IRB Issues and Procedures

LINDA GOODFELLOW, PHD, RN, FAAN
ASSOCIATE PROFESSOR, SCHOOL OF NURSING
CHAIR, INSTITUTIONAL REVIEW BOARD
Overview of Presentation

- Belmont Report
- Definition of Human Subject Research
- Types of Reviews
- Resources Needed to Begin the IRB Process
- IRB Application Process
- IRB Documents to Prepare
- IRB Issues to Consider
- Amendments
- Time from Submission to Approval
- Mentor IRB
1. The Principle of Beneficence

- Freedom from Harm
- Freedom from Exploitation
- Benefits from Research
- Risk/Benefit Ratio
2. The Principle of Respect for Human Dignity

- Right to Self-Determination
- Right to Full Disclosure
- Right to Respect
3. The Principle of Justice

- Right to Fair Treatment
- Right to Privacy
- Informed Consent
Definition of Human Subject Research

- **Research** is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

- **Human Subject** is a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information.

  *Office for Human Research Protections (OHRP), 2011.*
Do you need to obtain IRB approval?

1. Does your research project meet the definition of research according to OHRP?
2. Does your project involve human subjects?
3. Are you collecting identifiable data?
4. Will the results be disseminated via publication or presentation?
5. Will the results only be disseminated internally?
1. **Exempt Review**

- Exempt status does not mean that the IRB process is by-passed.
- Minimal Risk; Usually anonymous; **survey designs**
- Once the status is approved, IRB oversight is not required.
- Termination report is required.
2. Expedited Review

- Involves minimal risk to subjects but does not involve vulnerable groups of people as subjects.
- Minimal Risk – no greater than would be expected from everyday activities.
- Risk can be physical, financial, social or psychological.
- Risk applies to the storage and publication of data where loss of confidentiality could negatively affect subjects’ lives.
Examples of Expedited Reviews

- Research involving data, documents, records or specimens collected for non-research purposes, such as medical records
- Collection of data from audio or visual recordings
- Research on individual or group characteristics when considering the subject’s own behavior (including perception, cognition, motivation, identity, language, communication, socio-cultural beliefs, practices or behavior) or research employing survey, interview, oral history, focus group or program evaluation measures for purposes of research
3. Full Board Review

- Applies to research in which procedures involve greater than everyday risk
- Participants are defined, as a group, as vulnerable
Criteria for Full Board Review

- Under the age of 18
- Are pregnant
- Frail elderly subjects
- Incarcerated subjects or persons on parole
- Mentally impaired subjects
- Procedures involving false or misleading information given to subjects
- Procedures involving information such that informed consent is in question
- Procedures requiring debriefing of subjects
- Biomedical procedures
- Procedures that are not accepted as ethical practice in the field
- Risky procedures or anticipated harmful effects
Resources Needed to Begin the IRB Process

- http://www.duq.edu/research/compliance
  - Link for CITI Training
  - Duquesne University IRB Policies and Procedures
  - HIPAA Guidelines and Forms
  - Mentor IRB User Guidelines/Link to Mentor
  - Protocol Summary Form & Consent Form templates

- https://www.axiommentor.com/login/axlogin.cfm
  - All guidelines, policies and procedures, and forms can be accessed via Mentor Info page and IRB Documents tab
IRB Application Process

- Complete CITI Training and upload certificate of completion to Mentor IRB under PI Document tab
- Complete Protocol Summary Form
- Develop Consent/Assent/Parental Permission Forms
- Develop/collection pertinent documents such as instruments for data collection; semi-structured interview forms
- Create recruitment fliers; email blurbs to recruit
- Access Mentor, Create Protocol Page, Upload Documents
1. Statement of the research question
2. Purpose and significance of the study
3. Research design and procedures
4. Instruments
5. Sample selection and size
6. Recruitment of subjects
7. Informed consent procedures
8. Collection of data and method of data analysis
9. Emphasize issues-interactions with subjects and subjects' rights
Cover Letters/Consent

- Use Duquesne University Letterhead

- For anonymous studies and/or studies collecting data via a secure online data collection site use cover letter format; do not request signature

- Include statement – “By completing and submitting the questionnaires you are voluntarily consenting to participate in this project”

- Cover letter should address all categories as per informed consent
Consent/Assent/Parental Permission Forms

- PI and Advisor/Co-Investigators – Contact Information
- Funding
- Purpose - **Include inclusion criteria**
- Procedures – **Be specific**
- Risks & Benefits (direct or indirect to benefit society or profession)
- Confidentiality - **Maintain records for three years**
- Compensation
- Right to Withdraw - **How? Will data already collected be used in the analysis should the participant withdraw?**
- Summary of results
- Voluntary Consent Statement
Other IRB Issues

- **Anonymity versus confidentiality**
  - Can only assure anonymity if participants are not known - **No signed consent form**
  - Must always maintain confidentiality of study materials including participants’ responses and identity - **Keep consent forms and codes linking identifiers separate from study materials**
Plan Time for the Review Process

- If student allow **time** for Advisor to review + revisions
- Allow **one to two weeks** for School IRB representative to review + revisions
- Allow **one to two weeks** for Chair of the IRB to review + revisions
- **Do Not** begin any research activities including recruitment until after you have received letter of approval
- **Use stamped forms with IRB approval:** Protocol Summary; Consent Forms; Recruitment Fliers; Instrument for Data Collection
Annual Review

- Mentor will notify you **ONE** month prior to expiration of Expedited and Full Board protocols
  - Submit annual report or terminate study (must do prior to graduation) using the Continual Renewal tab on your Protocol Page
- IRB oversight is **NOT** required for Exempt Studies
  - Complete and upload Termination Report to your Protocol Page after study is completed and prior to graduation
- Your IRB protocol should stay active until data analysis is completed
  - Researcher should request renewal with no enrollment
What if Changes are Needed after IRB Approval?

- Submit an **Amendment** should you need to propose a change in your study.
- The **Change** may influence the review status.
- Submit the Amendment Form to Mentor via your Protocol Page under Amendment tab.
- Include all pertinent documents – highlight the changes.
- **Do not** begin to make the proposed changes until after you receive IRB approval.
Mentor IRB

- Access Mentor
  [https://www.axiommentor.com/login/axlogin.cfm](https://www.axiommentor.com/login/axlogin.cfm)
- Complete Pre-Diagnostic Survey
- Create your Protocol Page; Request type of review, select criteria for review & complete all questions
- Upload Protocol Summary Form, Consent Forms, HIPAA Forms, Recruitment Flier, Permission Letters
- Always remember to click Save/Submit at the bottom of your Protocol Page!