The IRB Process – An Overview

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Overview of IRB - Origins

- The Nuremberg Code (Post-WWII, 1949)
- Tuskegee Study of Untreated Syphilis in the Negro Male (1932-1972)
- Milgram Experiment (1962)
- Stanford Prison Experiment (1971)
Overall Sequence of Events:

Regulations:
- 1932-1972 – Tuskegee Study of Untreated Syphilis in the Negro Male
- 1946-1948 – Guatemala Syphilis Study
- 1949 – Nuremberg Code
- 1962 – Milgram Experiment
- 1966 – Beecher Report
- 1971 – Stanford Prison Experiment
- 1974 – National Research Act and earliest version of 45 CFR Part 46
- 1978 - Belmont Report issued

Regulations:
- Subpart A – Common Rule - revised 1981 & 1991
- Subpart B – Pregnant women, neonates - 1975
- Subpart C – Prisoners - 1978
- Subpart D – Children – 1983
- Subpart E – IRB Registration Instructions - 2009
The Nuremberg Code

1. Required is the voluntary, well-informed, understanding consent of the human subject in a full legal capacity.
2. The experiment should aim at positive results for society that cannot be procured in some other way.
3. It should be based on previous knowledge (like, an expectation derived from animal experiments) that justifies the experiment.
4. The experiment should be set up in a way that avoids unnecessary physical and mental suffering and injuries.
5. It should not be conducted when there is any reason to believe that it implies a risk of death or disabling injury.
6. The risks of the experiment should be in proportion to (that is, not exceed) the expected humanitarian benefits.
7. Preparations and facilities must be provided that adequately protect the subjects against the experiment’s risks.
8. The staff who conduct or take part in the experiment must be fully trained and scientifically qualified.
9. The human subjects must be free to immediately quit the experiment at any point when they feel physically or mentally unable to go on.
10. Likewise, the medical staff must stop the experiment at any point when they observe that continuation would be dangerous.
Overview of IRB – Belmont Principle

- **Respect**
  - Ensuring that individuals can make informed choices about their participation in research, and protecting those individuals with diminished autonomy

- **Beneficence**
  - Ensuring that the potential risks of a study are minimal, or are justified by the potential benefits, with ethical treatment

- **Justice**
  - Ensuring that the selection of, and benefit to, research participants is fair, and not based simply on their ease of availability, their willingness to participate, or other considerations not directly related to the problem being studied
Federal Definition of “Research”:

- A *systematic investigation*, including research development, testing and evaluation, *designed to develop or contribute to generalizable knowledge.*
Overview of IRB – Key Definitions

- **Federal Definition of a “Human Subject”:**
  - 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.

- **RU’s definition of whether human subjects are involved may be more stringent in some cases and require greater protection of privacy.**
  - This is determined in the review process.
What is clearly NOT Research?

Course evaluations or other programmatic evaluations for the sake of curriculum or other program improvements, but not for use in later publication.

- Retrospective studies may be an option for future use of data for publication in some cases.

- Data collected from students in a class which is used for demonstration/learning purposes only.

- Data collected by students purely for the purpose of learning research methodology that will not be published.
Review Categories

- Classroom Exercises
- Exempt
- Expedited
- Full Board
Review Category General Examples

- **Classroom Exercises:**
  - No minors or other vulnerable populations, **no illegal activity, no sensitive topics**, no images or recordings of any kind, etc.
  - See policy on RU IRB website for details or contact the IRB Office.

- **Exempt:**
  - Does not have to be anonymous but no risk to the person can exist if the identities were to be “leaked”.
  - Thus no sensitive topics where the person is revealing personal information.
  - No vulnerable populations though some exceptions for children are provided.
  - See the RU IRB website, RU IRB policy manual, OHRP regulations and/or contact the IRB Office for more information.
Review Category General Examples

- **Expedited:**
  - Must also be of minimal risk so most of the Exempt criteria pertain but more latitude for sensitive topics and identities of participants to be known.
  - Can also audio- or video-record sessions.
  - See the RU IRB website, RU IRB policy manual, OHRP regulations and/or contact the IRB Office for more information.

- **Full Board:**
  - Allows for review of:
    - Vulnerable populations
    - Deception research
    - Biomedical research
Overview of IRB

Types of Participant Risk to Consider:

- Inconvenience
- Physical Risk
- Psychological Risk
- Social Risk
- Economic Risk
- Legal Risk
Ways to Mitigate Risk to Participants

• A truly anonymous survey...
  • Keeping in mind detail levels of demographics, open-ended questions, etc.

