Conducting Human Subject Research at the University at Albany

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Institutional Review Board (IRB)
Office of Regulatory and Research Compliance (ORRC)

- IRB reviews all proposed human subject research
- IRB allows University to use federal funds for human research
- ORRC provides operational support to the IRB
- ORRC ensures compliance with federal/state/university requirements
- ORRC provides resources, education and support to investigators

Presentation Overview

I. History of Human Research Ethics
II. What is Human Subject Research?
III. IRB Review of Human Subject Research
IV. Ethics training, forms and templates

I. A (Very) Brief History of Human Research Ethics

A Brief History of Research Wrongs (Germany)

1939-45: Nazi scientists experiment on concentration camp prisoners

1945-46: Nuremberg Trials of Nazi war criminals

1947: Nuremberg Code (Counsel for War Crimes)

- Scientifically necessary
- Voluntary and informed consent
- Conducted by qualified personnel
- Risk should not exceed benefit
- Right to withdraw without penalty

A Brief History of Research Wrongs (USA)

1932-1972: Tuskegee syphilis study (US Public Health Service)

Research passed off as medical care, diagnosis/treatment withheld

1939: The Monster Study (U Iowa)

Orphans given positive/negative speech therapy, permanent stuttering resulted

1963: Willowbrook Hepatitis study (Yale, NYU)

Institutionalized disabled children intentionally exposed to hepatitis

1971: Stanford Prison Experiment (Stanford U, Palo Alto Police)

College students in prison/guard roles, not voluntary, halted due to trauma

Development of Research Ethics (USA)

1974: National Research Act (first federal protections)

- National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research

1979: The Belmont Report (ethical principles)

- Respect for Persons: subjects voluntarily choose to participate after being given adequate information about the research
- Beneficence: all reasonable steps are taken to mitigate any potential for harm resulting from the participation in research
- Justice: the selection of participants is fair to all, and "vulnerable subjects" are given extra protection

Development of Research Ethics (USA)

1981: "The Common Rule"

- Requirements for assuring compliance by research institutions
- Requirements for obtaining and documenting informed consent
- Requirements for Institutional Review Board (IRB) membership, function, operations, review of research, and recordkeeping.

1991: 45 CFR 46 ("the regs")

- The Common Rule incorporated into Code of Federal Regulations
- Added protections for pregnant women and fetuses, prisoners, children and other "vulnerable subjects."

II. What is Human Subject Research?

Human Subject Research (45 CFR 46)

Research

A systematic investigation that is designed to develop or contribute to generalizable knowledge

Human Subject

A living individual about whom an investigator obtains data through intervention or interaction or [by obtaining their] identifiable private information

Research Interventions and Interactions

- Physical procedures (blood collection from finger stick)
- Behavioral test or task (word recognition test, role-playing task)
- Manipulation of subject environment (stimuli, staging)
- Study of individual/group characteristics (survey, interview)
- Any interaction between investigator and subject for research purposes

Research Involving Private Information

- Access to information provided for specific purposes, usually to an institution, with the expectation that it will not be shared publicly (e.g., medical, employment or financial records)
- Information collected in contexts where people don't expect to be formally observed or recorded for research purposes (e.g., engaged in a personal conversation, participating in a support group)

University Policy on Human Subject Research

- No research with human participants, including the recruitment of participants, may begin until the Institutional Review Board (IRB) has reviewed and ***approved*** the research.
- All individuals who will be involved in the conduct of research involving human participants must first receive training in the ethical conduct of such research before they are permitted to engage in research activities.

When is someone conducting human subject research?

When any University-affiliated person performs any of the following tasks on projects that meet the definition:

- Recruiting people to participate
- Obtaining Informed Consent from participants
- Administering research interventions or otherwise interacting for research purposes
- Accessing identifiable human subject data
- Serving as an advisor to a student researcher

III. IRB Review of Human Subject Research

The Institutional Review Board (IRB)

Volunteer ethics board of scientists and non-scientists that reviews and approves, disapproves or requires changes in human subject research proposals by applying:

- Ethical principles of The Belmont Report
- Federal regulations for protection of human subjects
- State and local laws
- University policies

IRB Submission and Review Process

1. Investigator completes required ethics training (CITI program).
2. Investigator creates application using the IRB's standard forms. Protocol must describe how the research affects human subjects with enough detail for IRB to perform its ethics review.
3. Research Compliance Administrator (RCA) works with investigator to ready the protocol for IRB review.
4. IRB reviewer(s) may ask questions or request modifications, which RCA communicates and facilitates.
5. Once all concerns are satisfied and/or revisions are complete, IRB makes a determination.

