RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

Navigating the IRB Review Process

Dr. Kathryn Greene

Professor, Communication

IRB Board Member

Introduction

- Overview of presentation
  - Background, submission, resources, timing, procedure, certification, forms, risk, consent, quality submissions, changes in protocols
- ~60-75 Minutes plus question and answer
- Regulations change and interpretations are updated, so this area requires regular education

Why IRB? Tuskegee, Nazi, Zimbardo, Willowbrook

Why IRB?….Look at History

1948 Nuremberg Code (post WWII)

1964 Declaration of Helsinki (World Medical Assn.)

1974 Response to the Tuskegee Syphilis Study:

US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research met from 1974-1978 (in the Belmont Conference Center of the Smithsonian Institute)

1978 Belmont Report issued

2014 Questionable research continues . . .

One study manipulating facebook feeds to alter people's emotions (deception) and another study trying to alter judicial elections in US states

What's different about IRB?

- Federally mandated process
  (not like other committees)
- Some issues NOT at discretion of members (regulations)
- Regulations dictate much of the process
- Investigators do not have authority to determine level of risk
- Compliance issues can potentially affect entire Rutgers community (i.e., it's about all of us, not just about you)

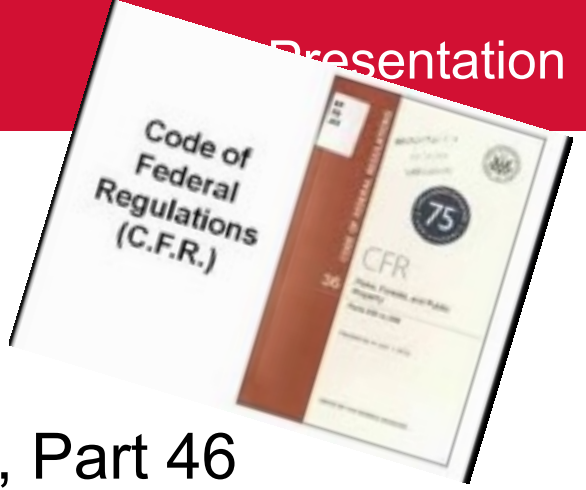
What is the IRB?

- Institutional Review Board for the Protection of Human Subjects in Research
- Guidelines for IRBs in Federal regulations (45 CFR 46 & 21 CFR 50)

- The Rutgers IRB reviews and approves all humans subjects research conducted at the University. The IRB has the authority to:
  - Approve, require modifications in or disapprove all research activities
  - Monitor research activities records (Random Audits)
  - Suspend or terminate any research (non-compliance)

- The IRB is now known as the Arts & Sciences IRB, within Office of Research Regulatory Affairs (ORRA). Located in downtown New Brunswick.
- RBHS has the Health Sciences IRBs which are located on both the Newark and New Brunswick/Piscataway Campuses.
- The IRB website includes specific details along with applications, instructions and other FAQs. Please review the website first before completing any forms.

Do I have to submit?



Title 45 of the Code of Federal Regulations, Part 46

- Involves research
  - Research is defined as a systematic investigation, including research development, testing and evaluation, designed to produce or contribute to *generalizable* knowledge (45 CFR 46.102)

AND

- Involves human subjects
  - Human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains (either): data through intervention or interaction; or private, identifiable information (45 CFR 46.102(f)).

What makes something “Generalizable”?

- Draw conclusions across some group/phenomena
- Research may have “predictive value”
- Difference between one interview & sampling for interviews

  Examples could include public figures (politicians), sports figures, survivors of a disaster, etc.

- Oral histories, while scholarly, MAY not meet the criteria for submission; this depends on the individual case (submit to IRB and have them determine)

What do I do before I start?

- **Become certified to conduct human subjects research**
  - Pass the Collaborative Institutional Training Initiative (CITI Program)
  - View the online power-point presentation followed by a test
  - You must be certified before you can start your research
- **Work with Faculty Advisor to obtain IRB approval for research**
  - Submit a new protocol for review and approval OR
  - Request an amendment (modification) to an existing protocol
  - Undergraduates are not allowed to submit protocols on their own at Rutgers; graduate students must have Co-PI full time faculty

Belmont Report: Three Basic Ethical Principles

- Respect for persons (operationalized by Informed Consent)
  - Voluntary informed consent
  - Respect for privacy
  - Added protections (children, prisoners, pregnant women/fetuses)
- Beneficence ("do no harm")
  - Good research design and manage conflicts of interest
  - Maximize benefits, minimize risks
- Justice
  - Equitable selection of subjects, inclusion and exclusion criteria
  - Equal distribution of both benefits and burdens of research

Two Levels of Risk

The charge of the IRB is to protect the rights and welfare of research participants –the IRB must weigh risks vs. benefits

How a protocol is reviewed depends on the level of risk to subjects

Minimal risk:

Federal guidelines state that, "**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."

