Obtaining IRB approval for class projects and assignments

Presented by the SUNY Potsdam Institutional Review Board
Workshop Purposes

- Identify the types of classroom projects and class assignments that require IRB review
- Describe the process for requesting IRB review for a classroom project or class assignment
- Describe instructors’ responsibilities when students are collecting data from humans, whether or not IRB approval is required
Campus Policy

- SUNY Potsdam Policy on the Use of Human Subjects in Research
  - SUNY Potsdam’s interpretation of federal regulations
  - Available on the IRB website
When is IRB review required?

In general, for class projects or assignments, for internships, student teaching or clinical/field experiences.
Any research involving human subjects

Research is

- “… a systematic investigation… designed to develop or contribute to generalizable knowledge.” (45 CFR 46)

A human subject is

- “… 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)
Why would a class project or assignment require review?

- If it involves students in the collection of data from or about people
  - May be subject to federal regulations
IRB Review is required if **ANY** one or more of the following is true:

- The project is more than a pedagogical exercise
- Subjects are exposed to more than minimum risk
- Subjects are members of a vulnerable population
If the project is more than a pedagogical exercise → IRB review required

- The project is intended to contribute to the discipline, address a theoretical issue or otherwise contribute to generalizable knowledge

OR

- The results of the project will be published or distributed outside of the class
If subjects are exposed to more than minimal risk
→ IRB review required

- Collects sensitive, personal, incriminating or potentially harmful information
- Manipulates behavior beyond range of typical daily life
- Involves physically or psychologically invasive contact
- Involves deception
IF subjects belong to vulnerable populations

→ IRB review required

- Children (under 18)
- Pregnant
- Cognitively impaired
- Socially, economically or educationally disadvantaged
- Disabled
- Prisoners
- Those with significant health problems
Why would an internship, student teaching or clinical/field experience require review?

- If it involves students in the collection of data from or about people
  - May be subject to federal regulations
internships, student teaching and other clinical and field experiences

- Data collection activities that are
  - part of the host organization’s normal operations or
  - initiated by the host organization and consistent with the host organization’s normal operations

- Typically do NOT require IRB review.
Any student project involving data collection that is not part of the host organization’s normal operations is considered a class project

- Subject to the class project policy and may be subject to IRB review

Any student data collection project that will be published or distributed is considered research

- Subject to IRB review
Whether or not IRB review is required
Instructor Responsibilities – 1

- Carefully consider whether or not the project requires IRB review
  - Consult with IRB Chair if any ambiguity

- Make this determination BEFORE the semester begins
  - Ideally, any IRB review will occur before the class begins to ensure IRB review does not delay project
Ensure that students are familiar with and follow ethical guidelines (e.g., voluntary, informed consent, confidentiality, etc.)

- If IRB review is NOT required:
  - CITI training OR another method

- If IRB review IS required:
  - All students must complete CITI training
  - Submit Appendix F signature sheet (list training completion date for each student)

- www.citiprogram.org
CITI Training

- Usually, students are required to take ONLY the CITI student course.
- Unless the class project is federally funded (NSF, NIH), RCR training is NOT required
- HIPS training is generally NOT required unless students will be working with private health records

- PLEASE ENCOURAGE STUDENTS TO READ THE INITIAL QUESTIONS IN CITI CAREFULLY SO THEY DO THE CORRECT MODULES!
Review and approve all data collection instruments, methods, procedures and consent forms PRIOR TO their use.

- Ensure that students are working within project guidelines and IRB approval (if required)
- Consult with IRB chair if there are changes
Instructor Responsibilities – 4

- Ensure that students obtain appropriate permission to gain access to other organizations or institutions they wish to involve in their projects
  - If IRB review IS required, complete Appendix E for and obtain permission letter from each organization/institution
Supervise the student researchers

- Monitor all research activities and progress

- IF IRB review was NOT required, ensure that
  - students do not expose subjects to any more than minimal risk
  - students do not collect data from or about vulnerable subjects.
If your students will be
  ◦ collecting data from people
or
  ◦ using information that has been collected from people who are currently living,

Then contact the IRB to determine whether or not your project requires IRB review.
IRB Review Process

For class projects/assignments
When to begin?

- Ideally, the IRB process occurs prior to the semester during which students will be engaged in the project.
- Note that the IRB is available to review proposals over the summer as well as during the academic year.
Instructor must have current CITI training

Refresher course required every two years
Application Requirements – 2

- Complete Appropriate Application Form
  - Exemption
    - Can be submitted ANY TIME
    - See Appendix A for eligible projects
  - Expedited
    - Can be submitted ANY TIME
    - See Appendix A for eligible projects
  - Full–Board
    - Must be submitted by deadline listed on website & in Reporter for discussion at next scheduled IRB meeting
      - Always use the on–line version of the application form!
Complete Relevant Appendices

- Appendix A – indicate category of project
- Appendix B – if there is a co-teacher / co-PI
- Appendix C – if project is funded
- Appendix D – if there is a conflict of interest
Application Requirements – 4

✗ Complete Relevant Appendices (continued)

✗ Appendix E – if there is another organization involved

✗ If organization has an IRB, attach a copy of the organization’s IRB’s approval of the project
✗ If organization has no IRB, attach a letter of permission from the administrator (director, principal, CEO, president, etc.) on letterhead with original signature.

✗ Appendix F

✗ Submit Appendix F with the application
✗ ONCE THE CLASS BEGINS, submit completed signature sheet (new form) OR an Appendix B signed by each student (old form)
Complete Relevant Appendices (continued)

Appendix G – if email will be used to solicit participants on campus

per State University of New York at Potsdam Policy on Soliciting Research Electronically

This is a new appendix – will be available soon

Intended to speed up the process for those using email to solicit participation in research on campus
Application Requirements – 6

- Include Relevant Attachments
  - Recruitment materials
  - Consent and Assent Forms (templates on website)
  - Data collection tools
Submit an electronic copy and a paper copy to IRB Chair
After the application is submitted

IRB decision, review by Institutional Official, renewal and completion
IRB Decisions

- Approval
- Deferred Approval Pending Minor Modifications
- Resubmission with Major Revisions Required
- Disapproval
Review by Institutional Official

- Once the IRB has approved the proposal
  - Application is audited for compliance by RSPO staff
  - Application is sent to Institutional Official for review and signature
  - Investigator is notified of approval in writing
Project Renewal and Completion

- Approval period is for no more than 12 months
- Renewal of approval may be requested twice
  - Summary of work to date required
- At end of third year, a new proposal must be submitted if project is to continue
  - Summary of work to date required
- Final report must be submitted when project is completed
Resources

- SUNY Potsdam IRB Website
  - [www.potsdam.edu/rspo](http://www.potsdam.edu/rspo) – select “Institutional Review Board” from menu on left

- IRB Chair and Members
  - Individual consultation
  - Presentations to classes & departments

- The Reporter
  - Proposal Deadlines & Meeting Schedule
  - IRB Decisions