IRB 101
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Chair, IRB
Why do human subjects need protecting?
Protecting Human Subjects

Some examples:

- **1932-1972** - The Tuskegee Experiments where researchers withheld medication for African American prisoners with Syphilis.

- **1950's** – The Willowbrook experiment - Mentally retarded children housed at the Willowbrook State School in Staten Island, New York, were intentionally given hepatitis in an attempt to track the development of the viral infection. The study began in 1956 and lasted for 14 years.

- **1944-1980's** - The U.S. government sponsors secret research on the effects of radiation on human beings. Subjects were not told that they were participated in the experiments. Experiments were conducted on cancer patients, pregnant women, and military personnel.

- **1960** - Stanley Milgram conducts his "electric shock" experiments, which proved that many people are willing to do things that they consider to be morally wrong when following the orders of an authority. He publishes Obedience to Authority in 1974.
Federal Regulations

- Health and Human Services Policy for Protection of Human Subjects
- Title 45 – Part 46 (45 CFR 46)
- Compliance Oversight
  - Office for Human Research Protections (OHRP) in the Department of Health and Human Services (DHHS) – www.hhs.gov/ohrp
Purpose of These Regulations

- Ensure adequate protection of human participants in research by …
  1. Informed Consent
  2. Voluntary Participation
  3. Risk/Benefit Analysis (does the benefit outweigh any risk?)
  4. Anonymity/Confidentiality

- The IRB is responsible for ensuring all human subject research at SUNY Potsdam is in compliance with federal regulations and that studies are designed in a way that protects the rights of human subjects.
Informed Consent & Voluntary Participation

- Informed consent means that people who are participants in studies have consented/agreed to do so after being given information about the purpose of the study, the potential risks, and a statement about that participation being voluntary.

- That agreement must be voluntary and without coercion/duress. Consider the following examples:
  - Is there duress when an employer asks employees to fill out a survey about their workplace climate?
  - Do potential participants have free choice when their professor asks their students to complete a survey about their research on indicators of intellectual ability?
  - Will participants feel inclined to provide consent when a company says “take our survey to earn the best customer service our company has to offer”, fearing if they don’t, that they will not receive the best customer service?
  - A chronically ill patient is offered free “experimental” treatment for their disease and would consent because the compensation is outstanding – this is coercion.

- Voluntary participation also means that participants can cease their participation in any or all parts of the study at any time, no questions asked.

- Participants must also know that any data collected about them will either be anonymous or remain confidential (accessed only by the researchers).
Risk Benefit Analysis

- The IRB is also responsible for ensuring the risks of participating in a study are minimal.
- If the risks are more than minimal, then the IRB’s job is to ensure the researchers minimize the risks and/or that the benefits of participation outweigh the risks.
  - **Minimal risks** → where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.
  - **Risks** → The probably of harm; physical, social, emotional, legal; as a result of participation in the study (loss of time, injury, recollection of traumatic events, etc).
  - **Benefits of participating in the study** relate to the value of the study outcomes; they are limited for participants, and typically great for society.
Anonymity and Confidentiality

- Anonymity – researchers are not collecting any information about a subject that could identify them in any way
  - No names, no ID numbers (including SSN), etc
- Confidentiality – that if researchers do collect identifying information that they will keep it anonymous/not link personal information to responses/data
  - Securing data in locked cabinets, password protected computers, destroying the data, not reporting names, reporting only group data
  - Use codes to connect subjects to data
Types of IRB Review

1. Exempt review
   - No risk, voluntary participation, no vulnerable subjects used, no sensitive topics, no international research, using secondary sources of human subjects data (as long as it isn’t identifying)
     - Examples: Research with de-identified records about human subjects, anonymous surveys, evaluating the use of accepted or revised standardized tests, testing or comparing a curriculum or lesson by observation in the classroom or interviews with teachers, surveying teachers, nurses, or doctors about a technique or outcomes, interviewing public officials about a local or global issue, analyzing census data, most studies involving no interaction with subjects, sampling textures/tastes/smells, etc of food.
     - Researchers have to apply to the IRB Chair for an exemption (forms online)
2. Expedited Review

