University of Illinois
OPRS and IRBs

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Office for the Protection of Research Subjects
Who are OPRS?

- The Office for Protection of Research Subjects (OPRS) is the support office for:
  - Illinois researchers conducting human subjects research
  - Research participants who have questions or concerns about research
  - The two Institutional Review Boards (IRBs) that review and approve research for Illinois researchers
Who are OPRS?

• Office staff is comprised of:
  • Director
  • Human Subjects Research Manager
  • Four Human Subjects Research Specialists
  • Office Support Specialist
  • Office Support Associate
  • Two Student Office Aides
Academic backgrounds of OPRS staff include:

- Accounting
- Civil Engineering
- Elementary Education
- Gender Studies
- Gerontology
- Health Administration
- Higher Education Administration
- Social Work
- Sociology
- Psychology
- Urban and Regional Planning
Institutional Review Boards

- Illinois has two Institutional Review Boards
  - Social Behavioral
  - Biomedical

- IRB Members include:
  - Scientists and non-scientists
  - Affiliates and non-affiliates
  - Try to have good representation from “heavy user” departments
When does something need to be reviewed?

• When it is human subjects research (DHHS definition)
  • Research – a systematic investigation designed to develop or contribute to generalizable knowledge
  • Human subject –
    • A living individual about whom an investigator obtains data through intervention or interaction with the individual, OR
    • A living individual about whom an investigator obtains individually identifiable, private information.
  • If one or both of these definitions are not met, it is Not Human Subjects Research (NHSR)
Levels of Review

• Exempt –
  • Six categories of low-risk research that are exempt from compliance with the full set of DHHS regulations; up to the university, state, etc. for how they want to proceed
  • Illinois still adheres to federal regulations for exempt studies, but with more flexibility, a shorter application, and reviewed completely by OPRS specialists

• Expedited
  • Nine categories of research for studies that do not qualify as exempt but also do not need review from the full IRB; instead they are reviewed by one OPRS specialist and one board member

• Full Board
  • Studies that do not fit in any of the expedited categories, have higher levels of risk to participants, or involve specific topics/activities/populations (topics: illegal activity, suicidal ideation; activities: X-rays, drug and alcohol studies, maximal exercise; populations: prisoners)
General Suggestions Before Submitting

• Ensure all relevant CITI training is completed
• Proofread application
• Know expected turnaround times
• Understand primary investigator and co-investigator responsibilities

• To submit an application, send all submission documents to irb@illinois.edu
Investigator Responsibilities

• Primary Investigator:
  • Has ultimate responsibility for the ethical conduct of research and the protection of research participants
  • Knows and complies with 1) university policies, 2) federal, state, and local laws, and 3) policies of funding agencies and cooperating institutions
  • Provides complete and accurate information in the IRB application
  • Ensures research is conducted by qualified personnel
  • Does not implement changes without IRB approval
  • Maintains IRB approval throughout the research process
Investigator Responsibilities

• Student Investigators need to know when IRB approval is needed, such as for theses, dissertations, or independent projects

• Student Investigators:
  • Need to identify an eligible Primary Investigator
  • Communicate effectively with the PI about research plan and design
Human Subjects Research Conference

Exempt Approval Process

1. Submit exempt application (or new protocol application) and any supporting documents (e.g. surveys, consent forms, etc.)
2. Protocol is entered, given an IRB number, and assigned to a human subjects research specialist (HSRS)
3. HSRS reviews and emails with clarifying questions, comments, requests, etc.
4. Researcher responds to HSRS
5. HSRS approves! Exempt protocol approval is good for five years
Expedited Approval Process

1. Submit new protocol application and any supporting documents (e.g. surveys, consent forms, etc.)
2. Protocol is entered, given an IRB number, and assigned to an HSRS
3. HSRS pre-reviews and emails with clarifying questions, comments, requests, etc.
4. Researcher responds to HSRS
5. HSRS sends to one board member, then acts as a liaison between the board member and the researcher for any additional revisions
6. Board member approves, approves with stipulations, defers, or recommends to full board
   • Expedited protocol approval is good for one or three years
Full Board Approval Process

1. Submit new protocol application and any supporting documents (e.g. surveys, consent forms, etc.)
2. Protocol is entered, given an IRB number, and assigned to an HSRS
3. HSRS pre-reviews and emails with clarifying questions, comments, requests, etc.
4. Researcher responds to HSRS
5. HSRS sends to two board members, and the protocol is discussed at a board meeting; HSRS acts as liaison between board and researcher for any additional revisions
6. Board approves, approves with stipulations, or defers
   • Full board protocol approval is good for one year
What are the criteria for approval?

1. Risks to subjects are minimized.
2. Risks are reasonable in relation to anticipated benefits.
3. Selection of subjects is equitable.
4. Informed consent will be sought.
5. Informed consent will be appropriately documented.
6. The research plan makes for adequate provisions for monitoring data to ensure participant safety.
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.
Amendments

• Submit a protocol amendment form describing changes with any new documents or documents that have been revised due to the amendment

• When should an amendment be submitted?
  • Any time something in the application or supplementary materials is changing
Informed Consent

• Should give potential participants as much information as possible to decide if they want to participate in the research

• No coercive language and no exculpatory language

• Should be at an 8th grade reading level

• If possible, give potential participants the chance to ask questions before they consent
Required Elements of Informed Consent

• Who/what/why/where/when of study
• Voluntariness
• Confidentiality of data
• Risks and benefits
• Whom to contact with questions/concerns
  • Both PI and OPRS information should be included
• How consent is indicated
Types of Informed Consent

• Written consent – indicated through signature
• Oral consent – indicated through verbal yes/no; usually accompanied with an information or contact sheet
• Online consent – indicated through accepting a survey link or clicking yes/no on an online survey form
  • Both oral and online consent require a “Waiver of Documentation of Consent”
• Waiver of informed consent – for situations where the research is in no way possible if participants know about it, OR getting consent from everyone would be burdensome to researchers and risks are low
• Alteration of informed consent – deception is necessary to the study, so participants are not wholly informed about the research; debriefing must be included
Any questions?

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