

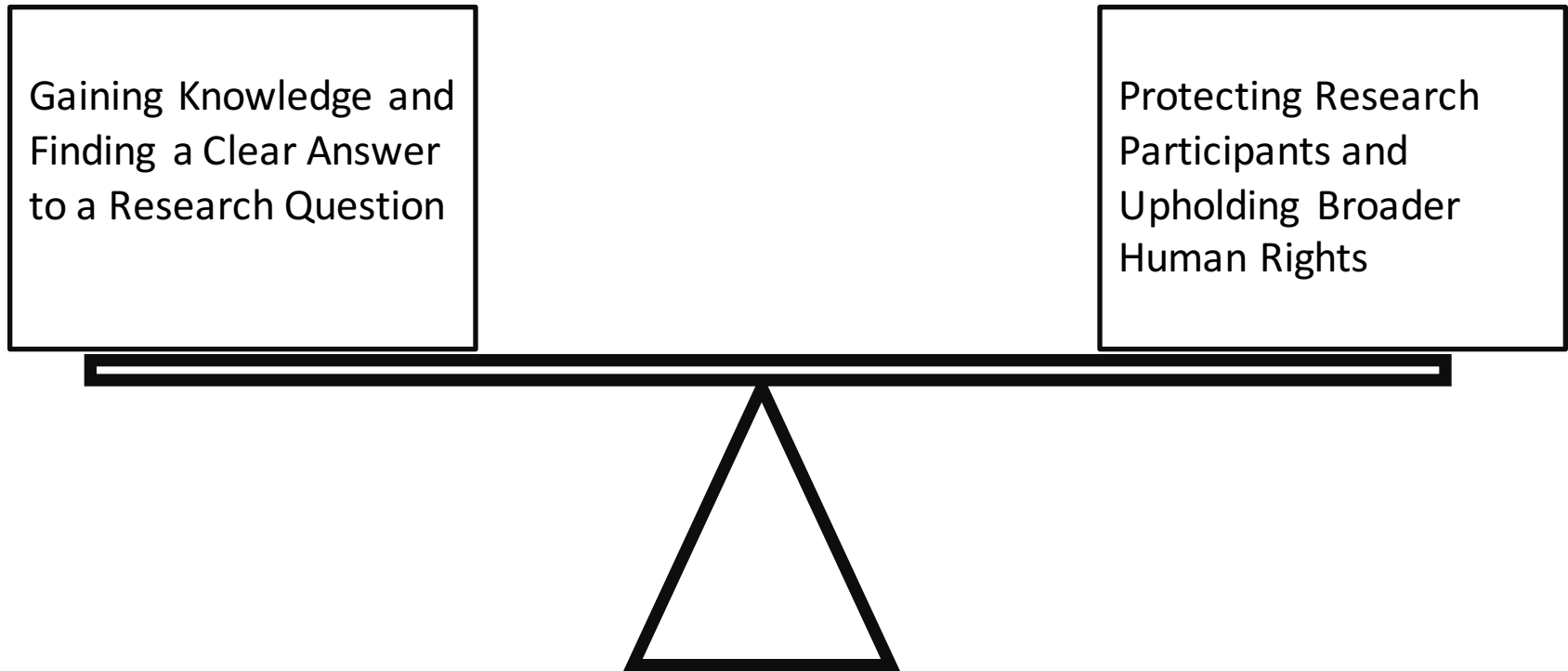
Research Involving Human Subjects

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CIAS Scholarship, Creativity & Research Strategic Plan
Implementation Committee Chair

Balancing Research Priorities



Source: *Understanding Research* by W. Lawrence Neuman, 2009. Pearson Education.

Most Common Causes of Unethical Research Behavior

- Lack of Awareness
- Pressure to Take Ethical Shortcuts

Source: *Understanding Research* by W. Lawrence Neuman, 2009. Pearson Education.

Research Involving Human Subjects

- History of Abuse
- Total Protection for Research Participants with Absolute Noninterference Would Make Research Impossible
- Balance is Necessary

Source: *Understanding Research* by W. Lawrence Neuman, 2009. Pearson Education.

Human Subjects?

- Intervention
 - Physical Procedures
 - Interventions Such as Diet and Exercise
- Interaction
 - Communication
 - Interpersonal Contact Between Subject and Researcher
- Identifiable Private Information

Human Subject Research

- Not all situations where information is gathered from individuals are considered “research with human subjects”
- Depends on intent: Why you’re asking the question and what you’re going to do with the data

Guiding Principles for Ethical Conduct by Researchers

- **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.

Identify and Minimize

- Physical Risks
- Psychological Risks
- Confidentiality and Privacy Risks

Informed Consent

- **Research Participation Must be Voluntary and Informed**
 1. **Purpose of the Research and Procedures**
 2. **Risks and Discomforts**
 3. **Anticipated Benefits**
 4. **Confidentiality (how their information will be protected)**
 5. **When there is greater than minimal risk**
 6. **Persons to contact if subjects have questions**
 7. **Voluntary participation, right to refusal or withdraw with no penalty**

RIT Human Subjects Research Office

- The Human Subjects Research Office (HSRO) was established to *safeguard the rights and welfare of all human subjects who participate in research projects conducted at RIT*. In compliance with Federal law and institutional policy, all research activities involving human subjects or human material must be submitted to the HSRO. Research activities conducted by the faculty, staff, and students of RIT, or outside researchers gathering data at RIT, are subject to the [Policy for the Protection of Human Subjects in Research](#), RIT's official policy in the Institute Policies and Procedures Manual.

HSRO Approval Process Begins with Submission

- **Complete the Form A**

http://www.research.rit.edu/formsagreements/docs/irb_form_a.doc

- **Attach Supporting documents**

Supporting documents

http://www.rit.edu/research/hsro/pdfs/submission_checklist.pdf

- Abstract in every-day language
- Data collection tools – surveys, interview questions, etc.
- Appropriate informed consent documents
- Any tasks you ask subjects to do
- All means of communication with prospective subjects (advertisements, emails, invitation letters, etc.)
- Letter of support if working in a school or similar setting
- Evidence of Human Subjects Protections Training
 - <https://www.citiprogram.org/>

HSRO Review

- Response to Investigator (three to four business weeks)
 - Possible request for additional information, clarification
 - If approved, Investigator can proceed
- If necessary, materials may be sent to IRB Chair for review
- Following review, response to Investigator
 - If approved, Investigator can proceed
 - If deferred:
 - Investigator may need to provide additional information or revisions to protocol, then subsequent review and decision

CITI Training

- Go to HSRO website's Training page

<https://www.rit.edu/research/hsro/training>

This explains how to register and pick your course(s)

Why RIT Protects Human Research Participants

- Promote the Safety and Well-being of Human Participants in Research
- Maintain the ethical values and principles underlying sound research
- Ensure scientifically valid research

HSRO Approval Process

- Protects RIT
- Protects Human Subjects
- Protects Students and Staff
- Protects You as the Researcher

- Is NOT Optional, Unnecessary, Silly, Overly Legalistic, Redundant, or Burdensome

More Information

<https://www.rit.edu/research/hsro/>

Questions regarding research activities, determining whether an activity requires review by the IRB, and training should be directed to:

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