HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD

Checklist for Submitting Your Research Protocol to the IRB Office

PRELIMINARY STEPS

☐ You have consulted the Exclusion Worksheet on our website and determined that the work meets the regulatory definition of human subjects research requiring submission of a protocol.

☐ Principal investigator or supervising faculty member (if investigator is a student) has completed a mandatory online human research protections training through the Collaborative Institutional Training Initiative in the last five years. Faculty and staff co-investigators are also required to complete the training. SJSU has integrated CITI training certificates into our online IRB submission system; however, you must be prepared to upload your training certificate if it is not accessible by the IRB office when requested.

DOCUMENTS FOR SUBMISSION

Screening Materials

☐ If applicable, you have prepared the materials used to determine whether a research subject meets the eligibility criteria for your study.

Data Instruments and Recruitment Materials

☐ If applicable, you have prepared all data instruments and other materials to be administered to participants (e.g., surveys, questionnaires, interview questions, data/observation intake sheets, recruitment materials).

Recruitment materials such as flyers, social media ads, SONA ads, emails, and scripts should, at minimum, include the title of the study; name, affiliation, and contact information for the investigator; a brief description what participants will be asked to do; and the time commitment.

Intervention Materials

☐ If applicable, you will provide any supplementary materials related to a study intervention in addition to fully describing the intervention in the IRB application.

Consent and Assent Materials

☐ If applicable, you have prepared the appropriate consent and assent documents (whether a form, an informational notice, or a script) containing all of the required elements as outlined in the Informed Consent Handbook. Templates for the most commonly used documents should be accessed on our forms page and the formatting on all consent documents must have a bottom margin of at least one inch to allow the IRB office to digitally stamp the document.

Translations

☐ If applicable, you have prepared translations of any study materials to be distributed to participants AND you have had a Verification of Translation Accuracy Form signed by someone other than the members of the research team who is adept in the language.

Agreements from Outside Institutions

☐ If applicable, you have obtained agreements from the appropriate authority at outside institutions, organizations, or agencies if they: 1) will administer any research procedures on your behalf beyond passing along a recruitment message, 2) will provide you with access to private secondary data about subjects, or 3) will provide privileged access as a result of research team members' employment or other affiliation with the institution. Agreements from outside institutions can either be on their letterhead or in email format, provided that the title and complete contact information of the person affirming the agreement are given. The agreement should also include the research team members' names, the title of the study, the inclusive dates for which the agreement is valid, and a description of the activities that are being agreed to.

☐ If you are conducting a collaborative study and intend to rely on an external IRB review, you have consulted our Collaborative and External Studies page and understand how to register your external approval with the IRB office as part of a reliance agreement process.

EXPECTATIONS

User Guides for Submission

☐ You have read the applicable user guide for submitting your protocol to our online system, IRB Mentor, and understand the instructions provided.

☐ You understand that the IRB application outlining the methods and procedures of your study is an online smart form; that the documents described on this checklist must be submitted as attachments rather than weblinks; and that all applicable documents are required regardless of the type of review the protocol undergoes.

Faculty Supervision

☐ If you are a faculty supervisor of student research, you have carefully read the student submission and associated materials and ensured that the submission is complete, well-written, and utilizes sound research design prior to approving the submission for delivery to the IRB.

Start Date

☐ You have consulted the information regarding timelines for different review types available on our website and understand that the IRB will not review or approve a study retroactively. The start date that you input into your online application must be reasonable and allow enough time for screening and IRB review.

Submission instructions and contact information are provided on our website.