RIT

Protecting Research Subjects

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Human Subjects Research Office | RIT

Research at RIT

- Plastic changes in Vision
- Leadership in Cross-Cultural Teams
- The Climate of ASL Profession: ASL Pedagogy, Curriculum and Assessment
- Social Media's Impact on Self-Perception of Weight and Appearance
- Progressing Eye Tracking Systems: Eye Image Collection for a Comparison in Techniques and Data Quality

Compliance Standards

- **The Federal Government mandates standards for the protection of human subjects.**

- **OHRP – Office of Human Research Protections**
  - Code of Federal Regulations, Title 45 CFR Part 46. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.htm

- **RIT maintains certain standards as well**
  - Agree to adhere to Federal Regulations
  - RIT Policy for the Protection of Human Subjects in Research https://www.rit.edu/academicaffairs/policiesmanual/c050

Are you conducting research with human subjects ?

To decide we ask two questions:

1.) Are you conducting research?

AND

2.) Are you working with information or biospecimens from a living person?

Question 1 “Research”

“Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” 45CFR46.102

- Information can go beyond the setting you collected it in and can be replicated by others in other settings
- Will add to a field of study
- Benefits always extend beyond the participants

Question 2 “What is a Human Subject?”

- **A living person from whom we obtain information or biospecimens.**
  - **Intervention** (physical procedures, manipulation of the subject or their environment)
  - **Interaction** (communication or interpersonal contact between subject & researcher)
  - **Identifiable Private Information** (the identity of the subject is or may readily be ascertained by the investigator or associated with the information)

Regulations and Ethics

Guiding Principles

- **Three principles guide the ethical conduct of research with humans. Derived from "*The Belmont Report*"**
  - **Respect for Persons (autonomy)** Individuals should be treated as autonomous agents, capable of deliberating and making decisions on their own.
  - **Beneficence** Researchers are obligated to minimize possible harm and maximize possible benefits.
  - **Justice** Research participants should be treated fairly and risks and benefits evenly distributed.

Steps to Protecting Subjects

1. **The Risk/Benefit Ratio - Risks to subjects must be reasonable in relation to the anticipated benefits**

2. **Have you identified all of the potential risks?**
   a. Privacy & Confidentiality
   b. Physical
   c. Psychological
   d. Social and Economic

3. **Are risks minimized as much as possible?**

4. **Are there plans to monitor data collection to identify issues before they become dangerous?**

Potential Risk Areas

Privacy & Confidentiality

- Under certain circumstances, an invasion of privacy or breach of confidentiality may present a risk of serious harm to subjects

- For example, when the researcher obtains information about subjects that would jeopardize their job or lead to their prosecution for criminal behavior if that information was disclosed by the researcher or accessed by people not on the research team

Protecting Confidentiality

- Confidentiality relates to the treatment of information that an individual disclosed in a relationship of trust. They expect that it will not be divulged to others in ways that conflict with what you tell them in the informed consent process.
- More elaborate procedures may be necessary in studies on sensitive matters to give subjects the confidence they need to participate and answer questions honestly.

1. Confidentiality & Privacy Risks

IDENTIFY

- What methods are being used to obtain information and how is subject identity vulnerable

WAYS TO MINIMIZE RISKS

- Restrict data access to certain people, password protect files and mobile drives
- Remove names, use code numbers for subjects
- Locked or restricted access to stored paper files
- Careful consent form distribution and survey collection
- Careful use of identifiable quotes and data in presentations or reports, discuss data in an aggregate

2. Physical Risks

IDENTIFY

- Minor pain, discomfort, injury

MINIMIZE

- Well defined inclusion/exclusion criteria
- Well defined procedures
- Pre-screening subjects for injury /sensitivity
- Having safety plan in place

3. Psychological Risks

IDENTIFY

- Temporary anxiety and distress, relapse, or triggering of behavioral disorder

MINIMIZE

- Get input from specialists while designing study
- Pre-screen or alert subjects to potentially disturbing material
- Acknowledge potential discomfort and offer appropriate counseling or support services, offer debriefing to determine if subject needs assistance
- Insert questions or opportunities to asses subjects

