CUNY UI IRB and the Baruch HRPP

9/11/2013
CUNY University Integrated Institutional Review Board

- The CUNY UI IRB is charged with protecting the rights and welfare of human research participants.
- The UI IRB ensures that the proposed research follows federal guidelines and accepted ethical principles.
What is the HRPP?

- The Human Research Protection Program (HRPP) provides oversight, administrative support, and educational training to ensure that CUNY research complies with federal and State regulations, University policy and the highest ethical standards.

- The HRPP concentrates on the review of IRB protocols and the quality of the overall research program university-wide.

- There are 19 on-site HRPP Offices at CUNY.
Human Subject Research Definitions

- **Research** – Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to *generalizable knowledge*.

- **Generalizable Knowledge** - The intent of the research is to add information to your field of study.
  - The results can be applied beyond the subject population to other settings.

- **Human subject** – A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

- If you are uncertain if your activities constitute human subject research, submit a Human Subject Research Determination form in IRBNet
  - The HRPP Coordinator will issue a determination of whether the proposed activities constitute human subject research.
Levels of Review

- Full (3)
- Expedited (2)
- Exempt (1)
- Non-Human Subjects Research/ CUNY Non-Engagement (1)
Workflow through the CUNY Human Research Protection Program

**Research Community**
- Project – Package
  - xxxx-1
  - xxxx-2
  - xxxx-n

**Campus HRPP Review**
- York College
- Borough of Baruch College HRPP Office

**CUNY IRB Review**
- UI-IRB 5
- UI-IRB 2
- UI-IRB 1

**Administrative Review**
- Exempt/Not Research Determinations
- Expedited Review
- Convened Review Routing

- Convener Review

**Substantive Review**
- Load Balancing
- Routing
# HRPP Review Procedure

<table>
<thead>
<tr>
<th>Processing step</th>
<th>Applicable document</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does the submission meet definition of <strong>“research”</strong> per CUNY Guidance section 3.1 or 3.2?</td>
<td>CUNY Guidance section 3.1 or 3.2</td>
</tr>
<tr>
<td>2. If yes, then does the submission meet definition of <strong>“human subject”</strong> per CUNY Guidance section 3.3?</td>
<td>CUNY Guidance section 3.3</td>
</tr>
<tr>
<td>3. If yes, then is the institution of CUNY <strong>“engaged”</strong> per CUNY Guidance section 3.9 and OHRP Guidance?</td>
<td>OHRP Guidance</td>
</tr>
<tr>
<td>4. If yes, then is the study <strong>“exempt”</strong> according to CUNY Procedure?</td>
<td>CUNY Procedure</td>
</tr>
<tr>
<td>5. If NO, then does the study qualify for <strong>“expedited review procedures”</strong> according to CUNY Procedure?</td>
<td>CUNY Procedure</td>
</tr>
<tr>
<td>6. If NO, then the study undergoes review during a convened IRB meeting, per CUNY Procedure.</td>
<td>CUNY Procedure</td>
</tr>
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Researcher Responsibilities

Education

- Researchers are responsible for taking training on the conduct of human subjects research prior to engaging in research activities.
- The PI is responsible for overseeing the training of all key personnel:
  - Principal Investigator, Co-Investigators, and research personnel who interact directly with human subjects or who have access to private information related to human subjects during the course of research.
- Taking the Collaborative Institutional Training Initiative (CITI) human subjects training is required for all PI's and Key Personnel:
  - [http://www.baruch.cuny.edu/hrpp/CITITraining.htm](http://www.baruch.cuny.edu/hrpp/CITITraining.htm)
Researcher Responsibilities

• **Ethical Principles**
  - Researchers are responsible for conducting research in accordance with the ethical principles outlined in the Belmont Report:
    - **Respect for Persons**
      - The autonomy of individuals to make an informed choice about participation in research providing suitable protection for vulnerable subjects
    - **Beneficence**
      - Research that has a scientific or scholarly value in which the potential benefits outweigh the risks which are justified and minimized
    - **Justice**
      - Ethical research is designed and conducted so that the burdens and benefits are fairly distributed regardless of age, race, gender, ethnicity, etc.
Researcher Responsibilities

• **Conduct of Research**
  - Researchers are responsible for the protection of human subjects throughout the research process:
    • Develop research studies using sound research design which minimize risks to subjects and does not unnecessarily expose subjects to research-related risks.
    • Maximize benefits to subjects (see Beneficence Principle in Belmont Report for details).
    • Plan and implement fair and equitable recruitment practices, which avoid the potential for coercion and undue influence.

