The Research Subjects Review Board (RSRB)

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October 22nd, 2010

What is Institutional Review Board (IRB) ?

- A University established system of ethical review boards (RSRB) to review research projects involving human subjects.
- Primary function is to protect the rights and welfare of human subjects
- Assist investigators in the process

Note: Investigator bear the primary responsibility for ensuring the research protocols meet the standards established by federal and state regulations and University policies.

When must RSRB review research?

- Initial – prior to enrolling or recruiting subjects
- Continuing review – at least annually
- Prior to initiating changes to approved research.

Researcher Certification - OHSP

- EPRP – Ethical Principles in Research Protection:
  - Required of all investigators conducting research involving minimal or lesser risk.
- HSPP - Human Subjects Protection Program:
  - Required of all investigators conducting research that involves greater than minimal risk.

Contact OHSP (Office of Human Subject Protection) at 3-4127

Research subjects" is the term employed by the Belmont Report, on which the RSRB bases its procedures.

What is Research?

- *A systematic* investigation (a study design in the form of a protocol or study plan)
- A contribution to *generalizable* knowledge (plan to contribute new knowledge to science and society)
  - ***Need both to qualify as "research"***

What is a Human Subject?

- Living individual about whom an investigator conducting research obtains:
  - Data through intervention or interaction with the individual , or
  - Identifiable private information

Vulnerable Population

Individuals with limited autonomy or those in subordinate positions are considered 'vulnerable subjects" in need of greater protection (prevent inappropriate enrollment).

- **Children** (under 18 years of age) can not give legal consent. Combination of assent (agreement) of child subject and permission of the parent is used as a safeguard.
- **Prisoners** (means any individual involuntarily confined or detained in a penal institution) require additional safeguards of protection because of their incarceration, maybe under constraints that could affect their ability to make a truly voluntary and un-coerced decision regarding participation in research

* *May also include pregnant women, the elderly, students, employees, fetuses, and the economically or educationally disadvantaged and persons with decisional incapacity.*

Exempt Review

- Very Little , if any associated risk
- Doesn't apply to:
  - Prisoners
  - Pregnant women
  - Fetuses
  - Human *in vitro* fertilization
  - Children *(less than 18 years of age)*
- Does not require **continued** review by RSRB.
- Review is conducted by Specialist and Chair

Exemption Categories

- *Activities that are not "research"* (Category A)
  - *Program evaluation, QA, Oral Histories*
- *Research that doesn't involve human subjects*
  - Review of animals, the deceased *(Category B)*
- *Educational research* (Category 1)
- *Most survey/interviews/observational public behavior* (Category 2)
- *Secondary use of anonymous, pre-existing data* (Category 4)

Examples

- Not Research (category a)
- Evaluation of a daycare program, to generate a report to the funding agency; Quality assurance projects.

- Not Human Subjects Research (category b)
- Lab studies conducted with samples from third party with no identifiers; autopsy materials

Examples continued

- Educational Research (category 1)
- Conducting surveys with children and teachers at a high school to see the effectiveness of type of teaching method.

- Survey/Interviews/Focus groups/observation of public behavior (category 2)
- Anonymous testing, surveys or interview of adults; non-anonymous testing, surveys or interviews of adults if the information is not of a sensitive nature. Observation of pubic behavior with no manipulation by the researcher.

- Secondary use of pre-existing data (category 4)
- Using a data from longitudinal study that was collected previously and being provided to the investigator as dataset with identifiers but does include PHI.

Expedited Review

- No more than minimal risk to human subjects e.g.:
  - Research involving prospective or pre-existing collection of identifiable data.
  - Survey research involving minors (children <18 yrs of age)
- Consent/permission usually required, but may be waived.
- Review conducted by the Specialist and Chair.

Expedited Categories /examples

- Collection of blood samples (minimal amounts)
- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice. (MRI, doppler blood flow, echocardiography)
- Collection of data from voice, video or digital recordings
- Research on individual or group characteristics or behavior or research employing survey, interview, focus groups.
- Prospective collection of biological specimens for research purpose by noninvasive means (nail clippings, saliva collection, amniotic fluid obtained at time of rupture)
- Research involving materials (data, documents, records, specimens) that have been or will be collected for non-research purpose.

Convened Meeting Review

- Studies posing greater than minimal risk (physical, social, financial, legal, stigmatization).
  - Research involving illegal behavior or particularly sensitive issues (e.g., spousal abuse, gay youth, cocaine use)
  - Research involving prisoners
  - Biomedical research involving invasive procedures (e.g., drugs/devices)
  - RSRB Chair can determine initial review of some minimal risk studies be conducted by convened meeting.

What about HIPAA?

HIPAA regulations are focused on privacy and security protections for individuals' health care information: "protected health information" (PHI).

What is PHI?

Protected Health Information (PHI) includes individually identifiable health and health care payment information, including the demographic data that is a potential identifier of the individual, maintained in the records of health care providers.

What does it mean for data to be "de-identified"?

A de-identified data set may not include any direct identifiers of the individual or of the individual's relatives, employers, or household members.

Principal Investigator

- Who can be a PI of a research study?
- Responsible for reviewing information both from the study site and external sources to ensure University and Federal regulations are being followed.
- Reporting any subject concerns or non-compliances.
- Provide research team with adequate training if not conducting the project.

Resources and Contact Information

- RSRB website: www.rochester.edu/rsrb/
- ROSS (RSRB On-line SubmissionSystem) www.rsrb01.urmc.rochester.edu/rsrb
- On line submission training—link on RSRB website (ROSS Training)
- Investigator Guidance – link on RSRB website (Investigator Guidance)
- RSRB Phone Contact: 275-2398