Policies and Procedures for the Protection of Human Research Subjects

105: Exempt Research	
Version: 1	**Effective Date: 06/02/2023**

Federal regulations designate certain categories of research to be exempt from IRB review.

At ISU, all projects meeting the definition of human subjects research must be submitted to the REC Office and receive documentation of an exempt determination prior to beginning the project. The determination of whether a study is exempt from IRB review is made by the Human Subject Research Specialist (HSRS), the IRB Chair, or designee. Principal Investigators (PI), research team members, and others who might have a conflict of interest regarding the project, are not authorized to make exempt determinations.

Submission Requirements

Projects determined to be exempt from IRB review must still follow a minimum set of standards for human subject protections, which include obtaining consent as required for nonexempt studies, reporting any adverse events or noncompliance to the IRB, and maintaining research records for at least three years after study completion.

Exempt determination submissions must include:

- Consent/permission/assent Information. Unless the study meets waiver requirements, submissions must include one of two options:
  - The PI will certify that a template approved by the ISU IRB will be used; or
  - If a pre-approved template is not used, the consent, permission/assent documents must be submitted with the protocol.
- Instruments, surveys, interview questions
- Research team information on the PI and any student who is using the study for their thesis or dissertation. The PI must maintain a current list of research team members and their CITI training in their study records, but the individuals do not need to be listed on the protocol.

The PI must maintain documentation of all required site permissions in study records, but documentation of site permission does not need to be attached to the protocol.

Researchers of exempt projects receive formal documentation of the exempt determination, which will include the exempt category the project falls under. Studies shall not commence until the exempt determination letter is received by the PI.

Modifications

Modification of exempt protocols must be submitted to the REC Office when the change may alter the exempt determination.:

Very minor revisions such as the following do not need to be submitted to the REC Office.

- Increasing participant number
- Minor wording changes
- Change in research team other than the PI or a student using the data for a thesis or dissertation
- Submission of site permissions
- Change in recruitment materials

Expiration/Close Out

Exempt determinations do not expire, so continuation is not required. PIs are expected to submit a closure submission once an exempt project is terminated or completed.