SONOMA STATE UNIVERSITY—INSTITUTIONAL REVIEW BOARD FOR THE RIGHTS OF HUMAN SUBJECTS

# Application for Approval of Research Involving Human Subjects

This application is designed to fulfill the responsibilities of Sonoma State University relative to the Code of Federal Regulations, Title 45, Part 46, regarding research involving human subjects. Failure to comply with the policies and procedures referenced in this application (1) may cause individuals to incur personal liability for negligence and harm; (2) may cause the University to lose federal funding, prevent individuals from applying for or receiving federal research funds, and prevent the University from engaging in research; and (3) will be viewed by SSU as a violation of university policies and procedures and will result in appropriate administrative action.

|  |
| --- |
| All research involving the use of human subjects conducted by SSU faculty, staff, or students —or sponsored in part or whole by SSU— must be reviewed and approved by the University’s Institutional Review Board (IRB) for the Rights of Human Subjects prior to the start of the project and then must be conducted in full compliance with University policies and procedures. It is the responsibility of the principal investigator to refer to the IRB any project involving human subjects, even if the subjects are not considered to be “at risk.” This includes research conducted in conjunction with classroom assignments that will be published or shared, as well as a student dissertations or theses. It also includes all interviews, questionnaires, surveys, observations, educational tests, and secondary analyses of previously collected data that will be incorporated into published research or other public presentations. Such projects may be undertaken only after appropriate approval and may be continued only so long as that approval remains in effect. Changes in a project, or continuation of the project following adverse or untoward occurrences during the project, are also subject to review and approval. **Research intended solely for classroom use (with no possibility of further disclosure or publication) and conference/workshop evaluation surveys do not require IRB review.** **Principal Investigators signed electronic applications must be submitted to** **Sonoma State University, Institutional Review Board** **electronically from your SSU email to** [**irb@sonoma.edu**](file:///%5C%5Cssu-alpha%5CFinancialServices%5CGrantsAndContracts%5CG%26C.Share%5C13%20INSTITUTIONAL%20COMPLIANCE%5C01%20HUMAN%20SUBJECTS%5Cirb%40sonoma.edu) **with a copy to the Co-Investigators (faculty advisor needs to be copied on student application submissions)**.**Due to the unprecedented circumstances surrounding the emergence of COVID-19** **pandemic signatures for the application and informed consent are accepted as follows:*** Picture of the signed first page of the document (student applications require their faculty advisor's signature).
* Type your name in the signature block and include a note in your email submitting the document that the typed name serves as your signature email consent. For applicants/**PI *it is required that you send all documents from your SSU email.*** Participants (human subjects) can utilize any private email.
* Fax consent (student applicant can send it to their faculty advisor by fax) final will be a picture sent by email to SSU’s Compliance Officer.
* For participants – Oral Consent (if the proper informed consent is prepared following oral consent federal guidelines)

**If you have any questions, contact the Office of Research and Sponsored Programs at 707.664.2066 or email** ***irb@sonoma.edu******.*** |

##### NOTE: Your complete application is due at least one month prior to the start of your research. It should include:

##### All Pages of this application plus additional pages for the Protocol Requirements as needed.

* A copy of your written[**Informed Consent Document**](http://orsp.sonoma.edu/forms) OR a request for waiver of written informed consent with a copy of the oral text you intend to use to inform your subjects of the points listed on the Checklist of Informed Consent (see <http://orsp.sonoma.edu/forms> for a **sample consent** form and checklist).
* SSU [**IRB Application Checklist**](http://orsp.sonoma.edu/forms)required forFaculty, Staff, and Student Researchers

**Complete all applicable gray form fields and check boxes.**

|  |
| --- |
| Your signature below certifies that:* You have read this packet of information and understand your responsibilities and liabilities as a principal investigator.
* You have reviewed the University’s policies and procedures on research involving human subjects and will ensure your research is conducted in full compliance. Copies of the policies and procedures are available from the Office of Research & Sponsored Programs at 1040 Salazar Hall. The information is also posted on the [ORSP website.](http://orsp.sonoma.edu/research-compliance/human-subjects)
* You have completed **“CITI IRB Training”** provided by Collaborative Institutional Training Initiative (CITI), at <https://citiprogram.org/>. ***All Applicants, Co-Investigator(s) and Faculty Advisor(s) must submit a Certificate of Completion for IRB training. Certificate of Completion is valid for five years.***
* You, your spouse, or your dependent children have no financial interest in your project that will or may be reasonably expected to bias the design, conduct, or reporting of your research.

