SGPP and Arizona Policy Lab Guidelines for IRB Processing

October 2023

Table of Contents

01. Broader IRB Submission Workflow

This general workflow outlining Steps 1 to 5 below needs to be completed fully when submitting an application for full IRB review, limited IRB review, or exempt status.

Step 1. Determining whether your project requires an IRB approval.

- If your project involves human subjects research, you should complete and submit the IRB Protocol for Human Subjects Research in eIRB (Steps 2 to 5) Human subjects research is systematic investigation with human subjects, such as focus groups, in-depth interviews, surveys, lab experiments, survey experiments, and secondary use research (e.g., the Add Health or social media entry scrapping), involving identifiable private information and/or biospecimens (e.g., polygenic risk scores and social media account handles) that may also be used in the SGPP research,
    - Please check the guidance on "What is Human Research?" by clicking here.
    - There are eight research categories falling under human subjects research, which might be exempt from the full IRB review. The exemption categories in brief are as follows (please see the respective details by clicking here):
        1. Research "conducted in an educational setting involving normal education practices."
        2. Research making "use of educational tests, surveys, interviews, or observations of public behavior."
        3. Research making "use of benign behavioral interventions in adults."
        4. Research benefiting from "study of data or specimens if publicly available or recorded such that subjects cannot be identified."

5. "Public service program research or demonstration projects."
6. Research involving "taste and food quality evaluations."
7. Research with "storage of identifiable information or biospecimens for secondary research use."
8. Research with "secondary research use of identifiable information or biospecimens"

An SGPP research might fall typically (but not exclusively) under items #1, 2, 3, 7, and 8 to be considered for an exempt review (please see Section 2 for further details).

◊ Even when falling under exempt research, there is limited IRB review requirement for data security and privacy protection, if your research falls under item #2, #3, and #8 above. There is also limited IRB review requirement for verification of broad consent, if your research falls under item #7 above. For further details, please refer to here.

Step 2. Completing the required trainings.

- Before proceeding to next steps, you need to have the required training listed below.
  - You need to complete the Collaborative Institutional Training Initiative (CITI) training (specifically, Social & Behavioral Research Investigators Stage 1 – Basic Course). Please take a look at the guideline here (under the tab "UA Affiliated Researchers: Required CITI Training") about signing up for the training. There are lectures first and then quizzes. You need to score at least 80% in each module.
  - You also need to complete the Conflict-of-Interest training, which is available here under the tab "REQUIRED TRAINING FOR INVESTIGATORS." Processing of the training completion on your account will be the next morning.

Step 3. Drafting the required forms and other submission documents below.

- IRB Protocol for Human Subjects Research (the document titled "IRB Protocol for Human Subjects Research [v June 2023]" is available here under the tab of "IRB Protocol Forms").
- CV/Resume of the principal investigator making the eIRB submission.
- Consent form (the document titled "Externally-funded - Social/Behavioral Informed Consent/Parental Permission Form [v. March 2023]" is available here under the subtitle of "Social/Behavioral Consents").
- Study materials (data collection tools, recruitment materials, and applicable appendices including the questionnaire and design flow)
  - NOTE: If there is an experimental manipulation in the design, a debriefing page by the very end of the survey flow (to be shared along with the survey flow diagram, consent page and questionnaire) would ease the full IRB review process.

Step 4. Obtaining required approvals for submission

- The necessary documents below are available here under the tab of "Attestation Forms:"

- Advisor/Co-I Attestation Form (if the person submitting the IRB forms for the study is not currently eligible to be the Research, Innovation & Impact [RII]) PI) to be signed off by the respective academic advisor.
- Scientific/Scholarly Review Attestation Form to be signed off by Dr. Fatih Erol
- Department/Center/Section Review Attestation Form to be signed off by Dr. Alex Braithwaite

Step 5. Submitting the IRB materials and applicable additional documents

- The submission is done electronically.
  - There are several moving parts to creating and submitting an online application for a study, which are summarized in the Human Subjects Protection Program's documentation.

    Training and how-to-do videos regarding eIRB are available here: eIRB. The most typical ones to rely on to run

02. Exempt Status Workflow

The process of submitting a study to an exempt reviewer works the same as any other new project submission whose workflow is as the following:

1. The principal investigator (PI) submits the study through eIRB.
    a. The investigator creates the submission in eIRB and indicates under Basic Study Information, Brief Description that the study is eligible for the "Exempt Review" process (please see below for an illustration).
2. The IRB Coordinator identifies the study as a study eligible for the exempt reviewer process.
3. The IRB Coordinator reviews the submission to ensure:
    a. all institutional requirements have been satisfied (sign offs, approvals, site authorizations, etc.)
    b. the project meets the criteria to be reviewed by the exempt reviewer process (i.e., does the study pass the exempt review checklist (please see the checklist below)?
4. If the project passes the criteria, the IRB Coordinator will automatically assign the exempt reviewer ([Dr. Fatih Erol]) as the "designated reviewer" for formal review.
5. The exempt reviewer begins their review as normal. The reviewer may correspond directly with research team via eIRB.
6. The exempt reviewer ensures that the Collaborative Institutional Training Initiative (CITI) training and conflict-of-interest (COI) disclosure has been completed by the research team.
7. Af8001 Tc 0.Qr4 (t)6 (e)1 (am)]TJ0 T1 Tc -0.001 Tw -36.567a1.5 0 Td[(A)1 (f)7 (8001 Tc(l)]T01 T7a1.5 0 -

PRIVACY	(Only if the project involves deception) Is there a plan to prospectively consent subjects to notify them of the deception prior to the start of research?[2] YES ☐ NOT APPLICABLE ☐	
	(Only if the project includes access to non-directory educational records that fall under the FERPA regulations) Does the project have a 'legitimate educational interest' to access the records?[3] YES ☐ NOT APPL	Does the project include access to medical records or protected health information (PHI) that fall under the HIPAA regulations? NO ☐

eIRB Brief Description Illustration