• An opinion survey...
  • Rather than a self-report survey asking about personal experiences
  • A survey where people are asked about their opinion about social norms, conventions, other peoples’ opinions, etc.
    • “Do you think society has a poor opinion about alcoholics?”
    • “Do you think that someone is judged for hooking up?”
Why Submit Your Research Project to the IRB?

- **In short:**
  - It’s federal law
  - **Bottom Line:**
  - Because you have to
  - If you don’t, you place your institution at risk of federal sanction and the loss of federal funding (potentially including student loans)
Required CITI Courses for IRB Training

• All Faculty:
  • “Social and Behavioral Research Investigators Basic/Refresher, Basic Course”

• Students working on projects involving only minimal risk:
  • “Students conducting no more than minimal risk research”; “Students – Class projects, Basic Course”

• Students working on projects involving greater than minimal risk:
  • Same course as Faculty – see above

• Tutorials and instructions are available on RU IRB website to help guide you to the correct courses
Is your Human Subjects Training in date (<3 years) and appropriate to the level of research to be conducted?*

No

Need to Create a CITI Account?

No

Log into CITI and complete the refresher course that is waiting for you. Or continue below to select the appropriate new course.

Yes

See the CITI New Learner Tutorial for assistance

Select and complete the appropriate Human Subjects course — for more information go to the RU IRB Human Subjects Training website:

All Faculty/Staff

Students: Conducting:

Greater than Minimal Risk Research (Full Board) — take ONLY the Faculty Course

Minimal Risk Research (Exempt/Expedited Protocols) — Complete ONLY the "Students conducting no more than minimal risk research" Course

Complete ONLY the "Social & Behavior Research-Basic/Refresher" Course

The IRB Office will verify training online when taken through CITI. There is no need to upload your certificate of completion in InfoEd unless the course is completed through NIH's training or another other institution’s training, which will be approved on a case-by-case basis.

Preparation for Human Subjects Research
Rev. 9/26/16

Notes:
• CITI Training is in light blue on left
• InfoEd directions are in pale red below
• All Consent templates and additional forms are on the RU Forms and Templates IRR website.

Need access to online submission system, InfoEd, but your RU ID doesn’t work when you try to log in?

Yes

All students and any faculty hired before mid-July of 2015 need to complete the InfoEd Global Access Request Form

View any desired tutorial videos on the InfoEd home page regarding how to use InfoEd

The Initial Application Form is located in the new submission you create in InfoEd. Investigator Agreement forms, a Word version of the Initial Application (optional but useful to draft a project, esp. in a group*), consent forms, etc., are located on the RU IRB Forms and Templates Webpage.

* Be sure to copy any text from Word into Notepad before copying into InfoEd

Faculty

Complete the initial application within InfoEd but complete any attachments on your computer and then upload them in InfoEd

Review, complete, and submit the project within InfoEd. The protocol will go to the PI for review and acceptance. Contact the IRB Office for help if needed for this step.

Co-PI (Faculty and all Students)

Project is then automatically locked to prevent further access and a notice is emailed to the RU IRB Office that your protocol is ready for review

Students

List your faculty mentor as PI during the initial protocol creation in InfoEd

When you are done uploading all of your study documents:

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Review Cycle for Submitted Applications

1. Pre-review for completeness by the IRB GA when it is received and entered into our database.
   - You will receive email detailing any missing information.
   - Please respond in a timely manner to ensure prompt processing.

2. Review (Exempt and Expedited), or preliminary review (Full Board).
   - Exempt and Expedited – protocol assigned to an individual IRB Member for review outside of a meeting.
   - Full Board – PI will be contacted with a meeting time and location for you to present and defend your submission before the Full Board.
3. **Reviewer comments returned to you for revisions or clarification, as needed**
   - Please respond in a timely manner to ensure prompt processing.

4. **Your Approval Letter and any stamped forms will be forwarded upon approval**
   - You must use stamped and in-date versions of consent and other forms stamped by the IRB Office when recruiting participants.

5. **Pay attention to your protocol’s approval period dates**
   - NO WORK may begin until you have received your approval letter.
   - NO WORK may continue after a protocol has expired if it is not properly Continued.
Important Tips for IRB Submissions

- Always download **NEW FORMS and/or TEMPLATES** from the RU IRB website before starting a new project.
  - Revisions are made periodically to improve the forms.
  - At some point, the previous version of forms are no longer accepted.

