The CWRU 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 short for *Institutional Review Board*. The CWRU 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 | IRB DECISIONS
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Exempt (45 CFR 46.101b) | Approved
Expedited (45 CFR 46.110) | Modifications Required
Full Board | Tabled (full review only)
| Disapproved (full review only)

WEBSITE
Visit the CWRU Research Compliance website for more information about our IRB.
[http://case.edu/research/faculty-staff/compliance/](http://case.edu/research/faculty-staff/compliance/)

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]

Remember: Informed consent is a process.

ELEMENTS OF INFORMED CONSENT
- Statement that the study involves research;
- Explanation of the purposes of the research;
- Expected duration of the subject’s participation;
- Description of the procedures to be followed;
- Identification of any experimental procedures;
- Description of any reasonably foreseeable risks or discomforts (consider psychological and/or social risks);
- Description of any benefits;
- Disclosure of appropriate alternative procedures/treatment that might be advantageous to the subject;
- 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.

Informed consent template: [http://case.edu/research/resources/forms-policies/](http://case.edu/research/resources/forms-policies/)
**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 CWRU 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)**

- Used to ensure that the implemented protocol is in compliance with what the IRB approved AND the IRB appropriately reviewed the protocol.
- Selected at random OR for-cause.
- Annually selects 10% of active protocols or 15 protocols, whichever is greater.
- Student research may be audited as well as responsible investigator/faculty research.