Human Subjects Research Overview: The Institutional Review Board

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Topics for discussion

- What is an IRB?
- Why is an IRB important?
- Ethical Principles
- Introduction to IRB review/requirements
- How to submit an IRB protocol for review

IRB = Institutional Review Board

An Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities

IRB Membership	• Columbia University has 5 IRBs on the Medical Center Campus and 1 IRB on the Morningside Campus. Consists of well qualified faculty, staff, and representatives from the community.
Authority	• The Morningside IRB meets twice a month and has the authority to review, approve, disapprove, suspend and monitor all research proposing or approved to include human subjects.
Operational Goal	• The Human Research Protection Office provides services that facilitate and strengthen human subjects research conducted by investigators at Columbia University.

Does the Activity Involve Research?

Federal regulations define "research" as "...a **systematic** investigation, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**."

- "**Systematic**" means protocol-driven, i.e., accepted research methods are employed to gather data that will be analyzed to explore a research question.

- "**Generalizable knowledge**" is knowledge that could be applied to populations or situations outside of the population or situation being studied.

Does the Activity Involve Human Subjects?

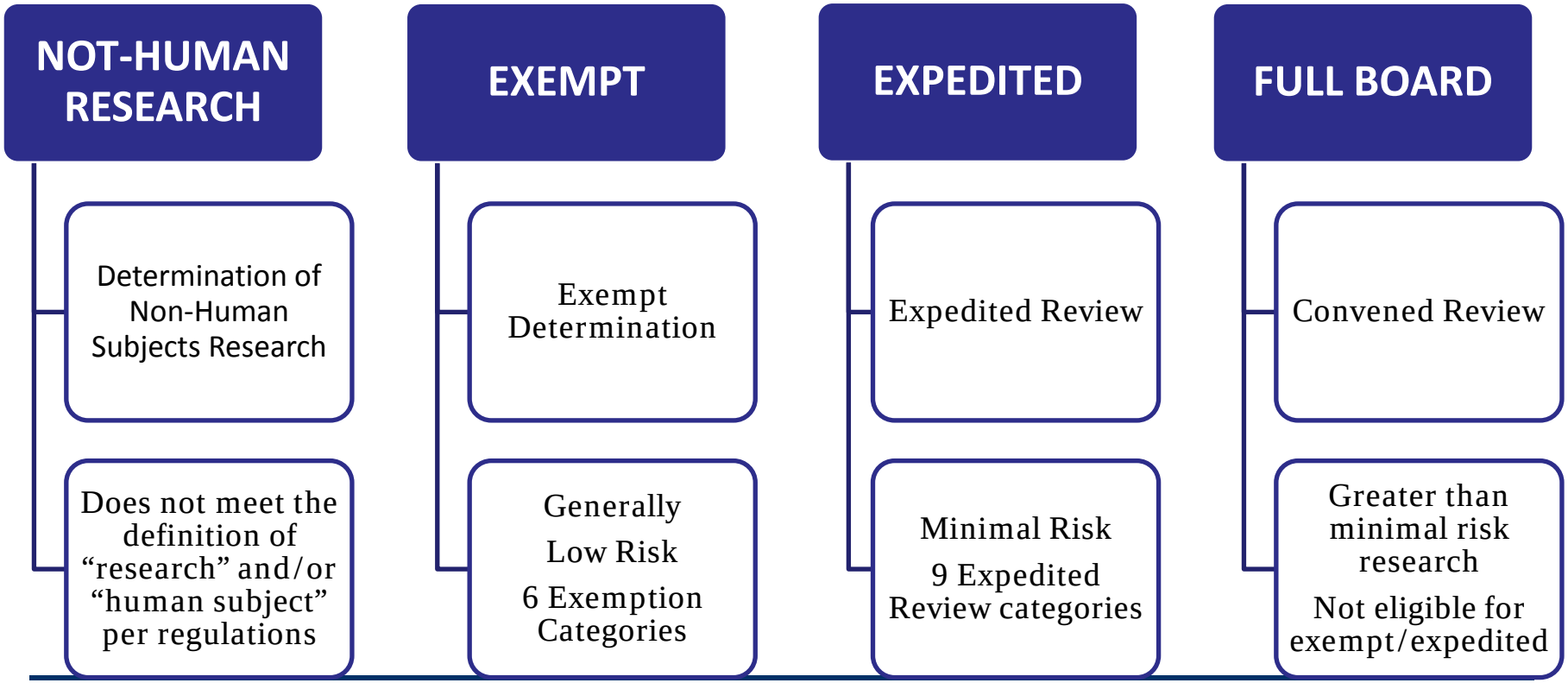
- Living individuals about whom an investigator conducting research obtains:

