

Institutional Review Board for the Protection of Human Subjects in Research (IRB)

A Guide to Research Involving Human Subjects

Presented By:

Office of Research and Sponsored Programs

What is IRB ?

- The Institutional Review Board for the Protection of Human Subjects in Research (IRB) is responsible for reviewing and approving applications involving human subjects in research to ensure that faculty and student researchers are compliant with federal and state regulations and guidelines.
- It is composed of seven (7) faculty members with strong backgrounds in research involving human subjects (one representative from each academic college and one additional faculty member representing each of the two colleges with the largest number of student IRB proposals). In addition, two (2) public, a voting and non-voting alternate, member representing general community interests to serve a one-year term to be appointed.

What is IRB? Continued

- The IRB process is comprised of three types of project classification:
 - Exempt
 - Expedited
 - Full
- Exempt and Expedited applications can be submitted at any time. Full review applications must be submitted a minimum of ten (10) **working** days before the regularly scheduled meeting.
- Each application must be approved and issued a docket number before beginning the research project.

IRB Classification - Exempt

- Exempt classification refers to various types of research that does not require monitoring by the IRB. The Office of Research and Sponsored Programs will determine if an application will fall under this category.
- Research activities that classify as Exempt must present no greater than minimal risk to participants.
- Exempt classification falls into six types of categories for the type of research that will be conducted.:
 - A
 - B
 - C
 - D
 - E
 - F

Exempt Categories Definitions

- Category A:
 - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Category B:
 - Research involving the use of educational test (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.
 - However, if the research involves information that could potentially lead to the human subjects being identified, the research will need to be reclassified as Expedited. Disclosure of the human subject's identity and response might place the participant at risk of criminal or civil liability or damage of reputation.

Exempt Categories Definitions

- Category C:

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior.
- This classification is directed towards human subjects that are elected or appointed public officials or possible candidates for public office.
- However, the research will become not exempt if there is identifiable information of the participant that becomes public.

- Category D:

- Research involving the collection of study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Exempt Categories Definitions

- Category E:

- Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures of obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- Category F:

- Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminants at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

IRB Classification - Expedited

- Expedited classification refers to research that presents no more than minimal risk to the human subjects and involves only procedures that are listed in the categories of Expedited.
- Expedited research will be reviewed by two (2) IRB committee members that are from a different college than the PI. This will allow for an unbiased review of the application.
- Expedited classification falls into nine types of categories for the type of research that will be conducted.:
 - G
 - H
 - I
 - J
 - K
 - L
 - M
 - N
 - O

Expedited Categories Definitions

- Category G:

- Clinical studies of drugs and medical devices ONLY when the following conditions are met:
 - Research on drugs for which an investigational new drug application is not required.
 - Research on medical devices for which (1) an investigational device exemption application is not required; or (2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling

- Category H:

- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

Expedited Categories Definitions

- Category I:
 - Prospective collection of biological specimens for research purposes by noninvasive means.
- Category J:
 - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwave. Where medical devices are employed, they must be cleared/approved for marketing.
- Category K:
 - Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

Expedited Categories Definitions

- Category L:
 - Collection of data from voice, video, digital, or image recordings made for research purposes.
- Category M:
 - Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identify, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Expedited Categories Definitions

- Category N:

- Continuing review of research previously approved by the convened IRB as follows where:
 - (a) the research is permanently closed to the enrollment of new subjects;
 - (b) all subjects have completed all research-related interventions; and
 - (c) the research remains active only for long-term follow-up of subjects; or
 - (d) no subjects have been enrolled and no additional risks have been identified; or
 - (e) the remaining research activities are limited to data analysis.

- Category O:

- Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the following conditions apply:
 - (a) Categories two (2) through eight (8) do not apply; and
 - (b) The IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

IRB Classification - Full

- Full classification refers to a review of research that involve participants selected from groups that are considered vulnerable to coercion or undue influence in research settings.
- These groups include children, fetuses, pregnant women, mentally disabled, prisoners, and economically or educationally disadvantaged persons.
- Full research will be reviewed by the entire IRB committee on the scheduled dates for the semester it is submitted on.
- Full classification falls into six types of categories for the type of research that will be conducted.:
 - A
 - B
 - C
 - D
 - E
 - F

Full Categories Definitions

- Category A:
 - Projects requiring the use of deception.
- Category B:
 - Use of prisoners, pregnant women, fetuses, the seriously ill, or persons with mental disabilities, or incompetent individuals.
- Category C:
 - Collection of information or recording of behavior which, if known outside the research, could reasonably place the subject at risk of civil, or criminal liability or damage the participant's social standing, financial standing, or employability.

Full Categories Definitions

- Category D:
 - Collection of information regarding sensitive aspects of the participant's behavior such as: drug and alcohol use, illegal conduct, or sexual behavior.
- Category E:
 - Studies in which the anticipated risks exceed the minimal risk definition.
- Category F:
 - Survey and Interview research involving children requires full IRB review.

IRB Application Submission Reminders

- Student-led research is subject to, at minimum, an expedited review, even if it would otherwise fall into an exempt category.
- If this research project is externally funded, an IRB approval and docket number must be issued before the grant funds may be used.
- Submission of an application to the IRB DOES NOT equal IRB approval. You MAY NOT BEGIN this research until you have received notification of approval and have been issued an IRB docket number.
- Please provide responses for all items in the form, attaching additional sheets as needed.
- The IRB Committee strongly encourages the faculty to carefully review their student's IRB Application before submission to the IRB. Better submissions from the beginning will smooth the approval process.

IRB Application Submission Reminders

- Signed informed consent documents and research data will be kept in a secure location approved by the Institutional Review Board for the duration of the project and for at least three (3) years thereafter.
- On the last page of the application, there is an attachment checklist to make sure you have all the necessary paperwork for a successful submission.
- Students are required to complete the CITI training on Student Led Research and attach their certificate of completion to the application. Faculty/Staff are HIGHLY encouraged to complete the CITI training, but not required.

IRB Changes and/or Termination Reminders

- ORSP will send out a reminder e-mail 30 days prior to end of your research project, however, it is encouraged for the PI to set their own reminders. If you are needing to make any changes or terminate the project, a change/termination form will need to be submitted to ORSP.
- If no response is made, ORSP will close the project out in the system.

Sources and Questions

- All potential PIs can find the following information on our website with the Office of Research and Sponsored Programs.
- All forms discussed today are listed on the site should you have any questions, but do not hesitate to reach out to ORSP for more clarification.
- You can find the IRB schedule on our website if you intend to submit a Full Review.
- Questions?