WORKSHOP PURPOSES

- Answer your questions and discuss your concerns about the IRB review process
- Provide an overview of IRB regulations, policies and procedures
PURPOSE OF IRB REVIEW

 Insuring adequate protection of human participants in research via
  + Informed consent
  + Voluntary participation
  + Risk/Benefit analysis and efforts to minimize risk
  + Confidentiality

 Insuring institutional compliance with federal regulations governing research with human participants
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
SUNY Potsdam Policy on the Use of Human Subjects in Research

- SUNY Potsdam’s interpretation of federal regulations
- Available on the IRB website
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)
CAMPUS INSTITUTIONAL RESEARCH POLICY

- Institutional Research
  - part of a program or service evaluation
  AND
  - intended SOLELY for the purpose of monitoring or improving the effectiveness or quality of the program or service being evaluated and NOT for the purpose of contributing to generalizable knowledge about such programs (i.e., not published/distributed)
  AND
  - poses no more than minimal risk to participants
- Not subject to IRB review
WHEN IN DOUBT...

- If you are 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
Full-Board Review

- Required for all research involving vulnerable populations, more than minimal risk, deception, work in another country, remuneration for participation and other categories specified in federal regulations and campus policy
- Proposal discussed at IRB meeting
- Investigator invited to attend
TYPES OF IRB REVIEW

 Expedited Review
 + To qualify for expedited review, research must pose no more than minimal risk to participants AND fall into one of the eligible categories listed in the federal regulations, which include
   - collection of data about individual or group characteristics or behavior
   - research using survey, interview or focus group methodology
   UNLESS the research involves deception, vulnerable populations, remuneration for participation or work in another country

 + Proposal reviewed by IRB Chair
 + Input typically sought from IRB membership
 + Federal regulations & campus policy specify eligibility criteria
Review for Certification of Exemption

- To qualify for certification of exemption, research must pose no more than minimal risk to participants AND fall into one of the eligible categories listed in federal regulations, which include:
  - Research using survey procedures if the participants are elected or appointed public officials or candidates for public office
  - Study of existing data, if the source is publicly available or the information is recorded in such a way that subjects cannot be identified

- Proposal reviewed by IRB Chair
- Input may be sought from IRB membership
- Federal regulations & campus policy specify eligibility criteria
APPLICATION REQUIREMENTS

- Complete training
  + Must be CITI training (available through IRB website)
  + Complete update every two years
- Complete Application Form & Relevant Appendices and Include Necessary Attachments
  + Consent and Assent Forms (templates on website)
  + Recruitment materials
  + Data collection tools
- Submit an electronic copy and a paper copy to IRB Chair
IRB DECISIONS

- Approval
- Deferred Approval Pending Minor Modifications
- Resubmission with Major Revisions Required
- Disapproval
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 - select “IRB”
- IRB Chair and Members
  - Individual consultation
  - Presentations to classes & departments
- The Reporter
  - Proposal Deadlines & Meeting Schedule
  - IRB Decisions