

Research Minute

IRB: The Institutional Review Board

Issue 3

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Every research institution—and many hospitals—have an office that promotes the ethical practice of research with humans. Known as the IRB, or Institutional Board, they examine each project prior to its implementation.

What projects need IRB review? IRB may want to review your project if you are gathering information about people in a systematic way, and you will be sharing your results outside your department or clinical group. The information may be qualitative (as in open-ended interviews) or it may be quantitative (as in test scores or lab values). The graphic below illustrates examples of projects the IRB Office wants to review, and their level of review. Briefly, they like to see *everything*—even Quality Improvement projects—and make a determination themselves. In some cases, they will document your project as “not research,” and you’re free to proceed.

What type of review do I need? This is dependent on the project’s risk to the participant.

Minimal risk projects include “**Non-Regulated Research**” (such as QI projects) and “**Exempt**” (such as anonymous chart reviews or surveys of adults). These are reviewed in-house by IRB office staff.

“**Expedited**” is also minimal risk to health, but may have risk to reputation or risk for coercion. These include not-anonymous data collection, or studies with vulnerable populations such as children or prisoners. These are reviewed by IRB office staff plus 1 or 2 IRB Board members (researchers).

A “**Full Board Review**” (noted below as “convened IRB”) is reserved for projects that pose ‘more than minimal risk’ to participants (as in clinical trials). These projects are reviewed by the IRB office, and then by an IRB Board of researchers, convened on a regular basis. This is the only type of project that has a deadline, due well before before the IRB Board meeting, to allow for review. Contact your institutions’ IRB for deadlines.

How do I apply for IRB? Contact your IRB office or website and ask for application information. In most institutions, the “Non-Regulated Research” application is simple. However, the other types of review can involve multiple forms and many questions about investigators, research sites, aims of the study, consent procedures, data collection procedures, and risks and benefits of the study. In most institutions, the turnaround is *NOT FAST*. It may depend on workload, frequency of IRB board meetings, or questions about the proposal. *When you plan a research project, include time for IRB approval.*

What does IRB want to know? Much of the information in an IRB proposal comprises a formal research proposal.

- Personnel—which researchers will be involved in this study?
- Site—where will it be conducted?
- Background—What is the rationale for doing this project? Cite the research literature on your topic.
- Aim—What is the aim of the study?
- Subjects—what type of people will you seek for this study, and how many? They will ask you to justify your sample size.
- Measurement—how will you measure your key variables? Include your survey or chart review forms.
- Intervention—if you do one, describe it thoroughly.
- Procedures—for consenting subjects, for gathering information, for protecting subjects’ privacy, and for minimizing other risks.
- Data analysis plans
- Consent forms
- Signatures

Non-Regulated Research	Research Not Involving Humans	Human Research Determined Exempt (Submit to OIRB for Determination)	Human Research Not Exempt but eligible for Expedited IRB Review	Human Research Not Exempt That must be reviewed by convened IRB
IRB Office Review			IRB Approval	
Examples: <ul style="list-style-type: none"> • Quality Improvement • Health Surveillance • Program Evaluation 	Examples: <ul style="list-style-type: none"> • Only using leftover, de-identified specimens • Only using commercial cell lines • Data / specimens from a repository (de-identified to recipient) 	Examples: <ul style="list-style-type: none"> • retrospective chart review & not recording identifying information • survey of adults • comparing two educational methods 	Examples: <ul style="list-style-type: none"> • prospective clinical data and specimens • non-invasive measurements • Survey of children 	Examples: <ul style="list-style-type: none"> • All greater than minimal risk research • Clinical trials • Any research use of radiation • Any research use of anesthesia • Any research use of invasive procedures
Non-regulated Research Forms	Non-human Research Forms	Exempt Research Forms	Human Expedited Review Forms	Human Full Board Review Forms