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

Login

ROSS Login

Board Member Resources

Policies/Guidelines

OHSP

HIPAA

Tools

OHSP Newsletters

Who's My Specialist

Feedback

Acronyms

Additional Resources

Assurances

University of Rochester
FWA00009386

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
  - Greater Than Minimal Risk Biomedical
  - Greater Than Minimal Risk Behavioral
  - Minimal Risk
- Additional educational materials available:
  - www.rochester.edu/ohsp/education
- Questions: contact the Director, Kelly Unsworth at (585) 275-5244

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Human Subjects Training

Initial Certification

Recertification

GCP Training

Education & Training

Education & Training Opportunities

Supplemental Training

Seminars

Professional Certification

Listserv Signup

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
- Questions: contact the main office (585) 275-2398

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RSRB Information

Policies & Guidelines

Compensation for Injury

Fee Schedule

Protocol Templates

Protocol Template Biomedical
Protocol Template Non-Biomedical
Protocol Template Specimen and Record Review
Protocol Template Exemption Requests

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Payment to Research Subjects(Finance)

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

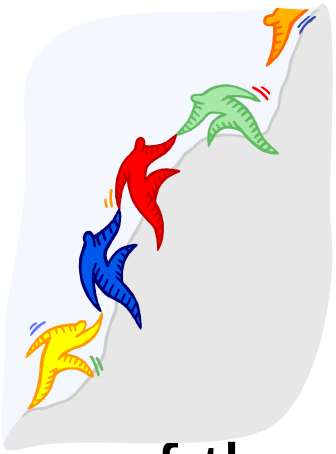
The Principal Investigator (PI) is the individual who has full and final responsibility for the conduct of the research.

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

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Additional Resources

Assurances

University of Rochester
FWA00009386
Expires: November 20, 2018
Read the Assurance.

Highland Hospital
FWA00002728
Expires: May 16, 2018
Read the Assurance.

- 400 - RSRB Functions and Operations
- 500 - Review of Research
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- 700 - Informed Consent And HIPAA Privacy Rule
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- 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?