How to Smoothly and Successfully Complete the Process for IRB Submission

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Introduction

• Overview of presentation
  – Background, submission, resources, timing, procedure, certification, forms, risk, consent, students, quality submissions, changes in protocols

• ~90 Minutes plus question and answer

• Introduce presenter(s)

• Regulations change and interpretations are updated, so this area requires regular education
Why IRB? Tuskegee, Nazi, Zimbardo, Willowbrook
Why IRB?….Look at U.S. (and others) 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
2008 (and beyond) Questionable research continues . . .
Belmont Report: Three Basic Ethical Principles

• Respect for persons
  – 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
Historical Context for IRB

• Federal guidelines vs. Rutgers implementation
  – Historical context of federal guidelines
  – Objectivity issue
  – Assurance between Rutgers and the Federal Government
  – State Law (example School Survey Law)
  – Rutgers University Policies

• Role of IRB: 1 and 2 (or 1 and 1a)

• Application is a contract describing specific research procedures
• Regulations are floor (not ceiling), that is: they are a minimum
• Required to release grant funds! (+ cannot use unauthorized data…)

Dept. of Communication
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)
Do I have to Submit?

  - Involves research
    - Research is defined as a **systematic investigation designed to produce or contribute to generalizable knowledge**
    - This includes research development, testing, evaluation, AND pilot studies
  - AND

- Involves human subjects
  - Human subject is defined as a **living individual about whom an investigator obtains (either): data through intervention or interaction; or private, identifiable information.**
What makes something “Generalizable”? 

- Effort to draw conclusions across some group or 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
Resources Available

- IRB Staff (new: 3 administrators for human subjects)

- Web resources--please read the site!
  - Including examples, instructions, forms, and FAQs
  - [www.orsp.rutgers.edu](http://www.orsp.rutgers.edu) Human Subjects Research

- Colleagues, IRB members in Departments

- IRB Advisor, pilot project 2008-2012 (see yellow handout)
  - Seminars
  - Office hours before submission deadlines
When to Submit?

• Cannot begin any type of data collection without approval
  – Approval **CANNOT be backdated!!!**
  – That means people have not been able to use data

• Plan ahead, maybe 2-3 months to be safe
  – If exempt (and you are certain), can be quicker (~3 weeks)

• For grants, often submitted as “pending”
  – If receive notice award or warning, submit ASAP
  – Cannot release ANY funds without IRB approval
Timing

• 12th of each month (except no August meeting)
• Plan for 6-8 weeks for normal review/approval
• **Expect any questions** 2-3 weeks after submission and respond ASAP (the board only meets monthly, so delay can send an application to the next meeting)

• If possible, consider designs that may be **exempt**
• Deadline each week, much shorter turn around
Procedure

• Each submission is 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 2011
Where to begin: Certification

• Must be certified to be approved (that is, ALL personnel)
  – Applies to even data entry people or interviewers, including design

• This will begin to expire (that is, require renewal 3-5 years)

• Several ways to accomplish certification:
  – Rutgers is moving to CITI (available soon through RU); timing is under discussion (how to phase this in) but begin to use CITI
  – HSCP: Rutgers exam (on sakai) is going to be withdrawn
  – Film has been recalled, not used after Spring 2010
  – Acceptable alternates: NIH, ask about others
  – UMDNJ uses CITI and does not accept RU, so if you collaborate…
3 categories of Submission

All human research protocols at Rutgers undergo review

- **Exempt** (minimal risk) – cannot self-exempt, must submit
  - Definition is “exempt from further (yearly) review” (not exempt from applying)
  - Children only Category 1, otherwise not exempt
  - Generally anonymous

- **Expedited** (also minimal risk) – Specific types of research qualify (7 categories)
  - Yearly Continuing Review
  - Careful of # of participants

- **Full Board Review** (less common) – higher risk and/or special populations (e.g., prisoners)
  - Yearly Continuing Review

- **Note:** only two RU forms but 3 categories (see handout)!
Examples of 3 Categories of Submission

• Exempt

• Expedited

• Full Board Review
Level of Risk

Minimal risk is defined as:

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:

“more than above” (that is the regulation…)
Consent

- Consent is a continual **PROCESS** in which the investigator shares all relevant information and potential subject has opportunity to ask questions: key aspect of any study

- The consent form is a permanent record of conveyed information and subject’s willingness to participate (can be withdrawn).

