University of Pittsburgh

Institutional Review Board (IRB)

Student Researcher:

What Are My Responsibilities?

Topics

- What is the IRB?

- Student Responsibilities

- Mentor Responsibilities

- Student Project Becomes Research

- Research Education Requirements

- IRB Review Processes and Timelines

- Common Errors Encountered

What is the IRB?

- Institutional Review Boards were established by the federal government to protect the rights and welfare of human subjects participating in research activities

  - Responsible for ensuring that physical, psychological, and social risks to research subjects are minimized, and that the risks associated with the research are commensurate with the importance of the research and/or the knowledge to be gained

Belmont Report (1979)

- Ethical Principles and Guidelines for the Protection of Human Subjects of Research **http://ohsr.od.nih.gov/guidelines/belmont.html**

- Basic principles:
  - **Respect for Persons**
  - **Beneficence**
  - **Justice**

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Additional Responsibilities

- The IRB reviews human research activities to ensure that the University, affiliate institutions, and investigators are compliant with the ethical standards and the regulations governing human subject research.

- These regulations are summarized in the Code of Federal Regulations (45 CFR 46) from the U.S. Department of Health and Human Services and from the Food and Drug Administration (21 CFR 50; 56).

Administrative Review

- Minimal risk projects are reviewed by the IRB staff and most student research falls under one of these categories

  - **Expedited** projects must be no more than minimal risk and must meet one of the nine categories for expedited research

    - Requires annual review and approval

  - **Exempt**, **Not Human Subject Research**, or **Not Research** –The IRB makes a determination that the project meets one of the six criteria for exempt research or does not meet the definition of human subject research or research

Types of IRB Review

- Greater than Minimal Risk projects
  - Full Board review is conducted at convened meeting of IRB members comprised of scientific, non-scientific, and community members

  - Requires at least annual review and approval

Risk Determination

- **Minimal risk** means that the 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. (average person)

- **Greater than minimal risk** means the harm or discomfort is considered greater than that of the daily life for "the average person"

Student Responsibilities

- With appropriate faculty member supervision, students are encouraged to serve as the principal investigator for their research project to gain the experience of managing a study

- Principal Investigators are responsible for the overall conduct of the research study and compliance with local, state, and federal regulations, and university policies

Student Responsibilities (Cont'd)

- Follow the study procedures as stated in the IRB approved application

- Consult faculty mentor before making changes to your project

- Note: All changes require IRB review and approval before implementation

- Schedule regular meetings with your mentor to ensure appropriate oversight is maintained during the conduct of the study

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- If you are conducting research at a site outside the University, you must obtain written permission from the site

  - Shopping malls, schools, businesses, health fairs, etc.

  - Some sites (schools) may have their own IRB

- International studies are more complicated; speak with IRB staff before submitting your IRB application

Mentor Responsibilities

- Meet with the student prior to the development of a research project to discuss basic principles of research ethics

- Assist the student in determining whether IRB review/approval is required

  - The mentor should contact the IRB staff for assistance if any questions/concerns arise

- Provide oversight and guidance for the student researcher and share in the responsibility for the ethical conduct of the research and to ensure compliance with local, state, and federal regulations and university policies

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Mentor Responsibilities (Cont'd)

- Mentor has access to all projects when identified as the mentor and should monitor the IRB applications

- Schedule regular meetings to supervise the research projects

- Complete the same research education modules as required for all members of the research community

Definitions

- Research is defined as "…a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**" (45 CFR 46.102.d)

- A Human Subject is defined as "…a living individual about whom an investigator (whether professional or student) conducting research obtains (1) **data through intervention or interaction** with the individual, or (2) **identifiable private information**" (45 CFR 46.102.f)

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- **Is the activity an investigation?**
  - examination or inquiry for facts

- **Is the investigation systematic?**
  - planned method to perform the investigation

- **Is it designed to develop or contribute to knowledge?**
  - goal is to advance, improve, or contribute new information

- **Is it likely the results will be generalizable?**
  - findings will be widely applicable

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Research Education

- Required to complete at a minimum the following two online education modules:

  - **Research Integrity**

  - **Human Subjects Research**

- Go to https://cme.hs.pitt.edu and browse the Responsible Conduct of Research folder

- It will take approximately 24 hours for OSIRIS to be updated and access to OSIRIS authorized

