***INFORMED CONSENT TEMPLATE***

***v. 6/2023***

***INSTRUCTIONS:***

***Delete all instructions in italics, like this one, before submitting the blank informed consent document for approval with your protocol*.**

***To Create Your Consent Form Draft for IRB Review:***

* ***Read through each section and add pertinent details and delete text as needed.***
* ***Remove the italicized instructions.***
* ***Delete double space between sections if necessary.***
* ***The section headers provide clarity for your research study participants, but you may remove them to save space if needed.***
* ***Keep the finished consent document draft to 1 or 2 pages if possible.***
* ***Use ordinary language. Writing to a 6th-8th-grade level in lay language is recommended for adult participants.***
* ***Provide details. The goal is to create a document that can be read by participants so that they can understand what they are agreeing to participate in; the details about the activities they will do; the risks; how their information will be used; and how their personal information will be protected..***
* ***Use the pronoun “you” throughout this document to refer to the research participant.***
* ***Call yourself and collaborators “the researcher,” “researchers.”***

**California State University East Bay**

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

**(INSERT Research Title Here)**

## **PURPOSE AND BACKGROUND**

The purpose of this research study is to *\_\_\_\_*

*(State in one or two sentences why the study is being conducted, for instance “to learn more about the effect of using math games in teaching sixth grade math.” Do not use academic or discipline-specific jargon. Make sure that whatever you write on this document is also written or described in the protocol you submit to the IRB. For example, the purpose you write here should be in sync with the purpose you describe in your IRB protocol).*

The researcher, \_\_\_\_\_\_\_\_\_\_\_\_\_\_, is a professor/ graduate student/staff member at California State University East Bay conducting research for…

*[example-a master’s degree/honor’s thesis.] List all researchers and roles as applies to the data collection and use team.)*

You are being asked to participate in this study because you…

(S*tate here the reason for recruitment, e.g. “you are a student in the Psychology department.”)*

*Be specific.*

# [**PROCEDURES**](http://tips_informed_consent.htm#b)

*List* ***all*** *research activities for the participant. Be concise and clear****. Adapt this to your own research****, use only your own procedures.*

***Sample:***

 If you agree to participate in this research study, the following will occur:

* you will be interviewed for approximately thirty minutes about \_\_\_\_\_\_.
* the interview will be audiotaped to ensure accuracy in reporting your statements.
* the interview will take place in the researcher’s office at a time convenient for you. (or/ it will take place at a time and location convenient to you.).
* the researcher may contact you later to clarify your interview answers for approximately fifteen approximately forty-five minutes.
* total time commitment will be \_\_\_\_\_\_\_\_

*(Please state only those procedures that the participant will undergo. State* ***where*** *the research will take place****, how long*** *it will take, and* ***when*** *it will occur****. Include the information you would like to have if you were going to participate in this project as a research subject****. List the time each procedure will take, and also the total time commitment for the participant, not the researcher. Make sure you describe the same planned activities in your IRB protocol.)*

1. [**RISKS**](http://tips_informed_consent.htm#c)

***Sample****:* There is a risk of loss of privacy. However, no names or identities will be used in published reports of the research. Only the researchers will have access to the raw research data.

 (*Add other risks if they exist, such as “There is a risk of discomfort or anxiety due to the nature of the questions asked; however, the participant can answer only those questions* *he/she chooses to answer, and can stop participation in the research at any time.”*

*If others will have access to the research data, say that and describe who else will have access.*

*If you are conducting focus groups, see focus group consent under Forms and Templates*

*for additional protections for participants in group discussions. Don’t confuse focus groups with other types of participant activities.*

***If you are interviewing children or youth under the age of 18,*** *see the Guidelines for Obtaining Minor Assent and sample assents; you will also need a Parental Permission for a Minor to Participate in Research, also found in Forms and Templates.*

*Include this paragraph under C. Risks if the study has risk of injury or more than minor risks.* If You are Injured While in This Study

“If any injury arises as a direct result of participation in this study, we will assist you in obtaining appropriate attention. If you need treatment or hospitalization because of being in this study, you are responsible for payment of the cost for that care. If you have insurance, you may bill your insurance company. You will have to pay any costs not covered by your insurance. California State University, East Bay and the CSU East Bay Foundation will not pay for any care, lost wages, or provide other financial compensation. For more information, however, to report injuries or to report what you feel is a claim against the State or the Foundation, please contact irb@csueastbay.edu to obtain the appropriate forms.”

