Human Subjects Research and the IRB

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What is an IRB?

IRB = Institutional Review Board:
- Group charged with reviewing research that involves human subjects
- Part of the Human Research Protection Program (HRPP)
  - 3 IRBs at CUNY; HRPP offices at college campuses
  - HRPP Office processes submissions, answers questions, provides consultation and training
IRB Review

Belmont Report
• Ethical foundation:
  – Respect for persons (autonomy)
  – Beneficence (do no harm)
  – Justice (fair distribution of risks/benefits)

The Common Rule
• Regulatory framework:
  – Rules for the IRB and review of research
  – Requirements for informed consent
  – Additional protections for vulnerable populations
What is Research?

• An activity is research when it is “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

• Defined in CUNY policy and in the “Common Rule”
What is Research?

**Systematic:**
- Attempts to answer research questions
- Is methodologically driven, collects data in an organized and consistent way
- The data or information is analyzed in some way
- Conclusions are drawn from the results

**Generalizable:**
- Publication of the findings in journals, papers, dissertations, theses, etc.
- Presentation of the findings
- The primary beneficiaries of the research and the knowledge generated are other researchers, scholars and practitioners
- The knowledge contributes to an established body of knowledge or theoretical framework
- The results are expected to be generalized and/or replicated
What is a Human Subject?

• A human subject is a living individual **about whom** an investigator conducting research:
  
  (1) **obtains** information or biospecimens through **intervention or interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or

  (2) obtains, uses, studies, analyzes, or generates **identifiable private information** or **identifiable biospecimens**.
What is a Human Subject?

• “about whom”
  – What about experts and key informants?

• Intervention or interaction
  – Surveys, interviews, focus groups, manipulation of the environment, etc.

• Identifiable private information
  – Must be both ‘identifiable’ and ‘private’
What is a Human Subject?

• **Identifiable:**
  — Direct identifiers
  — Code list that links the data back to identifiers
  — Combination of data points could make the person readily identifiable

• **Private:**
  — Reasonable expectation that no observation or recording is taking place
  — Provided for specific purposes with a reasonable expectation of privacy (i.e., medical records or school records)
Research with Existing Data

• Identifiable means that the identity of the subject is or may **readily** be ascertained by the investigator or associated with the information
  – Data connected to identifiers through a code list
  – Data with no direct identifiers (name, SSN) but with a combination of demographics/other information that could identify individuals
  – Restricted Use Data Set
  – Latanya Sweeney, Harvard: linked “de-identified” patient-specific medical data to a population register (e.g., a voter list) to re-identify patients by name. [http://latanyasweeney.org/work/identifiability.html](http://latanyasweeney.org/work/identifiability.html)
IRB Review

• All research with human subjects, must be submitted for review and approval prior to implementation
  – Some activities look like research but are not (for example, some program evaluation activities)
  – Some projects involve interactions with people who are not human subjects (for example, experts reporting on policies)
  – Class assignments, with no plan to publish/present, are generally not considered “research”
  – Some research with human subjects is “exempt” from IRB review – but still requires a formal submission and exempt determination
Is the activity "research"?

Does the research involve "human subjects"?

Is the research with human subjects "exempt" from the requirement for IRB review?

Minimal risk research that meets certain federal regulatory criteria may be exempt from IRB review. This determination is made by the College HRPP Office or by an IRB member and cannot be made by the researcher. The ethical principles of the Belmont Report - autonomy, beneficence, justice - still apply.

Is the non-exempt human subjects research eligible for expedited review?

Non-exempt human subjects research that is minimal risk and meets certain federal regulatory criteria may be eligible for review by a designated IRB reviewer. Research that is greater than minimal risk or that does not fit such criteria is reviewed by a convened IRB.
IRB Review

- **Minimal risk**: the probability and magnitude of harm or 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.

- **Exempt**: Minimal risk research that meets certain regulatory criteria is exempt from IRB review – but Belmont ethical principles still apply!

- **Expedited Review**: An IRB reviewer can conduct the review independently when research presents no more than minimal risk and fits into a specific list of categories, or for minor changes in previously approved research during the current approval period.

- **Convened Review**: Research that presents greater than minimal risk must be reviewed by the IRB as a group.
## IRB Review

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

• Respect for persons requires that research participants, to the degree that they are capable, be given sufficient opportunity to choose what shall or shall not happen to them.

• Informed consent is the process by which research participants are provided information about the research and can make a decision about participation.
Informed Consent

• Minimize the possibility of coercion or undue influence.
• Language understandable to participant
• information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
• concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
• present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
• No exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence
Informed Consent

• What do research participants need to know?
  – A statement that the study involves research, the purpose of the research, the expected duration, and a description of procedures, noting which are experimental
  – Risks or discomforts
  – Benefits to participants or others
  – Who to contact with questions about the research, about rights as a participant, and in the event of research-related injury
  – Statement that participation is voluntary
  – Alternative procedures, if any – important for clinical research
  – If identifiable info or specimens are collected: statement about future research use
  – Compensation for research related injuries – for greater than minimal risk research
  – Other elements may be appropriate depending on the nature of the research
    (Unknown risks, additional costs, approximate number of participants, and others)
Informed Consent

Waiver of written documentation of informed consent

1. Signed consent would be the only record linking the participant to the research, and breach of confidentiality is the primary risk.
   – Sensitive or illegal topics, vulnerable groups
2. Minimal risk research where signed consent is not required outside of the research context.
   – Surveys, interviews, etc.
3. Cultures where signed consent is not the norm.

