

The Case IRB in a Nutshell

DEFINITION OF HUMAN SUBJECTS RESEARCH

The following definitions are provided in the federal regulations (45 CFR 46):

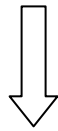
- Human subject: A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual OR identifiable private information [45 CFR 46.102(f)]
- Research: A systematic investigation that is designed to develop or contribute to generalizable knowledge [45 CFR 46.102(d)]

WHAT IS AN “I-R-B”?

“IRB” is an acronym for *Institutional Review Board*. The Case IRB is a committee of faculty members and community representatives who are responsible for reviewing the human subject research that is conducted by faculty, staff or students.

TYPES OF REVIEW

Exempt (45 CFR 46.101b)
Expedited (45 CFR 46.110)
Full Board



(increased
IRB Oversight)

IRB DECISIONS

Approved
Modifications Required
Tabled (full review only)
Disapproved (full review only)

CONTACT INFORMATION

Visit the Case Research Compliance Website for information, applications, types of review and tips -- <http://ora.ra.cwru.edu/research/orc/index.cfm>

Staff contact information:

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INFORMED CONSENT

“...no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.”
[45 CFR 46.116]

⌘ Informed consent is a process ⌘

ELEMENTS OF INFORMED CONSENT

- A statement that the study involves research;
- An explanation of the purposes of the research;
- The expected duration of the subject's participation;
- A description of the procedures to be followed;
- Identification of any experimental procedures;
- A description of any reasonably foreseeable risks or discomforts; (consider psychological and/or social risks)
- A description of any benefits;
- A disclosure of appropriate alternative procedures/treatment that might be advantageous to the subject;
- A statement describing confidentiality;
- If greater than minimal risk, an explanation regarding compensation and where treatment for injury may be obtained;
- Contact information for questions about the research, research subject rights, and research subject injuries;
- Statement that participation is voluntary; and
- Additional elements, as appropriate.

Risks can be high as long as benefits outweigh them!

Informed consent template:

http://ora.ra.cwru.edu/research/orc/Case%20IRB%20System/orc_humansubjects_CWRU_IRB.cfm

ADDENDA REQUESTS (requests for revisions to currently active protocols)

- Only the RI or CI may make addenda requests.
- The *written* request must include (a) a description of the proposed change and the reason for it, (b) a copy of the new or revised materials (e.g., consent form, questionnaires, scripts, etc.), and (c) other relevant documents (e.g., letter of cooperation).

ADVERSE EVENTS

- May include unanticipated social (i.e., financial, occupational), psychological (i.e., emotional), legal or physical problems that occur as a result of the research.
- Investigators must report all adverse events to the IRB within 3 days of the occurrence.

CONTINUING REVIEW

*The Case IRB conducts continuing review of research at intervals appropriate to the degree of risk, but **not less than once per year** [per 46 CFR 46.109(c)].*

QUALITY IMPROVEMENT PROGRAM (QIP)

The Purpose:

- To ensure that (a) the implemented protocol is in compliance with what the IRB approved AND (b) the IRB appropriately reviewed the protocol.
- Selected at random OR for-cause.
- 10% or active protocols or 15 protocols, whichever is greater – selected annually.
- Student research may be audited as well as responsible investigator/faculty research.