**D. CONFIDENTIALITY**

*Sample*: “The research data will be kept in a secure location (*or/password protected program*), and only the researcher will have access to the data. At the conclusion of the study, all identifying information will be removed and the data will be kept in a locked cabinet or office. “

***Describe where and how the data will be stored, and include the final disposition of the data, that is, what you will do with the data when the study is* *completed.***

(*If taping interviews and transcribing them for the content: ‘*Audiotapes or videotapes will be destroyed at the end of the study’.)

*If keeping original tapes or data for future research, data may be used in the future only for research purposes consistent with the original purpose of the research stated in this consent. If the data is de-identified, i.e* ***all*** *identifiers have been removed including coding, the data will not need IRB review for future research use.*

*If you might use non-anonymous specimens/data you collect now for future research, you must include the following language:*

“As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We may plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding [*describe disease, condition, or potential purpose*], or other diseases or conditions. This could include studies to develop other research tests, treatments, devices, or that may lead to the development of a commercial product and/or its research or that of partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.”

**E.** [**DIRECT BENEFITS**](http://tips_informed_consent.htm#d)

*Sample:* There will be no direct benefits to the participant.

(*There is almost never a direct benefit, unless the research involves an intervention or clinical trial in which a subject may get an experimental treatment.)*

*(Any indirect benefits can only be anticipated, because you can’t guarantee anything since you have no results yet. If you talk about anticipated benefits, do so briefly and use the conditional tense, as in “*Benefits **may** include…..”)

**F.** [**COSTS**](http://tips_informed_consent.htm#e)

*Sample:* There will be no cost to you for participating in this research.

(Or) The only cost to participants will be transportation to the research site.

**G.** [**COMPENSATION**](http://tips_informed_consent.htm#f)

*Note: Do not offer compensation if you have not read the* [*ORSP Guidance for Providing Research Incentive Payments*](https://www.csueastbay.edu/orsp/files/docs/policy/orsp-research-incentives-guidance.pdf)*.*

*Sample:* There will be no compensation for participating in this research.

(Or) *Sample*: Compensation for participating in this research will be a Cal State East Bay T-Shirt.

**H.** [**ALTERNATIVES**](http://tips_informed_consent.htm#g)

*Sample:* Alternate therapies for this condition exist such as extended bed rest.

*(This section is typically used for clinical trial when a medical treatment is being studied, to let the participant know that there are options other than the study.)*

**I.** [**QUESTIONS**](http://tips_informed_consent.htm#h)

If you have any further questions about the study, you may contact the researcher by email at \_\_\_\_@\_\_\_\_ or phone at (510) 885-xxxx.

Questions about your rights as a study participant, or comments or complaints about the study, may also be addressed to the irb@csueastbay.edu or (510) 885-4476.

**J.** [**CONSENT**](http://tips_informed_consent.htm#i)

**Please keep a copy of this form in case you would like to read it again in the future.**

**PARTICIPATION IN THIS RESEARCH IS VOLUNTARY. You are free to decline to participate in this research study, or to withdraw your participation at any point, without penalty. Your decision whether or not to participate in this research study will have no influence on your present or future status at California State University East Bay.**

**ADULT**

**I am an adult participant 18 years of age or older. I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.**

Signature of Research Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_

**LEGALLY AUTHORIZED REPRESENTATIVE (When Applicable)**

**I am the legal Authorized Representative of the Participant, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.**

**I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in this study.**

Signature of Legally Authorized Representative \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Legally Authorized Representative \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_

**PARENT /GUARDIAN OF A MINOR PARTICIPANT (When Applicable)**

**I am the Parent/Guardian of the Minor Participant, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.**

**I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give my permission for my child to take part in this study.**

Signature of Parent / Guardian \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Parent / Guardian #1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_

Signature of Parent / Guardian \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Parent / Guardian #2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_

**MINOR ASSENT (When Applicable)**

**I have had this student explained to me in a way that I understand, and I have been given the opportunity to discuss it, and I have had the change to ask questions. I agree to take part in this study.**

Signature of Minor Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Minor Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_

**RESEARCHER**

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_

 Researcher

*(Signature of researcher is optional.)*