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Consent Process

- Written informed consent must be obtained prior to study initiation if the study undergoes expedited or full board review
  - There must be a 'consent process' and someone with knowledge of the project must discuss the project with potential participants and be able to answer any questions
  - It is NOT acceptable to merely hand someone the consent form
- Under certain circumstances, a waiver of consent is permissible

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Types of Consent Waivers

- **Waiver to _Document_ Consent**

  - Minimal risk and involves no procedures for which consent is required outside of research or the potential risk is breach of confidentiality

- **Waiver of Consent – must meet (4) conditions**

  - Research involves no more than minimal risk to the subjects

  - The waiver or alteration will not adversely affect the rights and welfare of the subjects;

  - The research could not practicably be carried out without the waiver or alteration; and

  - Whenever appropriate, the subjects will be provided with additional pertinent information after participation. 18

Review Timelines

- It is important to **plan ahead and allow appropriate time for review** and approval of your project

- Timeline is **dependent on the complexity of your project** and required reviews and/or documentation from other sites or individuals (e.g., international studies)

  - Expedited and Full Board studies require scientific review prior to IRB review

Failure to Obtain IRB Approval

- Important: There is **no retroactive approval** process!!

- May jeopardize the use of the data collected
  - May prevent publication of the data for a dissertation or other purposes

- May place you in violation of university policies and federal regulations

IRB Reports

- Submit Renewal Reports

    – Required for Expedited or Full Board projects

- Submit Unanticipated Problems Reports

- Submit a Final Report

    – Do not leave the university without closing your study

- Mentors should be working closely with the student throughout the project and ensure proper reporting

Creating a New Study in OSIRIS

- Log into OSIRIS www.osiris.pitt.edu
  - Enter your email address and password used to complete the required modules

- Start by clicking on ⟹ **Create** 📋 New Study

- Answer the questions and click on Continue >>

- Short training video available at http://www.irb.pitt.edu/OSIRIS/

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OSIRIS Submission Process

- Principal Investigator clicks on the '**Submit**' button

- Email notification is sent to the '**Mentor**' requesting their review and agreement to supervise the project

- Email notification is sent to the '**Scientific approver**' if applicable for documentation of merit (not required for Exempt projects)

- For most student projects no additional pre-IRB reviews are required and OSIRIS sends the project for IRB review

- IRB review is initiated

OSIRIS Submission Process

- You can track your application thru the process using the 'History' tab located in the mid-section of your project workspace

- Email notification are sent to you if changes are requested and when IRB approval or determination is finalized

OSIRIS Tips

- Answer the 'question'
  - Unsure how to answer the question
    - Contact an IRB staff person or email irb@pitt.edu

- Use the History tab to track the project
  - Displays current state
  - Common error is one thinks they submitted the project when it is not

TIPS for Uploaded Forms

- Title documents so all users can identify the content

- Upload documents into the appropriate sections
  - Prevents the display of multiple versions of the same document

- Click on uploaded document to ensure it can be viewed instead of the error 'Page cannot be Displayed'
  - Eliminates wasted time to request changes so the document can be uploaded properly

Rule # 1

- All student projects require the supervision and guidance from a faculty member

- International project
  - Student researcher and faculty mentor should schedule a meeting with the IRB early and before submitting the project for IRB review

- Contact Michelle LeMenager, Student Liaison lemenagerms2@upmc.edu

Rule # 2

- No research should be initiated without IRB review or approval
  - Unclear whether IRB approval is necessary
    - Contact the IRB office
      - Erin Grabowski, Student Liaison
      - Email us at askirb@pitt.edu
- Absolutely no data can be collected or solicitation for research participants can take place without prior IRB approval if study is considered to be human subjects research

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Conclusion

- Recommend all students request an IRB consultation (especially first time users)

- Select a faculty mentor who has the expertise and time to provide guidance and support

- Remember that all changes require IRB approval

- Protect the privacy of the participant and confidentiality of the research data

Conducting Research is a Privilege

The IRB is here to support you

Just Ask Us…

askirb@pitt.edu

IRB Education Programs

Go to www.irb.pitt.edu **Calendar of Events**

- The IRB holds two sessions a month during the academic year called 'Ask the IRB'. As the name infers, it is time that you can use to ask questions of the IRB staff and engage in discussion.

- Many of our programs are recorded and can be viewed at a later date

- Go to the IRB website to join our mailing list