4. Social and Economic Risks

IDENTIFY

- Research on sensitive, stigmatizing, or illegal topics may require additional protections (e.g. substance use, STI status, domestic violence)

MINIMIZE

- Consider data collection sites and circumstances
- Comprehensive data safety practices
- Careful discussion of results

Informed Consent & Recruitment

The Belmont Report – Respect for Persons

- Informed consent is an ongoing, educational process
- Objectives of the consent process are to:
  - Inform prospective subjects as clearly as possible
  - Ensure their free choice to participate
- **Unless a waiver is granted, all RIT human subjects research includes consent information – it may look different because it will depend on how the subject and researcher interact.**

Required Elements of Informed Consent

1. Purpose of the Research and Procedures
2. Risks and Discomforts
3. Anticipated Benefits
4. Confidentiality (how you will protect their information)
5. If the research is greater than minimal risk
6. Persons to contact if subjects have questions
7. Voluntary participation, right to refusal or withdrawal with no penalty

Keep in Mind:

- Consent – Obtained from adults over age 18 (in NYS)
- Assent – Agreement from children
- Parental Consent – Consent from parent or guardian for their child to participate
  - Research with children requires parental consent AND assent from child
- **All subjects participate in the consent process and receive written information**

Consent Process Design

Elements of the consent process/form

- **Title of project, name and contact info (include advisor for student research)**

- **Defined sections:**
  - Purpose
  - Procedures/What will happen if you take part
    - Detail about what happens and when - tasks, activities, surveys, etc.
  - Risks/Benefits

Defined sections continued:

- Confidentiality –
  - what you are doing to keep their data safe; where and how you are sharing the results (quotes, anecdotes, description of subjects?)
- Rights as research participant (voluntariness)
- Incentives
- Directions for questions, withdrawing from study
- Signature line for Non-exempt research and some Exempt

Key Information Section for Non-exempt research

Recruitment Materials

Anything used to advertise the study

- Flyers, emails, social media posts, announcement in class
- Include purpose
- Any inclusion/exclusion items
- Special requirements – clothing, devices
- Don’t make incentive the main focus
- Include title of study and contact information in every message

Training

CITI Training

- HSRO website's Training page https://www.rit.edu/research/hsro/training
- This explains how to register and pick your course(s)
- For Human Subject Protections you ONLY need to complete one HSR course of your choosing
  - Biomedical Research Investigators *or*
  - Social and Behavioral Research Investigators
- CITI has additional courses that you can take (RCR, GCP, etc.)

Similarities of Soc/Beh & Biomedical Modules

- **Both:**
  - Belmont Report
  - History and Ethical Principles
  - Informed Consent
  - Populations requiring additional considerations
  - Conflicts of Interest
  - Recognizing and reporting unanticipated problems

Differences

Social/Behavioral

- Defining research with human subjects
- Federal regulations
- Assessing risk
- Privacy & Confidentiality

Biomedical

- Soc/Beh research for biomed researchers
- Records based research
- FDA regulated research
- Research and HIPAA

Review Process

Classifying Submissions

Research activities with humans are submitted and reviewed by the HSRO (Form A)

Excluded Category

Activities that don't fit the definition of research with human subjects. Not under the scope of the HSRO.

Exempt Research

Activity falls into *Exempt* category
Considered research
Category determined by HSRO

Expedited Research

Activities that fit in an *Expedited* category

Board Reviewed Research

Activities that go before the IRB

Review Process

- Initial Review in Human Subjects Research Office
- Response from HSRO to Investigator
  - Possible request for additional information, clarification
  - If necessary, materials may be sent on for additional review
  - If approved, Investigator can proceed
- If research requires review by Institutional Review Board a meeting is convened and Investigator may be asked to attend

Federal definitions at 45CFR46.102

- (2) *Intervention* includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.
- (3) *Interaction* includes communication or interpersonal contact between investigator and subject.
- (4) *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and can reasonably expect will not be made public (e.g. medical record).
- (5) *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

- ***(b) Clinical trial*** **means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.**

- **(e)(1) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:**

  (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

  (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

- **(j) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.**