- Project involves no more than minimal risk (social/emotional risk, psychological risk, risk to reputation, risk of physical harm, etc) – there can be risk, but it must be minimal and the benefits must far outweigh them
  - Minimal risk in answering surveys about attitudes/beliefs/behaviors, finger pricks from healthy subjects,
  - Vulnerable populations aren’t being used
  - No coercion or deception
  - No sensitive topics
  - No international research
- Most survey research falls into this category
- Researchers apply to the IRB chair to request expedited review of a proposal; process typically takes 3 weeks from the time the app is sent to the committee to IRB approval
3. Full board review

- Involves more than minimal risk
- Any research with vulnerable populations (children, pregnant women, people with cognitive/physical disabilities, Veterans, prisoners – although SUNY Potsdam does not approve studies with prisoners)
- Data is being collected in another country
- Study uses deception
- Researchers apply to the IRB Chair and the full IRB (all board members) must review, discuss, and vote on the submitted protocol
- Deadlines for submitting apps for full board are available online
Who has to apply for IRB Review

- Any investigator conducting research with human subjects, specimens from human subjects, or secondary data sources from human subjects
  - What is research?
    - "...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge." [45 CFR 46.102(d)]
  - What is a human subject
    - “… a living individual about whom an investigator… conducting research obtains (1) Data through intervention or interaction with the individual, or (2) identifiable private information” (45 CFR 46)
How to Apply

- Contact the IRB Chair (x2688, SUNYPotsdamIRB@potsdam.edu) to determine what level of review your project requires
- Consult with your research team (note: Students can’t be principle investigators and will need faculty supervision)
- Start the application - Application forms are available online
  - http://www.potsdam.edu/faculty/research/rspo/irb
How to Apply

- **Deadlines:**
  - For applications requiring full board review, deadlines are posted here [http://www.potsdam.edu/faculty/research/rspo/irb/schedule](http://www.potsdam.edu/faculty/research/rspo/irb/schedule)
  - Exempt and expedited protocols are accepted on a rolling basis

- **When submitting your application**
  - Hard copy with original signatures and all appendices (to IRB Office, Satterlee Hall 231)
  - E-copy to [SUNYPotsdamIRB@potsdam.edu](mailto:SUNYPotsdamIRB@potsdam.edu)
What happens after I submit my application?

- **Exempt protocols** – the IRB Chair will review the application for exemption and if no revisions are needed, exemptions can be approved immediately.

- **Expedited protocols**
  1. The IRB Chair reviews and requests additional information from the Principle Investigator as needed.
  2. The IRB Chair forwards to the IRB for review (as needed) and requests comments.
  3. Comments are submitted to the PI (as needed).
  4. PI revises the protocol, resubmits to the IRB Chair for review.
  5. Note that this process of revision can continue until the protocol meets the human subjects protections outline in Title 45 – Part 46 (45 CFR 46).
  6. Once the protocol is IRB approved, the Chair sends the protocol to the Provost/Institutional Official for final approval.
What happens after I submit my application?

- **Full Board Review**
  1. The IRB Chair reviews and requests additional information from the Principle Investigator as needed
  2. The IRB Chair then forwards the packet to the IRB for review
  3. The IRB convenes to discuss the protocol
  4. The IRB votes to either approve, approve with minor modifications, request for resubmission with major revisions, or disapprove
  5. The IRB Chair forwards requests for revisions to the PI
  6. The IRB reviews the revised protocol
  7. **Once the protocol is IRB approved, the Chair sends the protocol to the Provost/Institutional Official for final approval**
How long will it take?

- It depends!
  - Exempt typically takes 1 week (depending on how many revisions to the protocol are needed)
  - Expedited typically takes 3 weeks (depending on how many revisions are needed)
  - Full board typically takes 4 weeks (depending on how many revisions are needed)
1. Consult with the IRB Chair before submitting your application packet
2. Include all appendices, surveys, scripts, consent/assent forms, and other relevant material in your application packet
3. Mark all questions with an answer or N/A
4. Ensure all investigators (including students) have completed the CITI training course. Information about that course can be found [http://www.potsdam.edu/faculty/research/rspo/irb/cititraining](http://www.potsdam.edu/faculty/research/rspo/irb/cititraining)
For more information

- About CITI training - Kathy LaMay, Research and Sponsored Programs, x2131, lamaykm@potsdam.edu.
- Everything else –
  - Kelly Bonnar, Chair
  - X2688, x3188
  - bonnarkk@Potsdam.edu