Human Subjects Research

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Human Research Protection Program (HRPP)

• **HRPP** is the CUNY program that oversees protection of human subjects in accordance with federal regulations, State law and University policy.

  • Components:
    • HRPP administrative support at each CUNY College
    • Review by 5 CUNY-University Integrated Institutional Review Boards
    • Education and training of CUNY research community
    • Quality improvement of CUNY HRPP
What to submit for IRB Review?

• Activity that constitutes research AND involves human subjects

• **Research**: a systematic investigation designed to develop or contribute to generalizable knowledge.

• **Human subject**: a living individual about whom an investigator conducting research obtains:
  • Data through intervention or interaction with the individual, OR
  • Identifiable private information.
Pedagogical research?

• Pedagogical research may not require IRB review and approval if:
  • The data will be presented within the confines of the institution.

• IRB review and approval WILL be necessary if:
  • The results will be published, presented at a conference or generalized in some other way.
How to Submit to CUNY UI-IRB?

- Using CUNY’s IRB Net software system
  - Link from the CUNY HRPP web site: [http://www.cuny.edu/research/compliance/human-subjects-research-1.html](http://www.cuny.edu/research/compliance/human-subjects-research-1.html)
  - Need help?
    - Contact your College’s HRPP Coordinator. Names and contact information are available at the CUNY HRPP web site.
Levels of IRB Review

• **Non-human subjects research determination**
  • When researcher is in doubt as to whether the activity constitutes human subjects research
  • Determined at CUNY College level by HRPP Coordinator

• **Exempt from IRB review**
  • 6 categories of human subjects research
  • Determined at CUNY College level by HRPP Coordinator
    • HRPP Coordinator may determine that the submission does not qualify for exemption
Levels of IRB Review

- **Expeditied Review**
  - **Minimal risk** research: probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests
  - 9 categories of human subjects research
  - Determined at CUNY College level by IRB member
    - IRB member may determine that the submission does not qualify for expedited review
Levels of IRB Review

• **Convened IRB review**
  • More than minimal risk research
  • Reviewed by convened CUNY UI-IRB
    • 5 UI-IRBs meet on a rotation basis
    • Submission deadline and meeting calendar available at the CUNY HRPP web site
    • Membership rosters also posted on CUNY HRPP web site
Issues specific to pedagogical research

- **Voluntary participation**
  - Subjects should be permitted to decline participation without penalty
  - Subjects should be permitted to withdraw from participation at any time

- **Minimize undue influence**
  - Is participation for course credit coercive?
  - How is deference to authority avoided?

- **Informed consent**
  - Informed consent process ensures subject understanding of voluntary participation
  - Informed consent is obtained from subjects or parents of minors

- **Alternatives**
  - Alternatives are provided
  - Alternatives are comparable in time & effort

- **Confidentiality & Privacy**
  - Ensure confidentiality of subjects data
  - Ensure privacy of subjects