Human Subjects Research

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Belmont Report

- Respect for Persons (Autonomy)
  - Informed Consent
  - Protect vulnerable subjects
- Beneficence
  - Do Not Harm
  - Maximize benefit and minimize harm
- Justice
  - Equitable selection of subjects
  - Benefits and risks of research must be distributed fairly in society
University of Rochester
Office for Human Subject Protection (OHSP)
www.rochester.edu/ohsp

Director OHSP: Kelley O’Donoghue

- Research Education & Training
  Director: Kelly Unsworth

- Research Subjects Review Board (RSRB)
  Director: Tiffany Gommel

- Quality Improvement
  Director: Kathleen Wessman

- Regulatory Systems
  Director: Thai Nguyen
Research Subjects Review Board
"... to protect the rights and welfare of human research subjects at the University of Rochester. To accomplish this, we review, approve the initiation of, and conduct periodic review of research involving human subjects."

Research Education and Training
"To assist researchers in protecting the rights, welfare and safety of human subjects by providing educational opportunities and resources..."

Research Quality Improvement
- To assure the rights and wellbeing of human subjects are protected
- To educate researchers about how to improve study conduct
- To assess research risk areas
- To provide resources to the Research Community

Policies & Guidelines

100 - General Administration

200 - Research Education

300 - RSRB Scope and Organization

400 - RSRB Functions and Operations

500 - Review of Research

600 - Reviews Requiring Special Consideration

700 - Informed Consent And HIPAA Privacy Rule

800 - Reporting to RSRB

900 - Responsibilities of Investigators

1100 - Miscellaneous Guidelines
Institutional Review Board (IRB)

- **Purpose**
  - to *review research* to determine if the *rights and welfare* of human subjects involved in research are adequately protected.

- **Authority**
  - Initial Review - approve, disapprove, require modification
  - Monitor research - Consent process, Changes/amendments, Continuing review, Reportable events
3 Different Levels of Review

**Exempt - Little to No Risk**
- Surveys, focus groups, educational research, secondary use of de-identified pre-existing data
- Review/confirmation of exemption by RSRB Staff

**Expedited or “designated’ - Minimal Risk**
- Non-Invasive procedures & collection of biological specimens, blood draws
- Review/approval by RSRB Chair or designee

**Full Board - Greater than minimal risk**
- Invasive procedures, drugs/devices, significant amount of blood drawn, any amount of radiation
- Review/approval at a convened meeting
Informed Consent Process

- Information - contains the information needed for a *reasonable* person to make a decision
- Comprehension - provided in understandable language
- Voluntary - free from coercion
Informed Consent Process

A process of information exchange that takes place between the prospective subject and the investigator, **before**, **during** and sometimes **after** the study

- Recruitment
- Phone or in-person screening
- One-on-one time with potential subject
- Reading the consent
- Assessing the subject’s comprehension of the material
- Reconfirming consent throughout the study
1st Step – Investigator Education

- Require training in human subjects research
- Conducted through Collaborative Institutional Training Initiative (CITI Program) - [www.citiprogram.org](http://www.citiprogram.org)
  - Greater Than Minimal Risk Biomedical
  - Greater Than Minimal Risk Behavioral
  - Minimal Risk
- Additional educational materials available:
  - [www.rochester.edu/ohsp/education](http://www.rochester.edu/ohsp/education)
- Questions: contact the Director, Kelly Unsworth at (585) 275-5244
Research Education and Training

Purpose:
To assist researchers in protecting the rights, welfare and safety of human subjects by providing educational opportunities and resources in research ethics and human subject safety, with an emphasis on proper and responsible conduct of human subject research.

Goals:
- To enable study teams to conduct human subject research in compliance with Federal regulations, institutional policy and good clinical practice thereby mitigating risks to human subjects.
- To cultivate high quality research through study team support and outreach.
2nd Step – RSRB Submission

- Web-based submission system
  - ROSS (RSRB Online Submission System)
- ROSS Training offered 3rd Monday of every month
- Protocol and Consent form templates available
  - [www.rochester.edu/ohsp/rsrb](http://www.rochester.edu/ohsp/rsrb)
- Questions: contact the main office (585) 275-2398
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Protocol Templates

- Protocol Template Biomedical
- Protocol Template Non-Biomedical
- Protocol Template Specimen and Record Review
- Protocol Template Exemption Requests
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Consent Form Templates

To reference the Informed Consent Guidance document click here.

| Consent Form for Biomedical Study |
| Consent Form for Behavioral Study |
| Permission Form |
| Assent Form for 13-17 year olds |
| Assent Script for 8-12 year olds |
| Consent Addendum |
| Information Sheet |
The Principal Investigator (PI) is the individual who has full and final responsibility for the conduct of the research.
Policy 901 Investigator Responsibilities

• Purpose: To ensure research is conducted in accordance with the Office for Human Subject Protection (OHSP) and University policies and guidelines, as well as federal regulations, as applicable.
  – To ensure the rights, safety, and welfare of research subjects are protected during the study and after the study is complete
  – To ensure the integrity of the data collected
Summary Pages

• Policy is required to explain all requirements
• Problem: *Not very user-friendly*
• Single page “summary”
  1. Exempt
  2. Non-FDA Regulated
  3. FDA Regulated
• Each summary broken down by phase of the study
  – **Before** the research begins
  – **During** the conduct of the research
  – **After** the research is complete
400 - RSRB Functions and Operations
500 - Review of Research
600 - Reviews Requiring Special Consideration
700 - Informed Consent and HIPAA Privacy Rule
800 - Reporting to RSRB
900 - Responsibilities of Investigators

Policy 901: Investigator Responsibilities
Exempt Responsibility Summary Sheet
Non-FDA Regulated Responsibility Summary Sheet
FDA-Regulated Responsibility Summary Sheet
Guideline for Investigators Leaving the Institution
Policy 902: Investigator Conflict of Interest
Investigator Guidance

1100 - Miscellaneous Guidelines
QUESTIONS?