Greater than minimal risk (GTMR):

"more than minimal risk" (literally the definition…)

Type of Collected Data

- Anonymous
  - No link between name/identity and person
  - If identifiers are removed at data entry, CAN be anonymous
  - Note this involves specifics of details collected, not simply names
- Confidential
  - Have a link, even for a short time (e.g., some longitudinal studies)
- Cannot be both!!!

  Example: Application says that the PI will use a **linked code** and consent might read: "Your participation in this study is anonymous."

If you want to disclose a name (e.g., an interview), you must address this in consent form!

Three Categories of Review

- **Exempt** (minimal risk) – cannot self-exempt, must submit
  - Definition is “exempt from further (yearly) review” (does not mean exempt from applying)
  - “Anonymous”
  - No children outside of category 1
  - Note NHR
- **Expedited** (also minimal risk) – Specific types of research qualify (7 approved categories)
  - Yearly Continuing Review
- **Full Board Review** (less common) – greater than minimal risk and/or vulnerable populations (e.g., prisoners, pregnant women)
  - Yearly Continuing Review

Timing

- See CURRENT Deadlines Online: https://orra.rutgers.edu/irb-deadlines-meetings
  - Exempt Review: Due each Wednesday (5 pm). Plan for 2-3 weeks for review/approval
  - Expedited Review: Due 12th of each month (except in August-no meeting). Plan for 6-8 weeks for review/approval
- Expect any questions 1-3 weeks after submission via email and respond ASAP (the board only meets monthly, so delay can send an application to the next meeting)
- When responding, do so item by item (like a review)
- Notices of Approval/CR Reminders sent via email to PI/Faculty Advisor.

Procedure

- Each submission sent to IRB members (usually 2)
- The reviewers confer and may request clarification
  - Note timing, try to respond quickly
  - You will be working with Administrator through email
- When all inquiries are addressed, goes on official roster
  - Meets once a month
  - No meeting in August
  - Will need all letters of authorization, revisions for final approval
  - All notices now sent via pdf/email (no more campus mail), **new**
  - Note that the notice contains **expiration** date!

Informed Consent

- Consent is a ***PROCESS*** in which the investigator shares all relevant information about the study and the potential subject has the opportunity to ask questions and decide if he/she wants to participate
- The consent form is a permanent record of conveyed information and the subject's willingness to participate
- A subject can withdraw consent and drop out of the study at any time for any reason without penalty (Computerized surveys must be allowed to skip questions/prorate payments)
- Default: signed w/ copy to participant (can request alteration)

Basic Requirements of Informed Consent

8 basic consent elements

- Description of the research (purpose, duration, procedures)
- Foreseeable risks/discomforts
- Potential benefits
- Alternatives to participating (if any)
- Confidentiality (protection of personal information, data storage/protection)
- Compensation
- Contact Information (Investigator and IRB)
- Voluntary Participation

So, use the **templates** on the website and make it easier!!!

Consent: Waivers & Alterations

Waiver of Informed Consent –PI must request & address all points:

1. No more than minimal risk
2. Not adversely affect subjects
3. Could not practicably be carried out (definition: capable of being put into practice or of being done or accomplished; feasible, note this is not ease)
4. Additional information will be provided (debriefing)

Example: Secondary data analysis involving a large private dataset

In sum, it is very rare to waive informed consent!

Waiver of Written Consent –PI must request & address the following:

1. Consent is only record linking subject and research; the link poses risks; or
2. Research presents no more than minimal risk of harm to participants; and
3. Involves no procedures for which written IC is normally required outside of the research context

Example: Telephone-based research or research where you do not want to store names (e.g., not legally in the country)

To Make the Process go Smoothly

- Plan ahead
  - Students should plan to submit 2-3 months prior to when they plan to begin the research.
  - Review all current deadlines for IRB submissions

- Use Current Application Forms
  - See website for current versions: https://orra.rutgers.edu/irb-applicationsforms
  - Examples of consent forms available on the website and within the instructions attached to each application
  - Your Faculty Advisor/Mentor is your very best resource!!!!