**DEFAULT**: Written consent w/ signature AND copy given

- Includes ads/flyers and re-consent at **all stages** of a study
Requirements of Basic Consent Elements: 46.116(a)

- **8 basic consent elements (from Regulations)**
  - 1. Description (research, purpose, duration, procedures)
  - 2. Foreseeable risks/discomforts
  - 3. Potential Benefits
  - 4. Alternatives to participating (if any)
  - 5. Confidentiality (data collection, storage, & removal/destruction)
  - 6. Compensation/inducements (including partial)
  - 7. Contact Information (Investigator and IRB)
  - 8. Voluntary Participation
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 **practically** 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
Consent: Details

• Technical issues: see samples on ORSP website (and copy them)!
  – Voluntary and informed consent--federal definitions/requirements
  – Written in 8th grade reading level or lower!
  – Initials on bottom of each page
  – Separate signature for audio/videotape

• Information sheet (was called passive); “waiver of written consent”
  – You may also not WANT signatures (e.g., anonymous)

• Parental consent or vulnerable populations
  – Plus child assent--together or separate? (under 7, total parental; if 7-12 assent; if 13-18/21 can sign line on main consent)
  – Careful to wording changes (you/your child vs. s/he etc)
Deception

• Deception involves the intentional withholding of information from the subject regarding his or her research participation

• Required: discussion of the cost-benefit analysis, discussion of alternative methods, full explanation of the need for the use of deception

• Debriefing Statement: required for ALMOST ALL studies involving deception

• Most deception research is Expedited/Full, only very minor deception is reviewed as Exempt (Rutgers SOPs)
Anonymity

• 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 in one study**
  
  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!
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)
• If we combine with portions of UMDNJ…

• 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
What if my Study Changes?

- Alterations, even minor, must be sent to IRB, called “Amendment” (a modification to an approved project)
- 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 labels)
  - Adding new data collection sites
  - Altering an instrument (e.g., add items to a survey)
  - Staff person leaves project or new person is hired
What about Students?

• Rutgers faculty and staff can be PIs (Principal Investigators)
  – Must be full time!

• Graduate Students: must be Co-PI with a full-time Rutgers faculty or staff person as Co-PI, no longer solo:
  – Mentoring
  – Editing
  – Also graduate program director contact info

• Undergraduates: cannot be PI, full-time faculty member must be PI but students can be cc’d on correspondence (training)
Ensure your Proposal is “Complete”

• Include certification for all personnel working on the project

• No missing attachments (including Appendix A & B)
  – **Attachment 1**-protocol: *1-2 page summary*, NOT a 30-50 page dissertation proposal (if submitting grant proposal, **in addition** write a one page brief summary of rationale and methods).
  – **Attachment 4**-Consent, see samples on website, all IRB contact info
  – **Attachment 7**-The survey or interview items
  – Attachment 6-authorization letters for non-Rutgers sites
  – Attachment 9-Debriefing required if any deception
  – Attachment 3-Any flyers or advertisements
  – **Do NOT miss 1, 4, and 7**

• Attach a cover letter (if needed) to clarify any aspects
• Sign everything (at least **three** current signature lines)
Applications that are Well-Written

• Overall protocol quality
  – NOTE--IRB does NOT comment on the science (theory, design, etc) [unless it affects human subjects!]; this is not a grant review
• Address level of risk - demonstrate understanding of the balance between risks and benefits **to subjects** (not to science more generally)
• Include categories for exempt or expedited
• Consent form is in layperson language (readability programs)
• Complete (ie: title, check Appx. A & B, signatures)
• Label everything (especially appendices & different consents)
• If Amendment, make the changes clear (highlight, track changes, good cover letter etc).
To make the Process go Smoothly

- Plan ahead
- Use samples/resources
  - For example, multiple consent forms available on the website
- Call IRB staff with questions (send good times to call back)
  - Deadline weeks are tough (12th) as are meeting dates (often 1st Wed)
- Ensure the submission is complete
  - If something is “pending” please note
  - Add a cover sheet if needed
  - Don’t ignore check off sheets or questions, must list NA or no even if seems obvious!
Use Current Form & Note Changes

• We all recycle forms, but they do change (6.08 currently)
  – We will have online submission that is paperless (and eco-friendly…)

• Forms for international research (conducted outside US borders) are currently required
  – Translate consent into English

• If you are unsure if you should submit as exempt or expedited
  – Ask beforehand
  – Use expedited form - longer but may save time in the long run
Conclusion

• Remember: first and foremost, the charge of the IRB is to protect the rights and welfare of research participants

• Research + human subjects = submission to the IRB

• Contact ORSP or the IRB Advisor with any questions including whether or not you are conducting human subjects research. Remember: there is no retroactive approval for human subjects research
Questions?

• What haven’t we covered that you’d like to ask?

• We will stay afterwards for a few minutes for specific questions about individual projects

• Thank you!