ABCs of the IRB:
The Basics

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What is an IRB?

IRB = Institutional Review Board

- Group of people who review and approve proposals to conduct "research with human subjects"
- IRB review is required by federal regulation & CUNY policy
- Guided by The Belmont Report (ethical principles), The Common Rule (regulations), institutional policies

HRPP = Human Research Protection Program

- 3 IRBs at CUNY
- Central HRPP office at CUNY – sets policies, manages IRB
- HRPP staff at CUNY colleges - process submissions, make "exempt" determinations, answer questions, provide consultation and training

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What is "research with human subjects"?

- Specific definitions of "research" and "human subjects"
  - Found in CUNY policy and in the federal regulations
  - Not all activities are "research" by this definition
  - Not all research involves "human subjects"
- The IRB is only concerned with research that involves human subjects
- You need to submit an IRB application if you intend to conduct research that involves human subjects
  - Some research with human subjects is "exempt" from IRB review but still requires an IRB application

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What is "research"?

Research is a systematic investigation…designed to develop or contribute to generalizable knowledge.

Systematic:

- Attempt to answer research questions
- Methodological, collect data in an organized and consistent way
- Analyze data or information
- Draw conclusions from the results

Generalizable:

- Publication of the findings in journals, papers, dissertations, theses, etc.
- Presentation of the findings
- Research findings benefit other researchers, scholars, practitioners
- Knowledge contributes to an established body of knowledge or theoretical framework
- Results are expected to be generalized and/or replicated

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What/who are "human subjects"?

A human subject is

1) a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens…

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What/who are "human subjects"?

In other words… a human subject is a person who provides information or samples as a participant in a research project.

- A human subject might complete a survey, answer interview questions, provide a blood or saliva sample, participate in an experiment, etc.
- The researcher collects information/samples from the person and analyzes the information/samples to answer the research questions
- This is "primary" collection of information/samples; the information/samples are created or collected specifically for the research

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What/who are "human subjects"?

OR … A human subject is

2) a living individual about whom an investigator conducting research obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens...

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What/who are "human subjects"?

In other words… a human subject is a person whose information/samples are used for research.

- This is secondary analysis – using information/samples created for some purpose other than the research
- The information/samples must be both "identifiable" and "private"

Identifiable:

- Direct identifiers, or
- Code list that links the data back to identifiers, or
- Combination of data points could make the person readily identifiable

Private:

- Reasonable expectation that no observation or recording is taking place, and/or
- Provided for specific purposes with a reasonable expectation of privacy (i.e., medical records or school records)

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Okay, I'm confused… Do I need to submit an IRB application?

YES: if you intend to conduct research that involves human subjects:

- Systematic investigation to produce generalizable knowledge, **AND**
- Primary data collection through interaction/intervention (survey, interview) **OR** secondary analysis of identifiable private information/samples about individuals (data you get from some other source)

Research with human subjects requires an IRB application and must be approved BEFORE you start.

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Okay, I'm confused… Do I need to submit an IRB application?

NO: if what you want to do is not research, or if it does not involve human subjects:

- Some activities look like research but are not:
  - Class projects to learn about how to conduct research, but where results will not be shared outside of the class

- Some research does not involve "human subjects"
  - Fact-finding interviews with experts (primary data collection but not about individuals…the participants are not the subjects of the research)
  - Secondary analysis of only de-identified data (no primary collection and no way to identify individuals)

Not sure? Consult with the HRPP Coorrdinator before you start!

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Ok, I need to submit an IRB application…what's involved?

You should be aware that the IRB considers ethical principles, regulations and policies when reviewing research with human subjects.

The Belmont Report (ethical principles):

- Respect for persons (autonomy)
- Beneficence (do no harm)
- Justice (fair distribution of risks/benefits)

The Common Rule (regs) and CUNY policies:

- Rules for the IRB and approval of research
- Requirements for informed consent
- Additional protections for vulnerable populations

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Criteria for IRB Approval and Belmont Principles

Criteria for IRB Approval (Common Rule/CUNY policy requirement)	Related Ethical Concepts (Belmont Report)
- Risks are minimized	- Beneficence
- Risks are reasonable in relation to benefits	- Beneficence
- Selection of subjects is equitable	- Justice
- Informed consent is sought and documented	- Respect for Persons
- Data will be monitored for safety (when appropriate)	- Beneficence
- Privacy and confidentiality will be maintained (when appropriate)	- Beneficence, Respect for Persons
- Additional protections for vulnerable populations (children, pregnant women, prisoners)	- Beneficence, Justice, Respect for Persons

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That's a lot to think about… where do I start?

