

More on IRB Requests for Protocol Review

Adapted from Lafayette College, Institutional Review Board for Human Subjects.

ONE FORM... 3 REVIEW TYPES

Exempt

Still considered human subjects research!

Eligibility:

- Presents no more than minimal risk to participants, **and**
- Involves any of the following:
 - Research that involves normal educational practices that are not likely to adversely impact students
 - Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior*
 - Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording*
 - Secondary research uses of identifiable private information or identifiable biospecimens*
 - Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs
 - Taste and food quality evaluation and consumer acceptance studies
 - Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use
 - Research involving the use of identifiable private information or identifiable biospecimens for secondary research use*

* = specific criteria must be met

Expedited

Studies that involve no more than minimal risk but which do not meet any of the criteria for exempt status may be eligible for Expedited Review. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Eligibility:

- Presents no more than minimal risk to participants, **and**
- Does not involve any vulnerable populations (e.g., children, prisoners, individuals with impaired decision-making capacity), **and**
- Involves any of the following:
 - Collection of data from voice, video, digital, or image recordings made for research purposes
 - The study of existing data, documents, records, pathological specimens, or diagnostic specimens
 - Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research will not involve stress to subjects beyond that routinely experienced
 - Research on individual or group characteristics or behavior, or research employing survey, interview, oral history, or focus group methodologies
 - Research involving materials that have been collected, or will be collected, solely for non-research purposes (such as medical treatment or diagnosis)
 - Collection of data through noninvasive procedures routinely employed in clinical practice (not X-rays)*
 - Clinical studies of drugs and medical devices*
 - Collection of blood samples by finger stick, heel stick, or venipuncture*
 - Prospective collection of biological specimens for research purposes by noninvasive means
- Minor changes to research previously approved by the IRB *may* also qualify for expedited review

* = specific criteria must be met

Full Board

If the proposed research does not qualify for Exempt or Expedited review, it will be subject to a Full Board review.

Research subject to Full Board review involves any of the following:

- **More than minimal risk** to participants
- **Vulnerable** human subjects (e.g., **Children** under the age of 18 **Prisoners**; Individuals with **impaired decision-making capacity**; Economically or educationally **disadvantaged persons**)
- Procedures that might cause **physical harm**, and/or that might cause **significant psychological/emotional distress**
- Collection of information about **highly sensitive topics**, and/or of **information about illegal behavior**, and/or of **information that could seriously harm the participant** legally, socially, financially etc. if other people could identify them.

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