a. data through intervention or interaction with the individual, or

b. Identifiable private information

Levels of IRB Review

All research projects are categorized based on the level of risks introduced to human subjects and whether they meet the qualifications under specific categories established by the federal regulations at 45 CFR 46.



Applying Ethical Principles

Respect for Persons

- Informed Consent will be sought for each prospective subject
- Informed Consent will be documented
- Research plan adequately protects the privacy of subjects and maintains confidentiality

Beneficence

- Risks are minimized (consistent with a sound research design and does not unnecessarily expose subjects to risk)
- Risks are reasonable in relation to benefits
- Research plan adequately provides for monitoring the data collected to ensure safety of subjects
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards need to be included in the protocol to protect the rights and welfare of these subjects

Justice

- Selection of subjects is fair and equitable

What is the IRB looking for?

- Risks to participants are minimized
- Risks to participants are reasonable in relation to anticipated benefits
- Selection of participants is equitable
- Informed consent is sought from each participant (unless there is an approved waiver)
- Informed consent is documented (unless there is an approved waiver)

What is the IRB looking for? (cont'd)

- When appropriate, there should be adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- When participants are likely to be vulnerable to coercion or undue influence, additional safeguards should be included in the study to protect their rights and welfare.

Identifying Risks

- Social & Psychological Risks are TIME and SITUATION specific
- Social & Psychological risks are very subjective
- Examples:
  - discrimination
  - disruption of personal and family relationships
  - breach of confidentiality or privacy

Minimizing Risk

Three ways to minimize risk

- Alternatives
  - other procedures that are less risky
- Precautions
  - procedures to decrease the likelihood that harms will occur
- Contingencies
  - procedures to deal with harms if they occur

The Consent Process

Informed consent is not a single event or just a form to be signed -- rather, it is an educational process that takes place between the investigator and the prospective subject.

The basic components of the consent process include:

- full disclosure of the nature of the research and the subject's participation,
- adequate comprehension on the part of the potential subjects, and
- the subject's voluntary choice to participate.

Common Types of Research

- Studies involving:
  - Survey/Questionnaire
  - Interviews
  - Analysis of existing data
  - Observation
- IRB review is required for *research* that involves *human subjects*

IRB Review

- May be required, even if:
  - There is no funding involved
  - Research involves only one subject
  - Study is being conducted at another location
  - IRB at another institution has approved the work
  - Research is conducted in a foreign country
  - Data has already been collected
- If in doubt, consult with HRPO staff

Principal Investigator

- The Principal Investigator (PI) must be a full time member of the Faculty at specific ranks, or an Officer of Research as described in the Faculty Handbook. The Faculty Handbook can be found online at: **http://www.columbia.edu/cu/vpaa/fhb/.** The PI is responsible for the administrative and scientific management of the protocol.
- For student research the Faculty Advisor should be listed as PI on the student's IRB application in most cases; another qualified individual may be PI.
- Students should be listed as student investigators.

Investigator Responsibilities

- Ensure you have full approval from the IRB before beginning your research (recruitment, consent, information letters, etc.)
- Complete and maintain sufficient training prior to and during the conduct of research
- Conduct the research in accordance with the IRB-approved protocol
- Submit all changes to the research to the IRB before implementing the changes

Investigator Responsibilities (cont'd)

- Report any unanticipated problems to the IRB promptly.
- Ensure adequate and appropriate provisions to make sure research data is secure and maintained confidentially.
- Inform the IRB when the study is complete

Additional Documentation

Additional documentation for research conducted at off campus or international locations is generally required

Examples

- Some sites where research occurs have their own IRBs and may require internal IRB review
- If there is no IRB at a site, documentation of permission to conduct research at the site is required
- The NYC Department of Education (DOE) requires DOE IRB approval before research may be conducted in NYC public schools. In addition, documentation of permission to conduct the research in each school where it will occur is required from the head of the school.

