What Level of Review Does Your Study Need?

When it comes to IRB review, all research is not equal. A specific study's design and risk level determines if it's reviewed by a fully convened IRB or a designated IRB member, whether it qualifies for exemption, or if it doesn't meet the definition of human subjects research.

Within human subjects research, there are three levels of review:

1. **EXEMPT RESEARCH:** Research involving minimal risk to participants and included in one of the eight categories of research qualifying for exemption under the federal regulations (e.g., anonymous surveys, passive observation)
2. **EXPEDITED REVIEW:** Research studies involving minimal risk to persons (e.g., voice recordings, studies of existing pathological specimens with patient identifiers)
3. **FULL BOARD REVIEW:** Research studies involving human participants deemed higher risk than of the preceding examples

The IRB is the ultimate arbiter as to which level of review is applied to the research. That said, it may be useful for investigators to know which level of review likely applies to their study.

Follow this step-by-step process to determine your project's review level.

STEP ONE:

Does the Activity Involve Research?

Projects subject to the Common Rule:
To be considered "research," there should be systematic investigation throughout research development, testing, and evaluation.

This may include:

- A methodologically driven activity
- Organized data or information
- A prospective plan
- Data or information analysis
- A hypothesis
- Conclusions drawn from investigation results

Projects regulated by FDA:
To be considered a "clinical investigation," the experiment must involve a test article and one or more human subjects.

It must also adhere to one of the following:

- Meets the requirements for prior submission to FDA under the Federal Food, Drug, and Cosmetic Act section 505(i) regarding new drug applications (NDAs) or 505(g) regarding device classifications
- Does not need to meet the prior submission requirements, but the experiment's results are intended to be later submitted to (or held for inspection by) FDA as part of a research or marketing permit application

Does this activity involve research?

- **YES** — Proceed to step 2
- **NO** — 45 CFR 46 and 21 CFR 56 don't apply

STEP TWO:

Does the Activity Involve Human Subjects?

Projects subject to the Common Rule:
A human subject is defined as a living individual about whom an investigator is conducting research.

With human subjects (also known as participants), investigators:

- Obtain information or biospecimens through intervention or interaction with this individual — intending to study or analyze the information or biospecimens;

OR

- Obtain, study, analyze, or generate identifiable private information or identifiable biospecimens.

Projects regulated by FDA:
A human subject is an individual who is or becomes a participant in research.

- A subject can be either a recipient of the test article or a control
- A subject may be a healthy individual or a patient

If an activity does not meet the human subjects research definition, an IRB does not need to review.

Does this activity involve human subjects?

- **YES** — Proceed to step 3
- **NO** — 45 CFR 46 and 21 CFR 56 don't apply

STEP THREE:

Is the Activity Exempt?

When we refer to an activity as "exempt," we're saying the research is exempt from 45 CFR Part 46 regulations. Exemptions only apply to research involving no more than minimal risk to participants; i.e., the level of risk doesn't outweigh the normal, everyday risk a participant may encounter, or in routine medical, dental, or psychological exams.

There are eight possible exemption categories set out in the regulations:

1. **Category One:** Research conducted in an established education setting and is not likely to impact learning opportunities for students or an educator's assessment
2. **Category Two:** Educational tests, surveys, interviews, or observations of public behavior
3. **Category Three:** Benign behavior interventions, including harmless, painless, not offensive, not physically invasive, and not likely to leave a significant adverse lasting impact on subjects
4. **Category Four:** Secondary research uses of identifiable private information or identifiable biospecimens
5. **Category Five:** A federal department or agency supports or conducts the research and demonstration projects
6. **Category Six:** Taste/food quality evaluation
7. **Category Seven:** Receiving broad consent for storage or maintenance on identifiable private information or identifiable biospecimens obtained
8. **Category Eight:** Receiving broad consent for secondary research on identifiable private information or identifiable biospecimens obtained

Does this research qualify as exempt?

- **YES** — 45 CFR 46 doesn't apply
- **NO** — Proceed to step 4

STEP FOUR:

Does the Research Qualify for Expedited Review?

Expedited review may occur when there's no more than minimal risk to participants. Expedited isn't synonymous with "faster review"; it simply means a designated IRB member may review the project rather than the fully convened IRB.

The designated IRB member applies the same review criteria, but IRBs cannot disapprove research undergoing expedited review.

There are seven possible categories for expedited review of a new study:

1. **Category One:** Research on drugs without an investigational new drug (IND) application, or medical devices without an investigational drug exemption (IDE) required
2. **Category Two:** Blood collection from healthy, non-pregnant adults weighing at least 110 pounds
3. **Category Three:** Prospective collection of biological specimens for research purposes by noninvasive means
4. **Category Four:** Collecting data through noninvasive procedures routinely done in clinical practice
5. **Category Five:** Research involving materials previously collected or will be collected for non-research purposes
6. **Category Six:** Collecting data from voice, video, digital, or image recording specifically for research purposes
7. **Category Seven:** Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, or program evaluation

Does this research qualify for expedited review?

- **YES** — Submit for expedited review
- **NO** — a fully convened IRB must review this research

Get more information on IRB review criteria in our white paper:

"What Level of Review Does Your Study Need?"

advarra.com/levels-of-irb-review