- Ensure the submission is complete
  - Don't ignore check-lists, attachments, questions you think are irrelevant
  - Incomplete submissions will be returned without review

"Complete" proposals

- Use Current Application Forms: (2014.a right now)
- All CITI dates for ALL personnel
- No missing attachments---
  - Attachment 1: Research Protocol: On average, provide a 2-5 page summary NOT a 50 page dissertation proposal (some grants require attachment of grant proposal; in addition write a 1 page summary of rationale and methods).
  - Attachment 4: Consent (see sample on website, all IRB contact info)
  - Attachment 6: Authorization letters or Letters of Cooperation
  - Attachment 7: Outcome Measures-surveys, focus group guides or interview items
  - Attachment 9: Debriefing (required if any deception)
  - For International Sites-Must include Appendix C or D
- Attach a cover letter if anything is missing or unusual

Quality proposals--conceptual

- Overall protocol quality
  - NOTE that the IRB does NOT comment on the science (theory, design, etc.) [unless it affects human subjects!]

- Must address level of risk, demonstrate understanding of the balance and issues
  - Could be the topic, the population, etc.

- Consent form is in layperson language (readability programs)

Emerging Issues

- Regulations and guidance change over time; there is a current proposal under consideration to change regulations. At BEST, this would be several years away from implementation

- Important to update education
- RU moving to online for submission/review (eIRB)
- The merger is affecting many things (HIPPA issues)

- Examples of current "issues"
  - Anonymity and web-based data collection (**new FAQs** posted on website)
  - Expectations of privacy for online discussion groups (see **new FAQs**)
  - Genetic testing and medical samples
  - Storage of blood/tissue samples (with no expiration date)
  - Consent of cognitively impaired individuals

When Does IRB Review "end" for a Study?

- Includes data analysis (not just recruitment and testing/data collection)
- Be sure to notify of personnel changes (even new GA/RA)
- When the study is completed – terminate the approval (notify IRB staff)
- Expiration dates/renewals are PI responsibility!
  - Continuing review
  - IRB is not required to send a letter
  - Expiration date is on the approval letter
  - No work on a project can proceed if a proposal is closed
  - There is no "grace period" (prohibited by the regulations)

What if my Study Changes? (a form…)

- Alterations, even minor, must be sent to IRB, called “Amendment” (a modification to an approved project)
- Some can be approved by staff, others are sent to reviewers
- Sometimes shows up with Continuing Reviews; take care of this beforehand so your study is not interrupted
- Remember that the application is a signed document specifying very specific procedures and details

- Examples:
  - Number of subjects
  - Criteria for participant recruitment (even labe
  - Adding new data collection sites
  - Altering an instrument (e.g., add items to a survey)
  - Staff person leaves project or new person is hired

Summary

- Research **AND** Human Subject = IRB Review
- CITI, no longer HSCP
- Adherence to Approved Protocol (specific details)
- Continuing Review
- Ongoing Communication with IRB

The purpose and role of the IRB is to ensure the protection and safety, rights and welfare of human subjects in research.

Questions?

- Speak 1st with your Faculty Advisor
- Visit IRB Human Research Website for FAQs & to Obtain Templates
- If Contacting IRB staff for specific questions, you must copy Faculty Advisor

Main ORRA Website: https://orra.rutgers.edu/irb

Main Arts & Sciences IRB Human Subjects Research Website: https://orra.rutgers.edu/rutgers-irb

Inquiries should be directed to:

Any IRB Administrator listed under "Contact Us" page: https://orra.rutgers.edu/irb-contact-us

Submission must be emailed directly to:

irb-admin@grants.edu

IRB Submission Process

Step 1
- Confirm That You Are Submitting To The Correct IRB. Read Mo

Step 2
- Confirm If Your Study Involves Human Subjects And/Or Data. Read Mo

Step 3
- Select Your Review Type Based On Study Risk Level. Read Mo

Step 4
- Check Your Study For Vulnerable Populations. Read Mo

Step 5
- Complete Your CITI Human Subject Protection Training. Read Mo

Step 6
- Submit Your Study/Project For IRB Review. Read Mo

Step 7
- Review the IRB Approval Process. Read Mo

After IRB Approval

- Submitting an Amendment (Modifications / Addendums) to an Approved Protocol
- Submitting a Continuing Review (Full-Board / Expedited Studies Only)
- Reportable Events: Adverse Events / Unanticipated Problems / Protocol Deviation / Protocol Violations
- Closing Your Study
- Responsibilities After Your Study is Closed