# Note: After using the template to create your consent form, change all fonts to black and erase unneeded instructions.

#  [Insert the title of research study here. The title should be accessible to a layperson. Use a standard 14 pt. font, bold]

# Informed Consent

**[Erase this message from your form after reading: If you are proposing an international study, there may be additional mandatory language needed for your consent forms depending on the country/countries involved. Contact the IRB Office or IRB Chair to discuss your situation.)**

## INVITATION TO PARTICIPATE:

My name is[provide your full name]and I am a [identify your role/title at the university, e.g. “ graduate student,” “professor,” “staff member”] in [identify the program] of [identify the college/school/department] at California State University San Marcos. [change wording accordingly for multiple investigators and/or multiple universities.] You are invited to participate in a research study of [insert general statement about the study]. You were selected as a possible participant because [explain how the participant was identified]. Please read this form carefully and ask any questions you may have before agreeing to be in the study. You must be 18 or older to participate in the study.

**KEY INFORMATION ABOUT THIS RESEARCH STUDY:**

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is listed later in this form.

[The following should be in one paragraph:]

The purpose of this study is [insert purpose here]. You will be asked to [include a brief statement of the procedures that will be used. For example: You will be asked to complete a survey and a follow-up interview]. We expect that you will be in this research study for [hours/days/months/weeks/years, until a certain event]. The primary risk of participation is [insert primary risk]. The main benefit is [insert main benefit].

**STUDY PURPOSE:**

The purpose of this study is to [explain why the research is being done using language understandable to the participant. DO NOT use citations. Keep the explanation brief. Avoid making references like “variable” that is hard for a layperson to understand.]

**NUMBER OF PARTICIPANTS:**

If you agree to participate, you will be one of up to \_\_\_\_ [insert the total number of participants in the study. It may also be appropriate to clarify the number of participants in different cohorts, sites, or groups, if applicable.] participants who will be participating in this research.

**PROCEDURES FOR THE STUDY:**

If you agree to be in the study, you will do the following: [Explain in language understandable to the participants, the research activities they are expected to engage if they agree to be part of the study. This includes participating in questionnaires, surveys, interviews, focus groups, observations, audio or videotaping, artifact collection (e.g. meeting agendas), and field notes which may be employed in the study. Explain the research activities in the order the participants will experience. Explain where each activity will be performed (e.g. office, classroom, coffee shop, a place convenient to the participant, etc.), how frequently they will be performed, and the expected duration for each activity. Also specify the total duration of participation in the study. Use bullet points for each research activity for readability. If the study involves the collection of identifiable private information or identifiable biospecimens, state either: 1) that identifiers might be removed and the information or biospecimens could be used for future research studies or given to another researcher to be used without additional informed consent, or 2) that the subject’s information or biospecimens collected as part of this study will not be used for future research studies.]

**RISKS AND INCONVENIENCES:**

There are risks and inconveniences to participating in this study. These include:

[Insert the risks and/or inconveniences using a numbering system. For example: Risk/Inconvenience 1: \_\_\_\_\_. ]Examples of risks may include but are not limited to: Participants may be uncomfortable answering the survey or interview questions, participants may experience psychological distress or physical pain during the study, and/or participants may fear they will face negative consequences or loss of reputation at their workplace for participating in the study. The time participants spend for participating in the study might be considered inconvenience. There might be a risk of possible loss of confidentiality—Note that this is the case during focus groups or other group settings where the participant’s responses will be heard and/or seen by other participants in the study.]

Here is an example of the risks/inconveniences format for a hypothetical study:

Risk/Inconvenience 1: You will need to dedicate time out of your day to participate in the study.

Risk 2: You may experience psychological stress while recalling difficult childhood experiences in the interview

Risk 3: You may fear that you will face negative consequences at work if others learn about your survey answers.

Risk 4: There is a potential loss of confidentiality due to the nature of focus groups.

Risk 5:….. (List as many risks as needed; for in-person studies you may choose to end with the two risks for exposure to COVID-19: e.g. Risk 5: You may feel anxious and/or fearful of being exposed to COVID-19 in the study. Risk 6: You may be at risk of contracting COVID-19.)

**SAFEGUARDS:**

To minimize these risks and inconveniences, the following measures will be taken:

[Explain what measures you will take to minimize each risk and inconvenience you identified using a numbering system. For example, Safeguard 1 should address Risk/Inconvenience 1.] Examples of safeguards include, but are not limited to: Participants can skip any questions that they feel uncomfortable answering while taking the survey or during the interview. Participants may skip any part of the intervention. Participants will be provided with list of counseling and social support resources. Surveys, interviews, or observations will be scheduled at a time and place that are convenient for the participant at a place of their choosing that is private.]

Here is an example of the safeguards format for a hypothetical study:

Safeguard 1: Your study participation will be scheduled at a time and place that are convenient for you and provide adequate privacy. (If your study takes place in a lab or other non-negotiable setting, you can only emphasize the convenience of scheduling the time.)

Safeguard 2: You may skip any questions you do not want to answer and stop your participation in the study at any time. A list of community and online resources will be provided to you in the event you would like to seek out counseling or support services.

