

SGPP and Arizona Policy Lab Guidelines for IRB Processing

October 2023

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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 a study in Arizona Policy Lab would be the following:
 - ◇ 6.05 minutes long walkthrough on “[How to Create and Submit a Single Site Submission](#)”
 - ◇ 3.14 minutes long walkthrough on “[How to Create and Submit a Modification](#)” (when revising the research team or study design)
 - ◇ 3.43 minutes long walkthrough on “[How to Create and Submit a Continuing Review or Study Closure](#)”
 - ◇ A detailed 25-page long guide on single-site studies (such as the ones employing Arizona Policy Lab) about study submission, altering study documents, responses to the reviewers, continuing reviews, modifications, and reportable new information) is [here](#).

⇒ Brief visualization of the overall IRB workflow is [here](#).

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. After review is complete, the exempt reviewer completes the Designated Review.
8. The IRB Coordinator is notified/sends approval letter to the research team.

Does my study pass the exempt review checklist?

If the answers to any of the following questions do not match the required responses in the table below, an application is not eligible for the exempt review and rather should be submitted to the Human Subjects Protection Program (HSPP).

| | The answers to the questions below should be all YES (OR NOT APPLICABLE). | The answers to the questions below should be all NO (OR NOT APPLICABLE). |
|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| INSTITUTIONAL REQUIREMENTS | Do all personnel listed on the project have current CITI training? YES <input type="checkbox"/> | Is there a conflict of interest by the department reviewer with the project? NO <input type="checkbox"/> |
| | Does the application include all appropriate authorizations to conduct research? YES <input type="checkbox"/> | Is the project federally funded or since last approval has become federally funded? NO <input type="checkbox"/> |
| | Does the PI meet the requirements as outlined in the HSPP guidance 'PI Eligibility?' YES <input type="checkbox"/> | Does the application request the UA IRB review and be the IRB of record for a site not affiliated with the UA? NO <input type="checkbox"/> |
| | Does the project meet the requirements as outlined in the HSPP guidance for 'Data Security and Records Retention'? YES <input type="checkbox"/> | Is the project a clinical trial? NO <input type="checkbox"/> |
| | Does the project meet the requirements as outlined in the HSPP guidance for recruitment and payment of subjects? YES <input type="checkbox"/> | Does the project involve the use of Virtual Reality Headsets? NO <input type="checkbox"/> |
| VULNERABLE POPULATIONS | (Only if the research involves research design to evaluate children or minors [under 18]?) Does the research which involves children or minors include ONLY research conducted in established or commonly accepted educational settings, involving normal educational practices? YES <input type="checkbox"/> NOT APPLICABLE <input type="checkbox"/> | Does the project involve research with prisoners? ¹ NO <input type="checkbox"/> |
| | | (Only if the research involves research design to evaluate children or minors [under 18]?) Does the research which involves children or minors include observation(s) where the researcher is participating in the activities being observed? NO <input type="checkbox"/> NOT APPLICABLE <input type="checkbox"/> |
| | | Does the project involve research designed to take place in Indian Country or among international Indigenous populations, actively recruits Native Americans or international Indigenous populations for enrollment, and/or requires stratification of Native Americans or international Indigenous populations as one of the statistical analyses or study aims? NO <input type="checkbox"/> |

¹Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

| | | | |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 <input type="checkbox"/> NOT APPLICABLE <input type="checkbox"/> | | |
| | (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 <input type="checkbox"/> NOT APPLICABLE <input type="checkbox"/> | | Does the project include access to medical records or protected health information (PHI) that fall under the HIPAA regulations? NO <input type="checkbox"/> |
| | (Only if the project includes access to non-directory educational records that fall under the FERPA regulations) Does the project obtain prior written consent of the subject to access the non-directory educational information? YES <input type="checkbox"/> NOT APPLICABLE <input type="checkbox"/> | | |

NOTE: If the proposed study has an experimental setup, which falls under one of the exempt research categories (most likely, under “use of benign behavioral interventions in adults”, see [Step 1 of Section 1](#)) and fully aligns well with the checklist above, the principal investigator may try to get the exemption. The methodological precondition here (under Privacy) hints that disclosing that deception (including randomization to experimental arms) in the consent form (basically by saying that he or she will be unaware or misled regarding the nature or purpose of the research at some point during the flow) could make a study fall under an exempt review status. However, it would not be advisable that any researcher planning to run experimental setups follow the deception disclosure in the consent form (given the potential risks of experimenter demand effect biasing the average effect estimates and response styles; cf. [1], [2]). Any researcher with an experimental design ought to go the full IRB review process route and not attempt to get the exemption.

² The 2018 Revised Common Rule allows for deception to be approved as Exempt if participants authorize the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he or she will be unaware of or misled regarding the nature or purpose of the research and the research falls into one or more Exempt research categories.


³ A legitimate educational interest may include enrollment or transfer matters, financial aid issues, or information requested by regional accrediting organizations.


eIRB Brief Description Illustration


Basic Study Information



1. * Title of study:
CML Exempt Reviewer Test Case

2. * Short title: 
CML Test Case

3. * Brief description: 
This study is to demonstrate the new work flow. The project can be reviewed by the exempt reviewer in linguistics.



4. * What kind of study is this? 
 Multi-site or Collaborative study
 Single-site study
[Clear](#)

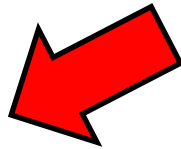
5. * Will an external IRB act as the IRB of record for this study? 
 Yes No [Clear](#)

6. * Local principal investigator: 
Sima Ehsani Chimeh 

7. * Is the local PI a student or medical school resident investigator?
 Yes No [Clear](#)

8. * Attach the protocol: 

| Document | Category | Date Modified | Document History |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---------------|---------------------------------------------------------------------------------------------|
|  IRB Protocol for Human Subjects Research Retrospective Data Review_2021-09.docx(0.01) | IRB Protocol | 9/3/2021 | History  |



It will be important for the research team to add into the Brief Description when they believe the study can be reviewed by the exempt reviewer process.