Signature of Principal Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name of principal investigator:       Telephone:      Home Address:       Email #1:       Email #2:       ***(SSU email is required****)*SSU School:       Department:       Title or Academic Status:      Co-Investigator(s) name followed by institution affiliated with:       |
| ***For student investigators:***Please print or type name of professor or faculty advisor:       Signature of professor or faculty advisor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title or Academic Status:      ***Faculty members are required to initial the IRB Application Checklist and submit a copy of your Certificate of Completion for IRB training with their student's IRB applications.***Department clearance: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Student investigators must obtain clearance from their department’s human subjects committee, if one exists.  |

# Protocol Summary Sheet

|  |  |
| --- | --- |
| If requesting Exemption or Expedited Review, specify category (see http://web.sonoma.edu/orsp/forms/ in: Full Board, Expedited or Exempt Review):       | Title of Project:      |
| Brief description of purpose of project:      |
| [ ]  New project [ ]  Modification[ ]  Sub-study [ ]  Previous study | Date Starting Interaction with Human Subjects:      | End Date:      | Funding Source (if any):      |
|  |
| Subjects |
| Number (in sample):      If the number increases after the protocol is approved, an IRB modification form is needed. | Population (indicate the full possible population number if known):       |
| Source/How contacted (be explicit and include copies of recruitment materials):       |
|  |
| **Instruments**Check all that apply: [ ]  Tests [ ]  Questionnaires [ ]  Interview guides [ ]  Other:       |
| How administered: [ ]  Telephone [ ]  Mail or email [ ]  In person ZOOM:       Length and frequency of procedure:       Setting:      ***COVID-19 pandemic regulations change rapidly. Effective immediately in person interviews are allowed following COVID-19 regulations. For those interested, remote virtual interviews are still and option. All remote interviews need to be conducted utilizing you SSU’s HIPAA compliant ZOOM account only accessible utilizing your Seawolf IDs/LDAP user names.***  |
|  |
| DataCheck all that apply. Data will be recorded by:[ ]  written notes [ ]  audio recording [ ]  video recording [ ]  photography [ ]  film [ ]  other:       |
| **Data will include:** |
| [ ]  information that can identify the subject (e.g., name, social security number, name, physical and email addresses, name of company, phone number and other unique identifier) specify:       | [ ]  codes linked to subject’s name by separate code key[ ]  codes not linked to subject’s name |
|  |
| Data will be used for:[ ]  publication [ ]  evaluation [ ]  needs assessment [ ]  thesis [ ]  other:       |
|  |
| Informed Consent[ ]  written (attach copy of consent form)[ ]  oral (attach text of statement and request for waiver of written informed consent)*For items checked above, see* <http://orsp.sonoma.edu/forms> *Human Subjects Application: Informed Consent Guidance* |
|  |
| THIS SPACE FOR IRB USE ONLY |
| This project:🞎 is exempt under category A- \_\_\_\_\_\_\_\_ 🞎 is eligible for expedited review under category B- \_\_\_\_\_\_\_🞎 requires IRB review  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Human Subjects Administrator Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Chair, IRB Date |
| Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

If you have any questions, contact the Office of Research and Sponsored Programs at 707.664.2066 or email irb@sonoma.edu.

|  |
| --- |
| Protocol RequirementsAnswer each of the following questions. Use as many pages as necessary to fully respond; most protocols can be covered in five pages or less. 1. What are your research objectives?

1. Discuss the significance and scientific merit of the study.

1. In what manner and to what extent will human subjects be involved?

1. What procedures, instruments, etc. will be employed? Provide copies of all questionnaires, scripts, and other research materials.

1. What existing individual data, if any, will be used? Data could include student records or personal documents. This does not include publicly accessible data that has informed your literature review.

1. What will the subjects be told about their involvement in the study?

1. Describe the procedures for obtaining and recording the informed consent of subjects. ***How and when will you ask and confirm consent to participate?***Indicate whether language translation of the informed consent is needed. Attach a copy of the consent and/or assent form, as appropriate, if written consent is planned. If oral consent is planned, attach a copy of the text of the statement and a request for waiver of written consent.

1. A. Describe any potential risks to the subjects, including psychological stress and physical hazards, even if minimal. B. How are these risks, even if minimal, outweighed by the sum of the benefits to the subjects and the importance of the knowledge to be gained? *Answer both 8A and 8B.*

1. Describe any interventions or manipulations of subjects or their environments.

1. What measures will be taken to safeguard the welfare of subjects, their right to privacy and confidentiality of information? This includes security measures for the management of confidential data. How are electronic and paper documents being protected, how long will they be kept? Will you be using a password protected devise?

1. Are school-age children or other minors to be involved? If so, please describe the subject population.

1. Describe how you will conclude your work with research participants. If necessary, what steps will be taken to deal with any after-effects of emotional stress or other issues that could result from your project?

1. What procedures will be taken to insure prompt reporting to Sonoma State University’s IRB of (a) proposed changes in the research activity, (b) any unanticipated problems involving risks to the subjects or others, (c) any injury to subjects, and (d) any non-compliance with policies and procedures? Loss of data, risk and injury to the subjects should be reported within 24 hours.

     1. What type of remuneration, if any, will be offered to subjects for their participation in the research? Please provide an explanation on how you plan to ensure that all participants who are eligible will receive what you promise and you will not have more participants than you have budget to pay them. This information also needs to be included as part of the informed consent and advertisements. Remuneration can not be tied to data quality or participation.
 |
|  |