Use the CUNY Oral/Internet based Informed Consent template
Informed Consent

Waiver or Alteration of Informed Consent

- Research is minimal risk
- Waiver or alteration will not affect rights or welfare
- Could not practicably do the research without the waiver or alteration
- When appropriate, participants will receive additional info after participating
Informed Consent

Waiver or Alteration of Informed Consent

• Could not practicably do the research without the waiver or alteration
  – Retrospective record review
  – Deception research – requires an alteration of informed consent

• When appropriate, participants will receive additional info after participating
  – Deception research: debriefing
Submitting an IRB application

• If you are conducting **research** with **human subjects**, you must submit your project for review prior to implementation

• What to do:
  – Work with your faculty advisor
  – Consult with John Jay HRPP Office with questions
  – Submit your application well in advance to allow adequate time

• What not to do:
  – Do not conduct research with human subjects without IRB approval
Submitting an IRB application

• How do I submit?
  
  https://ideate.cuny.edu/home/

  • Request an IDEATE account (email IDEATE@cuny.edu with your CUNY Portal username)
  • Use your CUNY Portal credentials
  • Identify your faculty advisor
Submitting an IRB application

• How long does it take?
  – Accuracy, completeness, consistency
  – Use the CUNY templates / language
  – Think about the Belmont principles when creating the application and consent form

• Exempt: a few days...
• Expedited: a week or two...
• Convened: a month or two or more...
Submitting an IRB application

• Get an early start
• Work with your faculty advisor
• Complete CITI training in Human Subjects Research AND Responsible Conduct of Research
• 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 that research has no risks
• Respond to queries/comments in a timely manner
After IRB approval

• Research must be executed as described in your application
• Any changes to the research must be reviewed and approved by the IRB prior to implementation
• If your project is given an expiration date, a Continuing Review submission is required if the research will continue beyond that date
• Informed consent is a process – be sure that you are obtaining informed consent from participants unless the IRB has waived this requirement
• Do not sign consent forms on behalf of your research participants
After IRB approval

• Amendments – Submit changes to your approved project BEFORE implementation; must have approval prior to modifying your project. This includes increases in target enrollment.
• Unanticipated Problems – Adverse events, bad things that happen
• Protocol Violations – Anything that is not consistent with the approved application, regulations or policies
• Continuing Review – If the project is given an expiration date
• Final Report – When the study is complete, or when you have completed recruitment, study procedures, and analysis of identifiable data.
Help!!!

• Schedule a consultation
• Call or email with questions
• Work with your faculty advisor
• Attend trainings
• CUNY HRPP website: http://www.cuny.edu/research/compliance/human-subjects-research-1.html
1. **Menu Bar**: provides access to major functions of the system based upon the role(s) assigned to the user.
2. **User Name and Log Out Function**
3. **To Do List**: The To Do List contains tasks for the logged in user to complete, and messages
4. **Finder**: allows you to search for records
5. **Subject**: provides additional user access based on security access.
Protocol Layout

1. **Menu Bar:** Provides access to major functions of the system based upon the role(s) assigned to the user.

2. **User Name and Log Out Function**

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Protocol Layout

1. Lifecycle Event Manager: Summary info about the protocol, submission history, and actions available to the user
2. Communications: access to all formal HRPP/IRB communications
3. Enrolled: displays participant enrollment information (number approved and total enrolled)
4. Summary: general info
5. Personnel: current and past research personnel
6. Research Sites: CUNY and non-CUNY research sites
7. Research Design: hypothesis, methods, procedures and risks, benefits, etc.
8. Funding: funding info (for funded protocols)
9. Protocol Components: this tab will be present if the research uses biologics, biological samples, drugs/vaccines/devices, radiation, or retrospective records review
10. Participants: info related to enrollment, recruitment, consent, privacy & confidentiality
11. Children: this tab will be present if the research involves children
12. Prisoners: this tab will be present if the research involves prisoners or their data
13. Attachments: the current list of approved attachments
Protocol Layout

Lifecycle Event Manager:

- Submissions: Shows a history of your submissions
- Lifecycle: Shows history of a given submission, including current location (i.e., whose To Do List it is on).
- Actions:
  - Delete or Withdraw a submission (DO NOT do this unless you are absolutely sure, as a deleted submission can not be recovered.)
  - Reassign Task: To reassign a current submission to another member of the Research Team who has Signatory Authority

Actions (Drop Down Menu)
- used to create Amendment, Event, or Final Report
Creating a New Application

1. Choose Create New from the Menu bar
2. Click on “IRB Application”
3. Enter the Protocol Title
4. Click Lookup to select PI
5. In the Find PI screen, enter the last name of the PI.
6. Select Department (pre-populated)
7. Click Begin Application
Creating a New Application

- Once you’ve Created an Application, it will then be present on your To Do List as a Task (Complete the Initial Application).
- You can only edit the draft application by accessing it from your To Do List.
- A task can be on only on person’s To Do List at a time.
- Refer to document “Completing_An_Application_Form.pdf”
Adding Research Personnel

All research personnel who are added to an application will receive an Invitation to participate, which will appear as a Task on her/his To Do List.

All invitations must be accepted or declined before an application can be submitted.
Post-approval

- **Amendments**: For changes to approved protocol; all changes must be approved prior to implementation
- **Continuing Review**: Required if research will continue beyond approval expiration date
- **Event Notification**: For protocol violation or unanticipated problem
- **Final Report**: A final report on the completed project
Thank you!

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