Human Subjects Research

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Belmont Report

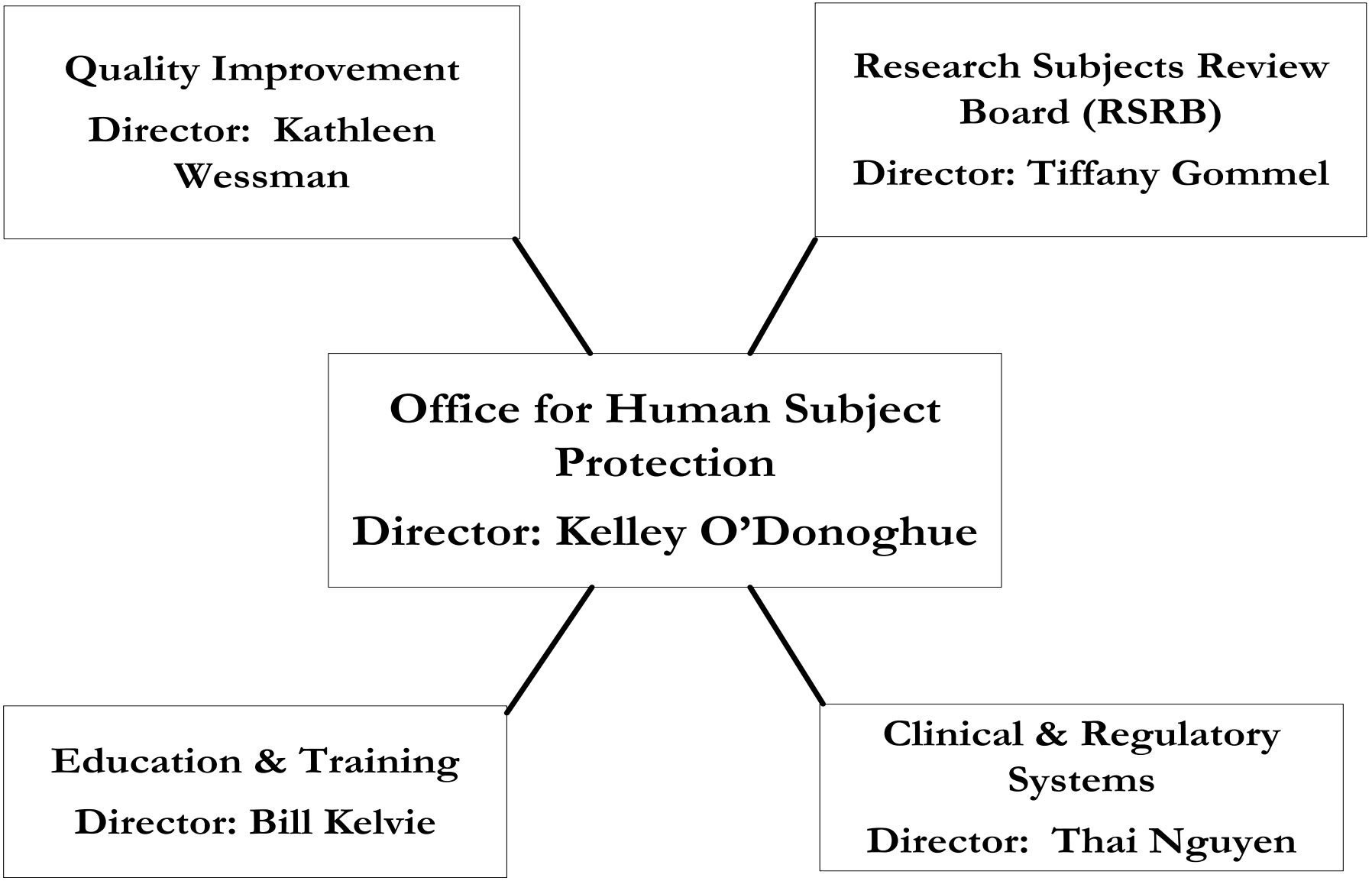
- In response to Tuskegee in 1974 Congress passed the National Research Act, which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

- 1979 –Belmont Report
  - 3 principles for the ethical conduct of research

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

OHSP Structure



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

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


http://www.rochester.edu/ohsp/#
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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
Next Seminar...
January 29,2013
ROSS Training ....
RSRB ROSS training 3rd Monday of every month from 2pm to 3pm.
Please Click HERE to sign up.
Quality Improvement
"To assess and assist the Investigator (PI) in assuring the rights and wellbeing of human subjects are protected and that the study is being conducted in accordance with IRB requirements, the approved protocol, applicable Federal regulations, U of R policies and best practice (GCP) standards."
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Acronyms
Office for Human Subject Protection
University Commitment to Ethical Research
In the conduct of research involving human subjects, the University of Rochester is guided by the ethical principles stated in the Belmont Report. The University's fundamental commitment to the protection of human subjects applies to all human subject research conducted by University faculty or staff, regardless of funding source or site of the research. The University follows the Department of Health and Human Services (DHHS) regulations at 45 CFR Part 46, and the Food and Drug Administration (FDA) regulations at 21 CFR Parts 50 and 56. In developing its policies and procedures, the University considers the guidance provided by the
http://www.rochester.edu/ohsp/#
Trusted sites
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QUESTIONS?