Instructions:

1) Fill in all required information in red text,
2) Fill in *applicable* blue sections, but delete blue underlined text,
3) Delete any blue sections that do not apply,
4) Delete this yellow highlighted section from your final version and ensure all text in this document is **black**.

(Regulated Research Template)
INFORMED CONSENT FORM
(TITLE of STUDY)

My name is (your name), and I am a (your role) at California State University, Sacramento, (School and/or Department). I am conducting this research study to (explain purpose of research at an 8th grade reading level). If you volunteer to participate, you will be asked to (participant procedures explained adequately at an 8th grade reading level). Your participation in this study will last (duration, in detail. provide the # of hours per session, # sessions per participant, etc.).

Your participation in this study is voluntary. You have the right not to participate at all or to leave the study at any time without penalty or loss of benefits to which you are otherwise entitled. Research alternatives (not common): disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

There are some possible risks involved for participants. These risks are (describe risks identified in the IRB application). Physical risks only (not common): An emergency plan will be executed in the event of a research related injury. (Explain emergency plan). In the event of a research related injury, please contact your regular medical provider and bill through your normal insurance carrier, and then contact the IRB at 916-278-5674. There are some benefits to this research, particularly that (benefits to subjects or society (most research does **not** result in direct benefits to the participant)).

Experimental Procedures Only (not common): The following procedures are considered to be experimental: (describe in an 8th grade reading level). This study is enrolling approximately (enter #) participants. *Only when applicable, add*: It is possible that some risks may be present that are currently unkown and any significant new findings that may relate to your willingness to continue participation will be provided to you.

Incentives/Compensation: If you are offering an incentive or compensation, such as gift cards or test results, explain what the incentive is and the requirements for receiving the incentive. Can they leave the study early or must they complete the study to receive the incentive? You must state HOW and WHEN they will receive it. Individual results (not common): receiving individual results can be viewed as an incentive to participate. Explain if, and under what conditions, individual results will be shared with participants.

Withdrawal procedures (not common): Studies requiring several visits should have a withdrawal plan. Describe the consequences of subject's decision to withdraw (if any) and procedures for participants to follow if they end participation. If YOU can withdraw a participant due to attrition, please describe those terms here. Lastly, address how their data will be handled once withdrawn (will it be kept or removed?).

It is anticipated that study results will be shared with the public through presentations and/or publications. Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. Measures to insure your confidentiality are (1. How will identities be protected during reporting of results? 2. data storage procedures and 3. de-identification plan). Raw data containing infromation that can be identified with you will be destroyed after a period of (how long will you keep identifiers on the raw data?) after study completion. The de-identified data will be maintained in a safe, locked location and may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. (If you plan on destroying de-identified data, state here how long it will be maintained until destroyed).

If you have any questions about the research at any time, please contact me at (your phone or email), (or (faculty advisor name and contact info, required for students)). If you have any questions about your rights as a participant in a research project please call the Office of Research, Innovation, and Economic Development, California State University, Sacramento, (916) 278-5674, or email irb@csus.edu.

Your signature below indicates that you have read and understand the information provided above, that you willingly agree to participate, that you may withdraw your consent at any time and discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Signature Date

_____ _____

You will receive a copy of this form to take with you.

Children in Research: Including minors in your study? Write this form for the **parent**. Change "you" to "your child" or "your student" and add signature lines for *both* parents. If the minor is 14 or over, add a third line for the minor to sign on this exact same form (parent and child can read and sign together). If the child is under 14, add a separate form that will serve as the child's *assent*. This can be a verbal script if the child is very young that looks for verbal or physical cues of consent, or a verbal consent with an information sheet that explain the general idea of the study AT THEIR READING LEVEL.