• **Voluntary Participation**
  - Researchers must ensure that participation is voluntary by providing sufficient information to consent
Researcher Responsibilities

• **Subject Enrollment**
  
  – Researchers may not initiate recruitment activities, including screening, or enroll subjects prior to the date of IRB approval or after the expiration date of IRB approval.
  
  – Researchers are responsible for enrolling only the number of subjects that was indicated and approved in application.
    
    • Researchers should submit an amendment form to increase subject enrollment numbers when they become aware that they will exceed maximum approved enrollment number.
    
    • IRB approval must be received *prior* to enrolling beyond the approved enrollment number.

• **Informed Consent/Assent**
  
  – Researchers are responsible for obtaining and documenting informed consent with the consent/assent forms(s) approved by the IRB unless waived by the IRB for the specific project.
Researcher Responsibilities

• **Revisions, Amendments, and Changes to Approved Protocol**
  - Changes to research design, procedures, number of subjects, etc. must be submitted to and approved by the IRB prior to the implementation unless the change is to remove an immediate hazard to subjects.
  - If an adverse event/unanticipated problem occurs, the HRPP Office must be immediately informed and a report submitted.
Online Application

✓ Go to IRB Net website and login
   ✓ www.irbnet.org
✓ Register and upload your CITI certificate
✓ Create a new project and package
   ✓ Complete Application for Approval to Use Human Participants in Research, Part I
   ✓ Download and complete all necessary forms
     ✓ Complete either Application Part II OR Request for Exemption
   ✓ Share and link ALL key personnel (this includes your advisor)
✓ Make sure that you have uploaded all relevant documents
   – See the IRB application check list
     www.baruch.cuny.edu/hrpp/documents/IRBNETCHECKLIST.doc
✓ Once you complete your application, you must contact your faculty advisor to have them sign your package and then you can submit
Tips for preparing an IRB application

• **Purpose of the research** *(simple, clear, written for a wide audience)*

• **How will you select participants?** *(vulnerable populations, principle of justice)*
  - Recruitment procedures may include using Baruch’s SONA system, contacting acquaintances, working with an organization, snowball techniques
  - Ensure that participation is voluntary
  - Provide a recruitment statement/script with application

• **Consent form** *(templates provided on IRB Net)*
  - Write in appropriate language
  - Describe the goal and procedures of the study
  - Note all risks and benefits to participants
  - If audio or videotaping, provide participants with an opportunity to actively agree or refuse recording
  - Provide enough information so that participants can make an informed decision for consenting
Tips for preparing an IRB application

• **Description of the procedure**
  
  – IRB wants to know what is going to happen to participants from recruitment to the end of the study

  • Provide a detailed, step-by-step description of all procedures

  • If you have multiple methodologies, describe them separately and clearly delineate which method you are discussing

  – Write your procedure so that if you were to hand it to someone else, they could conduct your study

  – Copies of surveys, behavioral tasks, interview questions and any other research instrument

  – Sensitive questions

  – Debriefing (optional for most protocols)
Tips for preparing an IRB application

• **Potential harms/benefits**
  - Must weigh potential risks and benefits for participants
  - There is always some form of risk
  - Discuss ways risk will be mitigated
  - Benefits include those for the participant, researchers, society

• **Confidentiality**
  - The research team is obligated not to disclose participant’s information to others outside the team, except as clearly noted in the consent document
  - How data will be coded
  - Where consent forms and data will be stored
  - Who will have access to data

• **Anonymity**
  - If no one can connect the data to the individual who provided it
  - While you may not collect direct identifiers, collection of indirect identifiers might make it possible to identify an individual
Useful Links

• **Baruch HRPP Website**

• **IRB Net PI Manual**

• **Training Presentations**
  – [http://www.baruch.cuny.edu/hrpp/IRBManager.htm](http://www.baruch.cuny.edu/hrpp/IRBManager.htm)

• **HRPP Forms and Documents**
  – [http://www.baruch.cuny.edu/hrpp/forms.htm](http://www.baruch.cuny.edu/hrpp/forms.htm)
Baruch HRPP Staff

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• Elliott Larson (Psychology), **HRPP Liaison**
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  elliott.c.larson@gmail.com

• Or stop by during my office by appointment or during office hours
  – Mondays 2:30-4:30, VC 8-270
Questions?