Additional Documentation (cont'd)

International research

- Local IRB/ethics board approval may be required
- Local context information is needed
- Translations are required if subjects are non-English speaking
- Qualifications/experience of researcher
- Local permissions may be required
- Local laws and regulations must be satisfied

Rascal Human Subjects Protections Training

required of all study personnel "engaged" in the research (having contact with subjects or access to identifiable data) available through RASCAL at **https://www.rascal.columbia.edu**.

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- **TC0087 - Human Subjects Protection Training**
  - **"FDA-regulated Research"** and **"Research with Minors"** modules are required as applicable based on protocol content
- **TC0019: HIPAA (only if PHI is involved)**
- **Conflict of Interest:**
  - Annual Disclosure Form (all workforce)
  - Protocol Specific

How to apply for IRB approval

- Rascal
  - Electronic based submission system
  - Access to training modules
  - Access to other compliance-based groups

- Website: https://rascal.columbia.edu
- Rascal Help: 212.851.0212

Submission Tips

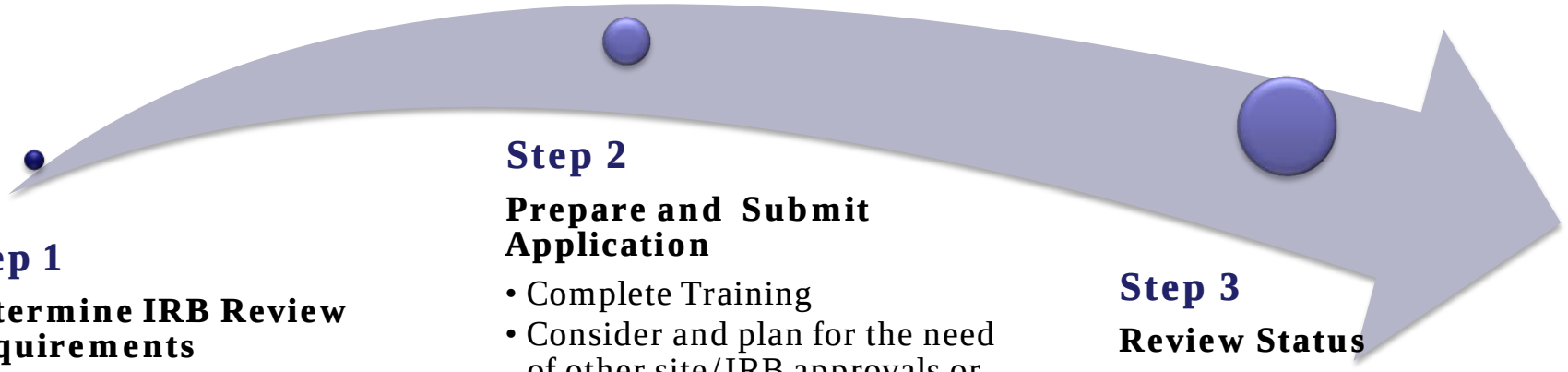
PLAN AHEAD!

IRB Contact: 212.851.7040

Email Inquiry: askirb@columbia.edu

Website: http://www.columbia.edu/cu/irb

Morningside HRPO office hours: Tuesdays from 10am-11am (no appointment needed)



Step 1

Determine IRB Review Requirements

- Consult with your Advisor (students)
- Contact HRPO staff with questions by scheduling consultation or come during drop-in hours

Step 2

Prepare and Submit Application

- Complete Training
- Consider and plan for the need of other site/IRB approvals or permission letters
- Prepare recruitment material, interview script/survey for submission
- Check IRB meeting deadlines (if applicable)

Step 3

Review Status

- Research may begin only if application is Approved – or-
- Non-Human Research Determination issued – or-
- Exempt Status Granted