- **Don’t put any locked submission forms into Google Docs or similar software that strips features from Word docs.**
  - This unlocks the form and removed the text boxes and some of the formatting from it.
  - **Google Drive** should be ok, but Google Docs corrupts the forms.
  - Corrupted forms are difficult to review & may not be accepted.
Important Tips for IRB Submissions

- **Check for completeness and accuracy throughout submission documents:**
  - If information is missing, the protocol will be returned.
  - **Grammar and spelling MUST be perfect on EVERY document that will be seen by participants.**
  - **Proofread carefully, or ask a colleague to proofread it for you.**
  - Consent form(s) must be on appropriate RU Letterhead unless provided online/electronically to participants.
  - Online consents **must have RU logo**, at minimum.
Important Tips for IRB Submissions

- Write participant materials at an appropriate reading level for your *participants*
  - This is especially important for recruitment materials, and consent and assent documents.

- Avoid discipline-specific jargon in the application or the participant materials

- Define acronyms at first use in each document
  - If the proposal can’t be easily understood:
    - the IRB can’t adequately assess it, and,
    - your participants *can’t provide truly informed consent* for their participation.
Important Tips for IRB Submissions

- Write your application for a wide range of reviewers
  - There may be someone on the IRB who is an expert in your field, there may not be.
  - If there is an expert in your field, there is no guarantee that your protocol will be reviewed by that person.
  - There is at least one lay-person on all IRBs
    - All submissions must be intelligible to that person, whether or not they actually review it for the initial submission. They may see it later.

- Avoid writing your application as though it were a grant, thesis or dissertation
  - Grants are intended to provide high-level perspective of project
  - IRB applications are to provide the actual details of the project.
    - This distinction is per federal guidelines.
  - Applications written in grant-type language will be returned.
Consistency throughout the submission is very important.

- Make sure every document agrees with each other.

- It is very easy to:
  - start with one plan (e.g., paper and online surveys),
  - decide to change part of the plan (e.g., eliminate paper surveys), then,
  - forget to realign the whole submission (e.g., to exclude paper surveys throughout.)

- If this happens, the study WILL be returned for revisions, thus incurring delays!
Important Tips for IRB Submissions

• Make sure that each step of the project is:
  • Described clearly and completely
  • Presented in logical order.

• Read the **ENTIRE question** for each item on the application form before answering it.

• The more you can do to enhance the quality of your submission, the faster we can process it.
Checklists for All Submission Types

- It is important that your submission is as complete as possible to minimize lost time in the review process.

- Available resources include:

  - **D2L Self-Registration Course titled “IRB User Resources”**
    - Includes numerous tutorials with screenshots to guide you

  - **RU IRB New Submission Checklist**, in the Resources section of the RU IRB Forms and Templates page
    - provides more detail about the process of preparing and submitting an IRB protocol
Faculty Tips for Student Projects

- The IRB Administrator is available to provide IRB presentations to your classes to facilitate the submission process.

- Please contact the IRB Office prior to, or at the time of, submitting semester-based protocols so that we can do our best to facilitate their processing.

- Please plan ahead when planning courses that include IRB reviews of student submissions.
  - IRB reviews take approximately 2-4 weeks for Exempt and 3-4 weeks for Expedited reviews.
  - Please allow adequate time for review for semester-based projects.
Student Tips for Student Projects

- Student Investigators may not be the PI of a project.

- They must specify their mentor as PI while setting up their protocol in InfoEd such that the faculty mentor is listed on both pages 1 & 2.

- The Mentor must submit or approve the submission of the protocol, if a student submits it first.

- Completed Student and Faculty Investigator Agreement forms are to be uploaded to InfoEd where indicated.
  - They no longer need to be sent to the IRB Office in hardcopy with original signature.
Privacy

- Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.
Anonymity

• Webster defines it as the quality or state of being anonymous:
  1: not named or identified
  2: of unknown authorship or origin
  3: lacking individuality, distinction, or recognizability

• Additionally, for IRB purposes, we need to:
  • avoid the risk of deductive disclosure or other accidental disclosures by incomplete de-identification, especially in qualitative data
De-Identification

- Webster threw up its hands at this word
- It means what it sounds like, the removal of identifying information from the subject’s data
  - However, you must keep in mind the risk of deductive disclosure or other accidental disclosures by incomplete de-identification, especially in qualitative data
Re-Identification

- Webster couldn’t cope with this word, either...

- It also means what it sounds like, the ability to reconstruct a participant’s identity from study data:
  - usually through **deductive reasoning** (deductive disclosure) across several data points,
  - sometimes through **accidental disclosure** in one or more data points, especially in qualitative data,
  - sometimes with the aid of bio-infomatics or other databases.

- This will be harder to guard against as technology advances. It is already much tougher to prevent re-identification than it was even 10 years ago.
Thanks for Listening!

Please feel free to contact me at lnoll@radford.edu or x5290