Safeguard 3: You will not be identified by name in this research or presentations or publications about this study. I will be referring to you by a pseudonym (made-up name) and all schools (companies, no-profits, etc). will be given pseudonym as well.

Safeguard 4: Although there is no way of assuring complete confidentiality of focus groups, I will be assigning all participants numbers that I will use to refer to you during the focus group. (If on Zoom: You can sign into Zoom with the number I have assigned you rather than your name and leave your camera off during the focus group.)

Safeguard 5: … (If you chose to list the COVID-19 risks, you should add these as the last two safeguards: e.g., Safeguard 5 (I am/ we are) taking the following precautions to minimize the possibility that you will be exposed to the virus:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Safeguard 6: Despite these precautions, the risk of exposure to COVID-19 is still present.

**CONFIDENTIALITY:**

Your responses [or information] will be [anonymous OR confidential; “anonymous” is applicable when unidentifiable data is collected (e.g. participants are assigned ID numbers during the study and/or there is no master list with participants’ personal information), “confidential” is applicable when the researcher knows, collects, or has a record of the participant’s name or other identifiable information such as e-mail address, phone number, address, birthdate, student ID, and/or social security but uses pseudonyms during reporting of the data, and the personal information is only accessed by the researcher or the research team who is doing the study. If using focus groups, add the following statement: “Due to the nature of focus groups, complete confidentiality cannot be guaranteed”.]

The results if this study may be used in reports, presentations, or publications but your name [or other personal information as applicable] will not be used. [If applicable, use the following statement: “Results will only be shared in aggregate form”. Additionally, the researcher must explain where the data will be stored (e.g. password-protected computers, shared drives, on Qualtrics, Zoom or Amazon Mechanical Turk, etc., in a locked file cabinet), who will have access to the data (e.g. the researcher, research team, social media platform administrators, etc..), and how long the data will be retained (e.g. up to 3 years after the project is completed) and whether the data will be disposed of and how if relevant (e.g., the paper records will be shredded, the digital files will be erased.)]

**VOLUNTARY PARTICIPATION:**

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty. Your decision whether or not to participate in this study will not affect your current or future relations with [insert appropriate entity, i.e., university, school/department.]

**BENEFITS OF TAKING PART IN THE STUDY:**

The benefits of participating in this study are [Describe any direct benefits to the participants. If there are no direct benefits to the participants, use the following statement instead: There are no direct benefits to participation in this study, however, your participation will help [explain the knowledge to be gained from this study and/or how the study will contribute to the field.]

**PAYMENT OR INCENTIVE:**

You [will OR will not] receive payment or an incentive for taking part in this study. [If payment is involved, explain the amount and the conditions under which the participant will receive compensation. If instead of payment the participants receive credit or other forms of compensation (e.g. gift card), this should be mentioned here. If participants receive compensation for different parts of the study, the compensation schedule needs to be mentioned here as well. Remember, compensation schemes should be incremental for multi-part studies and completion should not be a requirement for receiving an incentive.

Note that if you are using an opportunity drawing (do not refer to it as raffle), you should explain when it will occur (estimate month and year of the drawing), a fair method that will be used to choose the winner/s, and how you will notify the winner/s. Under California law, anyone who wants to must be able to enter an opportunity drawing must be able to do so. State in this section and in your recruitment documents that “participation in the study is not required in order to participate in the opportunity drawing” and explain how non-participants can be entered in the drawing.

**ALTERNATIVES TO TAKING PART IN THE STUDY:**

[Include this section only if there is an alternative activity for those who decide not to participate in the study—this usually applies to survey and curriculum/design studies.] If you decide not to participate in this study, you have the option to: [Explain how those who decline to participate will spend their time while participants of the study will engage in the research activities.]

**STUDY-RELATED INJURIES:**

[For studies with more than minimal risk (i.e., those that undergo full IRB review), you must explain whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. **Consent forms cannot include any exculpatory language that which the subject is made to appear to waive any legal rights or releases the researcher or institution from liability for negligence**.]

**CONTACT INFORMATION:**

If you have questions about the study, please e-mail me at [insert your csusm e-mail address] [If a student also add this phrase: or my advisor, Prof. \_\_\_\_\_\_\_\_\_\_ at [insert their email address and work phone number). You will be given a copy of this form for your records [if online instruct them how to save the completed copy for their records or explain how you will provide it to them]. If you have any questions about your rights as a participant in this research or if you feel you have been placed at risk, you can contact the IRB Office at irb@csusm.edu or (760) 750-4029.

**PARTICIPANT’S CONSENT:**

By signing below, you are giving consent to participate in the study. [Release statement for audio or video recording must be inserted here if applicable. If video and/or audio recording, add the following statement: “Please check the option that applies to you before signing” with the following options:

☐ I give permission for my [insert what is being audio/video recorded, e.g. interviews] to be audio (or video) taped.

☐ I do not give permission for my [insert what is being audio/video recorded, e.g. interviews] to be audio (or video) taped.]

If you are allowing people to be audio recorded but opt-out of being video recorded, create four checkbox lines, and address them separately.

Name of the Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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