SONOMA STATE UNIVERSITY

INSTITUTIONAL REVIEW BOARD FOR THE RIGHTS OF HUMAN SUBJECTS

INFORMED CONSENT GUIDANCE

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| Checklist for Informed Consent *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.*  ***NOTE: The new Common rule, effective Jan. 20, 2019, requires a major change in the beginning of the informed consent. See the Sample Consent Form below.***   1. **The *informed consent must begin with key information* that will assist the subject in deciding to participate (*see Sample below*). Items 2-14 are still relevant.** 2. The participants are informed that they are involved in research. Students must specify that the research is being done as part of a class or for a master’s degree at Sonoma State University. 3. There is a clear statement of the purpose of the research. 4. There is a description of the procedures to be followed in the research project. 5. The participants are informed of the duration of their participation and the time commitment expected of them. 6. There is a description of any foreseeable risks and discomforts. 7. There is a description of any benefits possible to the participant or others expected from the research. (“Benefits” refers to direct benefits; statements that the research may add to the total body of knowledge in the relevant field of study are inappropriate. If the participant will receive no benefits, this should be explicitly stated.) 8. There is an explanation of the procedures by which the participant’s confidentiality will be protected. 9. There is a statement that participation is voluntary, that there is no penalty for refusal to participate, and that the subject may skip a question or withdraw at any time without penalty. 10. If the participant does not speak English or is significantly disabled either emotionally or intellectually, the consent form is in a language which the subject can be expected to comprehend. (Include if applicable.) 11. If the researcher has a legal obligation to report an act to authorities, participants are so informed. (Include if applicable.) 12. Researcher’s name and the telephone number where researcher can be contacted for answers to questions are provided. 13. For student researchers, the name, telephone number, and email address of the professor or faculty advisor is provided. 14. 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. |

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| Waiver of Written Informed Consent Waiver of written informed consent will be considered for situations such as the following:   1. The subjects are from cultures that use oral rather than written traditions. 2. Written consent might greatly hinder rapport in building cross-cultural and/or cross-ethnic research. 3. The subject has sought participation in an adequately publicized activity. 4. The subject comes from a class of people well able to protect themselves, such as public officials and university administrators, and is being questioned on matters pertinent to his/her profession. 5. The research is performed using existing data held by a third party and no identification is possible. 6. Written informed consent would make research impossible, such as with telephone surveys.   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 oral consent is planned, a text of the oral statement must be submitted. |

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| **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 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."**  **Sample template below** |
| ***Copy and paste to a Word Document to use this template***  ***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 current or 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, YOU CERTIFY THAT YOU ARE ATLEAST 18 YEARS OF AGE AND FREELY CONSENT TO PARTICIPATE IN THIS STUDY.  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 witness, if any*.** |