when they will be erased. Remember, confidentiality refers to recording but concealing the subject’s identity or codes linked to the individual’s identity. Anonymity means that the identity of the subject is never known to the researchers and is never recorded or associated with the data collected.

Depending on the nature of your study, include that confidentiality will be maintained to the extent allowed by law. Inform the subject that there are times when certain information he/she/they shared may need to be disclosed to the appropriate authorities; if the investigator is a mandated reporter, they will need to notify the authorities if the subject experiences or witnesses suicidal ideation, homicidal ideation, child abuse, or elder abuse. The following is an example of wording you could use in such cases: “Please know that the investigator is a mandated reporter. If you mention having suicidal thoughts, intention to harm others, or have knowledge of child or elder abuse, the investigator will be required to report such information to the appropriate authorities.” Feel free to use the best wording that applies to your study.

Incentives to Participate: Incentives can be offered to subjects for their participation in the study. Subjects who are students can be offered extra credit as an incentive, but they should also be offered another way to earn extra credit so that there is no undue pressure to participate in the study. . **If appropriate, describe what is being offered to the subject and what is required of them to obtain it. If there is a payment offered, state the amount and any formula for prorating the funds should the subject discontinue participation before completing the study.** **You do not have to include this section if you are not offering an incentive.**

Voluntary Nature of Participation: A statement that participation, refusal to participate, or discontinuing participation at any point during the study will not result in a penalty or loss of benefits to which the subject is otherwise entitled. For example, you may include this statement: “Your choice of whether or not to participate will not influence your future relationship with California State University, Dominguez Hills [include the name of other institutions(s) involved in the research, if appropriate]. If you decide to participate, you are free to withdraw your consent and to stop your participation at any time without penalty or loss of benefits to which you are entitled”.

Questions about the Study or your Rights as a Research Subject: You have the right to ask any questions you may have about this research. You may call the investigator (name and campus phone number). All research with human volunteers is reviewed by the CSUDH Institutional Review Board (IRB), which is charged with protecting your rights and welfare. If you have questions or concerns about your rights as a research subject, you may contact the CSUDH IRB at 310-243-3756 or irb@csudh.edu.

For Biomedical Studies Only:

Compensation for Injury

There must be a statement as to whether any medical treatments are available if injury occurs, and if so, what treatment is available and where further information can be obtained.

You have also been given a copy of the ‘Research Participant’s Bill of Rights. (Available on the CSUDH IRB website).

## Your signature below indicates that you have read the information in this document and have had a chance to ask any questions you may have about the study. Your signature also indicates that you agree be in the study and have been told that you can change your mind and withdraw your consent at any time.

## \*Include only for research involving medical experimentation. You have been given a copy of this consent form. \*You have also been given a copy of “The Research Participant’s Bill of Rights.” You have been told that by signing this consent form you are not giving up any of your legal rights.

Name of Participant (please print)

Signature of Participant Date

Signature of Investigator Date

If you are requesting permission to audio-tape/video-tape or obtain visual images, please use the following CSUDH approved form.

[Audio/Video/Visual Image/Interview Release Form](https://www.csudh.edu/Assets/csudh-sites/ucm/docs/WORD-CSUDH-Visual-Audio-Video-Written-Release-Form-2018.pdf)

Subject recruitment and data collection may not be initiated prior to formal written approval from the

California State University, Dominguez Hills Institutional Review Board