|  |
| --- |
| SONOMA STATE UNIVERSITY  INSTITUTIONAL REVIEW BOARD FOR THE RIGHTS OF HUMAN SUBJECTS INFORMED CONSENT GUIDELINE *Use the following list to confirm that all required elements of informed consent are included in your attached consent form. Informed consent is required from all subjects regardless if the study qualifies for exemption or expedited review.*   1. **The *informed consent must begin with key information* that will assist the participant in deciding to participate (*see Sample below*).** 2. If the participant does not speak English or is significantly disabled either emotionally or intellectually, the consent form is in a language which the non expert subject can be expected to comprehend. (Participants should have an opportunity to discuss the information and ask any questions before they sign the form). 3. The participants are informed that they are involved in research. Researcher must specify their name and their position at SSU. In addition to their names, students must specify that the research is being done as part of a class or for a master’s degree at Sonoma State University. 4. There is a clear statement of the research purpose. 5. Include a statement that describes how the participant was selected, approximately how many people will be included in the study and the expected duration of the participant's participation. 6. There is a description of the procedures to be followed in the research project. 7. There is a description of any foreseeable risks and discomforts. 8. List potential risks and any benefits possible for the participant or others expected from the research. **If you plan to offer participant compensation,** indicate how much, how many participants are eligible, and how compensation will be distributed. For example, if you plan a participant drawing, you should indicate the odds that a participant will receive a reward, and when the drawing will occur. If you offer gift cards, you should make it clear how many participants you can cover and what you are doing to ensure that you don’t get more participants than you have the budget to pay. When there is no expected individual benefit to the participant, the participant should be made aware of this. (Because one cannot guarantee a project’s outcomes, it is not appropriate to describe the project as benefitting general or discipline specific knowledge). 9. There is an explanation of the procedures by which the participant’s confidentiality will be protected. 10. There is a statement that participation is voluntary, and that the participant may skip a question or withdraw participation at any time. 11. It should be made clear that participants may discontinue participation and refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. 12. One of the following statements about any research that involves the collection of **identifiable private** information:   (i) A statement that identifiable private information will be removed, and that, after such removal, the information 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 participant’s information collected as part of the research, and even after identifiers are removed, will not be used or distributed for future research studies.   1. If you plan to make video or audio recordings, include a statement about  * Where and how long you will keep the recordings. * Who will have access to the recordings (this includes clips shown to public or professional audiences). * How long they will be kept and the security measures that you will use. * Place for participant to indicate explicit consent to be recorded. * Place for participant to indicate explicit consent for recordings to be presented to the public. * Place for participant to indicate explicit consent that they recognize that video (or audio) recordings will not keep their personal information confidential or anonymous.  1. If the researcher has a legal obligation to report an act to authorities, participants are so informed. (Include if applicable). 2. Researcher’s name and the telephone number where researcher can be contacted for answers to questions are provided. 3. For student researchers, the name, telephone number, and email address of the professor or faculty advisor is provided. 4. Certification sentence should include the person certifies they are at least 18 years of age and freely consent to participate in this study. 5. Contact information for participants to call SSU’s IRB office with question about your rights as a human subject. The statement below should be bolded:  * **If you have a question about your rights as a human subject contact irb@sonoma.edu or phone 707.664.2066.**  1. If the research involves minors (under age 18) there is (a) an informed consent form for the parent/guardian and (b) an informative letter or script that explains the project to the minor, written in language appropriate for the participant’s age and allows the participant not to participate.  * ***For minors or others who cannot sign for themselves, provide a line for the authorizer to specify his/her relationship to the subject and to sign and date the form. Provide a line for the signature of a witness, if any*.** |

|  |
| --- |
| Waiver of Written Informed Consent Waiver of signed informed consent will be considered for some or all subjects for situations such as the following:   1. That the research involves no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. 2. The research could not practicably be carried out without the requested waiver or alteration, such as with anonymous telephone or internet-based surveys. 3. If the research involves using identifiable private information, the research could not practicably be carried out without using such information in an identifiable format. 4. The waiver or alteration will not adversely affect the rights and welfare of the subjects. 5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. 6. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. 7. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.   The IRB reviews each request individually, considering all aspects of the particular study. Requests for waiver must be in writing, providing a thorough explanation of the situation and a description of the proposed alternative method of obtaining informed consent. If waiver of written informed consent is requested, a text of the oral statement must be submitted by the investigator to provide participants or legally authorized representatives with a written statement regarding the research. Such statement must follow the same format as the Informed Consent Guidance. |

|  |
| --- |
| **Sample Consent Form**  **The following sample is provided as a reference from which a consent form can be developed. It is *not* provided with the intention that it be precisely emulated. NOTE: The Revised Common Rule, *effective Jan. 20, 2019,* requires that “the informed consent *must begin with* a concise and focused presentation of the key information that is most likely to assist a prospective subject or representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension."** |
| ***Informed Consent for Research Involving Human Subjects***  **Beginning statement example: You are invited to participate in a research project [*in which we hope to learn something about some topic*]. It is being conducted by [*a student, faculty, or group*]. If you participate it will require you to [*complete a task that will require some amount of time*]. You are selected because [*provide a reason].* The survey (*does/does not*) ask for personal information and contains (*procedural safeguards to protect your privacy*). Your participation is completely voluntary.**  If you decide to participate, we *(or Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and his/her associates)* will (*describe the procedures to be following, including their purposes, how long they will take, and their frequency). (Describe the discomforts and inconveniences reasonably to be expected.) (If applicable, add: We cannot and do not guarantee or promise that you will receive any benefits from this study.)*  *(Describe appropriate alternative procedures that might be advantageous to the subject, if any. Any standard treatment that is being withheld must be disclosed.)*  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 or as required by law. If you give us your permission by signing this document, we plan to disclose *(state the persons or agencies to whom the information will be furnished, the nature of the information to be furnished, and the purpose of the disclosure).*  *(If the subject will receive compensation, describe the amount or nature.) (If there is a possibility of additional costs to the subject because of participation, describe it.) (If physical injury is a possibility from physical activity or from such stimuli as light, noise, fumes, electrical apparatus, etc.)*  Your decision whether or not to participate will not prejudice your future relations with Sonoma State University *(and the named cooperating institution, if any).* If you decide to participate, you are free to skip a question or withdraw your consent and to discontinue participation at any time without prejudice.  If you have any questions, please ask us. My name is *(provide name)* and I can be reached *at (telephone number; email address). (Student researchers: also provide the name, telephone, and email address of your faculty advisor.)***If you have a question about your rights as a human subject contact** [**irb@sonoma.edu**](mailto:irb@sonoma.edu) **or phone 707.664.2066.**  You will be given a copy of this form to keep. *(optional)* YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE READ, UNDERSTOOD, AND AGREE TO THE ABOVE INFORMATION. IN ADDITION, YOUR QUESTIOS HAVE BEEN ANSWERED AND YOU CERTIFY THAT YOU ARE ATLEAST 18 YEARS OF AGE AND FREELY CONSENT TO PARTICIPATE IN THIS STUDY. If you plan to make either audio or video recordings, include a place for participant to indicate explicit consent to be recorded, and to present recordings to the public.  Print Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_  Research Participant  ***For minors or others who cannot sign for themselves, provide a line for the authorizer to specify his/her relationship to the subject and to sign and date the form. Provide a line for the signature of a legally authorized adult.*** |