IRB Review Criteria

- Risks are balanced by benefits
- Risks are minimized to the greatest extent possible
- Subjects are recruited and selected fairly
- Subjects are given the opportunity for Informed Consent
- Informed Consent is appropriately documented
- Subjects' privacy and the confidentiality of their data are protected
- There are appropriate safeguards for vulnerable populations

Developing the (Human Subject Protection) Protocol

Provide enough detail for the IRB to perform its ethics review:

- WHY is this study is being done? [Study purpose]
- WHO is being studied and WHY? [Inclusion/exclusion criteria, study purpose)
- HOW will prospective subjects be recruited? [Flyer, ad, email listserv]
- HOW will subjects provide their consent? [In person, online]
- WHAT will subjects be asked to do? [Research methods]
- WHERE will subjects undergo research procedures? [Research sites]
- HOW long will participation take? [Time cost]
- WHAT are the benefits and risks of participation? [Study purpose, safety, security]
- HOW will the risks be mitigated? [Safety plan]
- HOW will the privacy of subjects and their data be protected? [Data security plan]

Tips for Education Researchers

- Research design: interventional, observational, secondary analysis of data
- Recruiting must be opt-in; subjects contact YOU to participate
- Consent/permission/assent must be opt-in; there is no “passive” consent
- For adults, use standard Informed Consent process
- For minors and K-12 students, use Parental Permission + Child Assent processes
- Child Assent must be age-appropriate; no form/signature for younger kids
- Distinguish required educational activities from optional research activities
- Explain how you will protect subjects’ privacy & confidentiality of their data
- Plan classroom activities/compensation for participants AND non-participants
- If recording, include ONLY consented participants who gave permission
- Know the school/district policy for approval of research and “site permission”

IV. Ethics training, forms and templates

Ethics Training for Human Subject Researchers

- CITI program: online training for human subject researchers
- Create and manage your CITI account: www.citiprogram.org
- Take the ethics course for human subject researchers:

  "Human Subject Research (Investigators, Advisors)"

IRB Submission Forms and Instructions

https://www.albany.edu/orrc/

IRB Forms & Documents

Institutional Review Board (IRB) Forms & Documents

Does my project/research need to be reviewed by the IRB? If you are unsure you may contact the IRB or submit the **Screening Form** for a quick evaluation.	
Project **Screening Form** to determine if IRB review is required	Word

Applying For an IRB Exemption	
Federal regulation and university policy provide that certain human research activities may be eligible for a determination of "exempt" status by the IRB. A Principal Investigator must obtain such a determination from the IRB prior to initiating the study. An exemption from IRB review does not equate to an exemption from other prevailing regulations, laws, or university policies	
Application for IRB Exemption	Word
IRB Exemption Guidelines	Word
Additional Key Personnel for Initial or De Novo Submission	Word

Applying for IRB Review and Approval	
IRB Protocol Submission Form	Word
Additional Key Personnel for Initial or De Novo Submission	Word
Modification Request	Word
Change or Replace Principal Investigator	Word
Add or Delete Key Personnel	Word

Hours of Operation
Monday through Friday
Summer Hours:
May 15th-Sept. 1st
8:00am-4:00pm

Email Pre-Award
Phone: (518) 437-4550
Fax: (518) 437-4560

Email Compliance
Phone: (518) 437-3850
Fax: (518) 437-3855

Email the Director

SPIN

Quick Links
IRB Forms
IACUC Forms
CITI Training
COEUS
Laboratory Safety
Institutional Biosafety Committee
Radiation Safety Committee

Informed Consent for Research Participation	
Informed Consent Quick Guidance	Word
Informed Consent Guidelines	Word

Supplemental Forms Additional documents or forms that may be required for your submission	
Research involving **Sensitive Topics** (e.g., Sexual Behavior, Illegal Conduct, etc.)	Word
Research using **Deception**	Word
Research involving **Electronic/On-Line Data Collection**	Word
IRB Data Management Policy	PDF
Data collection using **Focus Groups**	Word
Research conducted in **International Settings**	Word
Research involving **Children as Participants**	Word
Use of the **Psychology 101 Participant Pool**	Word
Research involving use of **Experimental Equipment**	Word
Oral History or Ethnographic/Naturalistic Research	Word
Use of **Secondary/Existing Data**	Word
Research Conducted at **UAlbany Campus as Data Collection Site**	Word
Research involving use of **Human Tissue Samples**	Word

Questions?

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