1. Complete required CITI training: www.citiprogram.org
2. Review CUNY policies: https://www.cuny.edu/research/research-compliance/
3. Attend IRB trainings: http://www.jjay.cuny.edu/training-and-education
4. Work with and get support from your faculty advisor
5. Think about ethics when creating your IRB application and materials…

www.citiprogram.org
http://www.cuny.edu/research/research-compliance/training-education/citi-training/

Course	Responsible Conduct of Research	Human Subjects Basic (or Refresher)
Which curriculum?	CUNY Researchers	• HSR for Social & Behavioral Faculty, Graduate Students & Postdoctoral Scholars, OR • HSR for Undergraduate Students
Who takes it?	Anyone conducting research of any kind	Anyone involved in research with human subjects
How often?	Every 4 years	Every 3 years
CITI Completion Certificate	• Keep on file • Give to your college Research Integrity Officer • Attach to your IRBManager profile (recommended but not required)	• Keep on file • Confirm your IRBManager profile links to CITI • Attach to your IRBManager profile (optional if your profile is linked)

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Think about ethics…

- **Respect for Persons**: Treat individuals as autonomous human beings, capable of making their own decisions and choices
  - Describe your plan for obtaining informed consent
  - Describe how you'll respect privacy
  - Describe additional protections for individuals with limited autonomy
- **Beneficence**: Minimize the risks of harm and maximize the potential benefits
  - Use procedures that present the least risk and appropriate scientific design
  - Describe potential risks and potential benefits to participants (there may be none) and the importance of the knowledge to be gained
  - Describe how you'll handle data and then protect confidentiality
- **Justice:** treat people fairly; design research so burdens and benefits are shared
  - Describe recruitment and ensure that you will select subjects equitably
  - Justify recruitment of vulnerable populations

What is Informed Consent?

- Respect for persons (Autonomy):
  - Research participants should be given sufficient opportunity to choose what shall or shall not happen to them.
- Informed consent:
  - The process by which individuals are provided information about the research so they can choose whether or not to participate
  - Minimize the possibility of coercion or undue influence
  - Language understandable to participant
  - Concise and focused presentation of key Information
  - Sufficient detail and information a reasonable person would want to have in order to make an informed decision

What is Informed Consent?

- Informed consent: The process by which individuals are provided information about the research and can make a decision about participation.
  - In your IRB application, you will need to describe the consent process, select the type of consent, and attach the consent form
  - Does the consent form have to be signed by the participants?
    - In some research, you will be required to obtain a legally effective signature on a consent form from each research participant
    - In some research, you can ask the IRB to waive the requirement to obtain signatures. Instead, research participants would read (or listen to) the consent form and indicate their consent in some other way -- verbally, or by clicking "I consent" on an internet survey, etc.

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Is Informed Consent always required?

YES. Except… in some research, the IRB can approve a waiver of informed consent (no consent obtained) or an alteration of informed consent (some elements of consent are omitted or altered).

- In your IRB application, you would need to request this and justify the following criteria:
  - Research is minimal risk
  - Waiver or alteration will not affect rights or welfare
  - Could not practicably do the research without the waiver or alteration
    - Secondary research (waiver of consent – no consent obtained)
    - Deception research (alteration of consent – information omitted from consent)
  - When appropriate, participants will receive additional info
    - Debriefing document for research involving deception

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How do I submit an IRB Application?

- IRBManager: https://cuny.my.irbmanager.com
- Use your CUNY Login
- Go to “Notices” and:
  - Add your CUNY campus email address to your IRBManager profile
  - Access the IRBManager Researcher Manual
  - Watch the brief videos
- Go to Start xForm to create a new protocol form
- Register for training: https://www.jjay.cuny.edu/training-and-education
- Get in touch with questions

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What are the types of review?

- **Exempt**:
  - Some minimal risk research will be exempt from IRB review
    - Belmont Report ethical principles still apply
    - An IRB application (to receive an exempt determination) is required
- **Non-Exempt:**
  - Expedited Review: some minimal risk research requires IRB review but can be reviewed by just one IRB reviewer
  - Convened Review: Greater than minimal risk, research with prisoners, and other types of research require IRB review by a group of reviewers

What is "Minimal risk"?

Probability and magnitude of harm/discomfort anticipated in the research are not greater in and of themselves than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.

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How long does it take?

- Depends on you
  - How long it takes for you to submit your application
  - Your responsiveness and attention to comments
  - (And your faculty advisor, who will need to take an active role and sign off on your submission…)
- Depends on IRB workload and volume
  - Exempt: a few days…
  - Expedited: a week or two…
  - Convened: a month or two or more…

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Can I speed up the approval process?

- Complete CITI training in Human Subjects Research AND Responsible Conduct of Research
- Get an early start and work with your faculty advisor
- Use current CUNY consent form templates
- Be familiar with CUNY HRPP policies
- Submit application that is complete, consistent, accurate
  - Do not leave fields blank or enter ‘n/a’ without explanation
  - Do not assume your research has “no” risk or overemphasize benefits
- Respond to queries/comments in a timely manner

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What happens after I have approval?

- Amendments: Get approval before you make changes
  - Any changes to your research require approval prior to implementation. (This is true for exempt research too!)
- Final Report: BEFORE YOU GRADUATE
  - When the study is complete, i.e., recruitment, data collection, and analysis of identifiable data is complete.
- Other submissions:
  - Continuing Review: If the project is given an expiration date (unusual)
  - Unanticipated Problems: Adverse events, bad things that happen
  - Protocol Violations: Anything that is not consistent with the approved application, regulations or policies

How can I get help?!?

- CUNY HRPP: https://www.cuny.edu/research/research-compliance/human-research-protection-program/
- John Jay HRPP: https://www.jjay.cuny.edu/hrpp

- John Jay HRPP Coordinator, Jj-irb@jjay.cuny.edu

- IRBManager: https://cuny.my.irbmanager.com
- CITI Training: https://www.citiprogram.org/

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