**Below is the standard Informed Consent Template that all CSUB Investigators must use, please do not deviate from this format. Under each section are instructions for you to understand what each section requires. It should be written directly to your participant rather than just copying and pasting from your protocol. Please remember to remove the instructions only meant for the research team.**

**All text in RED is required.**

**All text in BLACK may or may not be applicable**

**CONSENT TO VOLUNTARILY PARTICIPATE IN A RESEARCH STUDY**

**Protocol Number:**

**Title of the Project:**

**Principal Investigator: [Name, credentials, institutional affiliation]**

**Co-investigator: [Name, credentials, institutional affiliation]**

**Faculty Advisor: [Name, credentials, institutional affiliation]**

**Student Researcher: [if applicable, Name, credentials, institutional affiliation]**

**Video Communication, Zoom, or Telephone Consent Procedures**

When data are collected from human subjects by video communication, videotelephony, or telephone, informed consent is still required.

Sometimes it is not possible to have obtained written informed consent in advance. If this is the case, then informed consent must be obtained orally, prior to collecting the survey or interview data. The same elements of informed consent should be used over video communication or the phone as would have been included in a written consent form.

Following is the preferred approach:

* Assemble the elements of informed consent into a script. Submit this with the protocol to be reviewed and approved by the IRB. Use a separate copy of the script for each potential telephone participant, with a space to check off each element as it is read to the participant. After checking off these elements, ask [and check off] the final two questions – do you have any questions, and do you agree to participate? When the person agrees to participate, write in the person’s name in a space at the bottom, and sign & date it to indicate that you have administered the elements of informed consent and that the person has agreed to participate.

**Identify**

Hello, my name is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. I am a (student/faculty member/staff member) from California State University, Bakersfield.

**Purposes of the research**

Instructions for Research Team: What we are looking for here is a statement that the study involves research, an explanation of the purpose(s) of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.

* Example: 20 Yes/No questions which will take about 5 minutes.

**Any reasonably foreseeable risks or discomforts to the subject**

Instructions for Research Team: What we are looking for here is a description of any reasonably foreseeable risks or discomforts to the subject.

* Note: Every study includes foreseeable risks, as minimal as they may be.

**Any benefits to the subject or to others that may reasonably be expected from the research**

Instructions for Research Team: What we are looking for here is a description of any benefits to the subject or to others that may reasonably be expected from the research. Important to note: most CSUB studies do not provide immediate benefits to the participants, and that is ok. If this is the case, please include a statement like “There are no immediate benefits to the participants”.

**\*Alternative procedures or courses of treatment, if any, that might be advantageous to the subject**

Instructions for Research Team: A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

**Confidentiality of records**

Instructions for Research Team: A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Here we need you to explicitly convey to the participants that it is your responsibility to keep all data confidential, including storage of the informed consent forms, whether physically or electronically, stored for a period not less than 3 years in a locked container or encrypted file and thereafter can be destroyed.

**Any psychological or medical treatments if injury occurs & who to contact**

Instructions for Research Team: What we’re looking for here is an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

**Who can I contact if I have questions or concerns about this research study?**

Faculty Investigator name

Faculty Investigator address

Faculty Investigator phone and email address

Student Investigator name

Student Investigator phone and email address

**Who can I contact if I have questions or concerns about my rights as a research participant?**

Dr. Isabel Sumaya

University Research Ethics Review Coordinator

Institutional Review Board/Human Subjects Research

California State University, Bakersfield

9001 Stockdale Highway

Bakersfield, CA 93311

(661) 654-2231

[isumaya@csub.edu](mailto:%20isumaya@csub.edu)

Dr. Marianne Wilson

University Research Ethics Reviewer

Institutional Review Board/Human Subjects Research

California State University, Bakersfield

9001 Stockdale Highway

Bakersfield, CA 93311

661-654-2075

[mwilson52@csub.edu](mailto:mwilson52@csub.edu)

**Voluntary Participation in the Study**

Instructions for Research Team: What we are looking for here is a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

**\*Collection of identifiable private information or identifiable biospecimens**

Instructions for Research Team: What we are looking for here is one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

**\*Risks to participants (or to the embryo or fetus), during Treatment or procedure(s)**

Instructions for Research Team: What we are looking for here is a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.

**Circumstances under which the participation may be terminated**

Instructions for Research Team: What we are looking for here is any anticipated circumstances under which the participant's involvement in the study may be terminated by the investigator without regard to the participant's or the legally authorized representative's consent.

**\*Any additional costs**

Instructions for Research Team: What we are looking for here is any additional costs to the subject that may result from participation in the research. Note: There may be instances where there are no additional costs, please state this.

**\*Significant new findings**

Instructions for Research Team: What we are looking for here is a statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the subject.

**\*Number of subjects involved in the study**

Instructions for Research Team: The approximate number of subjects involved in the study.

**\*Biospecimens**

Instructions for Research Team: If applicable, what we are looking for is a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

**\*Clinically relevant research results**

Instructions for Research Team: If applicable, what we are looking for is a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

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You are agreeing to be in this study. Make sure you understand what the study is about before you agree. The researcher(s) will give you a copy of this document for your records and will keep a copy with the study records for a period of 3 years and may be destroyed thereafter. If you have any questions about the study afterward, you can contact the study team using the information provided above.

\*Additionally, by agreeing to participate in the study, you are not exempt from:

(1) receiving emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

(2) local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

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Do you agree to participate in this study? Or Do I have your permission to begin asking you questions?

If participant agrees verbally, initial here\_\_\_\_\_\_\_\_\_\_ ­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_

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

Subject Name or Participant Code

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

Principal Investigator’s Signature Date

**Researcher Notes:**

* Date informed consent was obtained verbally \_\_\_\_\_\_\_\_
* Date video communication or telephone call was made \_\_\_\_\_\_\_\_\_\_\_\_
* What was discussed during the call: