Approval from an Institutional Review Board (IRB)

For a general summary see:
https://en.wikipedia.org/wiki/Institutional_review_board
UR website:
http://www.rochester.edu/ohsp/index.html

It is a **federal law** that all research activities must be reviewed by an IRB committee

What is the IRB, why is it important?

The Institutional Review Board (IRB) is an **independent committee** established to review and approve research involving human subjects. It protects the rights and welfare of the human subjects.

Make sure minimize chance of being physically injured or otherwise harmed (eg psychologically)
- traumatized or deeply disturbed
- humiliated (eg., lack of privacy)
- feeling maliciously deceived or violated
- mistakenly participates in something that violates their personal principles (eg., evolution, race & gender issues, animal testing)

Risk Spectrum

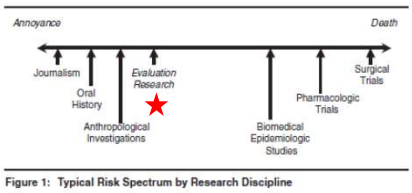

Figure 1: Typical Risk Spectrum by Research Discipline

Source: http://www.psych.nyu.edu/research/guides/RisksWrongs.pdf

What is the IRB, why is it important?

The Institutional Review Board (IRB) is an **independent committee** established to review and approve research involving human subjects. It protects the rights and welfare of the human subjects. It's around 5 people, has to be diverse.

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This is done by making sure the participant understands the research project: **"Informed Consent"** and the data are private: **"Confidentiality"**

How does the lab get IRB approval?

The PI and all staff/students complete ethics training and get certification to conduct research

The PI submits a protocol describing
- The credentials & IRB certification of the research team (all staff, students)
- The purpose of the research
- The methods (task, stimuli, subject response, all measures and data)
- The potential risks to the subject and protections against risks
- The potential benefits of the research (treatment, knowledge)
- The plan for keeping the data confidential
- The methods for recruiting subjects (eg., flyers, online, schools, etc.)
- Characteristics of the subject population
- Process of consent and consent form

The protocol is reviewed by the IRB board to determine approval

What do you (undergraduate student) have to do to be IRB compliant?

1) Make sure there is an IRB protocol in your home lab that covers your experiment (ask your supervisor: PI/Post Doc/Grad Student/RA)

2) Read the IRB protocol to make sure you understand the rules and requirements, the content of the consent forms, and how you're allowed to recruit subjects (flyers, FB)

3) Take the online CITI training courses to receive individual certification to conduct human subjects research ("initial certification"):
http://www.rochester.edu/ohsp/education/certification/initialCertification.html

4) Make sure your supervisor includes you as a researcher on the protocol (either by submitting a new protocol or amendment through ROSS):
http://rsrb01.urmc.rochester.edu/rsrb

What do you (undergraduate student) have to do to be IRB compliant?

You **cannot** submit an IRB application without a faculty member's approval

the faculty research advisor agrees to "accept ultimate responsibility for ensuring that this study complies with all the obligations listed above for the PI."

UR IRB Website (called RSRB instead of IRB but same thing)

http://www.rochester.edu/ohsp/rsrb/

If you have questions about IRB approval that your supervisor can't answer, contact:

BCS Specialist: Kathleen Buckwell
Phone: 585-275-7446
Email: kathleen_buckwell@urmc.rochester.edu

Most (probably all) of the projects in this class are in the "minimal risk" category

Minimal Risk: the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life

Other levels are:
"Greater than minimal risk biomedical"….drug testing, x rays, biopsies, etc.
"Greater than minimal risk behavioral"…collecting data on sensitive or illegal behaviors

Most (probably all) of the projects in this class are eligible for "expedited review"

Other types are:
"Exempt"…no review, eg., for anonymous minimal risk surveys where subjects are contacted in a typical testing environment

"Full Review"…for more than minimal risk

TABLE 3: Relevant Categories for Expedited Institutional Review Board (IRB) Review

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X rays or microwaves.
5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

SOURCE: Federal Register, Vol. 63, p. 60,364.

What **federal agency** is in charge of overseeing our research?

OHRP: Office of Human Research Protections
http://www.hhs.gov/ohrp/

Staff of 30

Reports directly to Assistant Secretary of the Department of Health and Human Services

Makes unannounced inspections of research protocols and records at universities

There are **consequences** for not following your protocol

TABLE 1: Select High-Profile Suspensions and Citations for Ethical Violations in Research

April 1998	Office of Protection from Research Risks (OPRR) cites the University of Maryland at Baltimore for "certain systemic weaknesses [in its protections for human research subjects]." The citation acknowledges that although informed consent documents "generally complied" with federal requirements, there were several documents that failed to properly inform subjects about research risks.
October 1998	OPRR suspends research at Rush–Presbyterian–St. Luke's Medical Center in Chicago, citing improper subject enrollment. Some subjects were ineligible because of preexisting symptoms; one died after an experimental treatment.
May 1999	OPRR suspends research at Duke University Medical Center after federal investigators determined that the university could not ensure the safety of subjects. OPRR found the administrative aspects of Duke's Institutional Review Board (IRB) inadequate.
August 1999	The Chancellor of the University of Illinois Chicago resigns after an OPRR suspends research. Violations include failure to obtain proper informed consent from all subjects in research projects and failure to obtain IRB approval before beginning research.
September 1999	Office of Human Research Protections (OHRP) suspends gene-therapy trials at the University of Pennsylvania, where Jesse Gelsinger, aged 18, died in a gene-therapy study. In November 2000, the Federal Drug Administration (FDA) notifies researchers that it had found evidence of numerous violations of the rules for conducting the research project. FDA notified the Principal Investigator he "repeatedly and deliberately violated federal regulations" and that the agency was moving to bar him permanently from conducting further drug research on human subjects.
January 2000	OPRR cites researchers at Virginia Commonwealth for mailing inappropriate questionnaires that asked twins sensitive questions about their family histories. Such proxy surveys raise numerous ethical concerns.