Current Human Subject Regulations (Part 2)

US275 Scientific Ethics
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OHRP
"Doing it right...together"

Office for Human Research Protections
U.S. Department of Health and Human Services

- Assurance of Compliance
  - institution must commit in writing to the protection of research subjects
- for all institutions
  - doing research with human subjects
  - funded by Department of Health and Human Services (DHHS)

Regulations provide Basic Protections to research subjects.

- Institutional Assurances
- Institutional Review Board (IRB) Review
- Informed Consent

Protection of Human Subjects is a Shared Institutional Responsibility

- Institutional Official
  - sets "tone" for respect of human subjects
- IRB
  - reviews and monitors human subject research
- Investigator
  - primary responsibility for protecting rights and welfare of human research subjects.

Institutional Review Board (IRB)

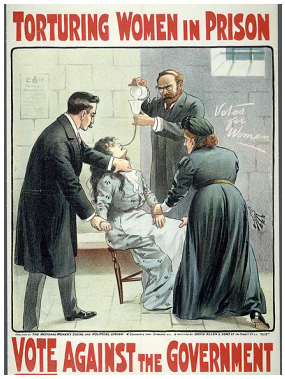
- Committee
  - varying experience and expertise
  - diversity of backgrounds
  - sensitive to community attitudes
- Human Research protocols
  - must have approval prior to start of research
  - annual review
  - can be suspended or terminated by IRB

Informed Consent

- Educational process
  - full disclosure of nature of research
  - adequate comprehension on the part of the potential subject
  - subject's voluntary choice to participate

Certain groups of individuals have Additional Protections

- Pregnant Women, Human Fetuses and Neonates
- Prisoners
- Children



Force feeding of Suffragette Kitty Marion while on a hunger strike.
poster from 1913

Waiver of Consent Process

- can be used when
  - research involves no more than minimal risk to subject;
  - waiver will not adversely affect the rights and welfare of subjects;
- FDA does not allow for waiver of consent, except in emergency situations
- example:
  - when only record linking subject to research is the consenting document and the risk would be harm from breach of confidentiality

Some types of low-risk research are considered exempt from review.

- Investigators still have ethical responsibilities
  - however, the research is not required to be reviewed and approved by the IRB.
- examples of research that is often exempt from review
  - educational settings using normal educational practices
  - research involved with study of existing data, records, or specimens

Assignment

Is the Common Rule Enough?

In your small discussion group:
Discuss whether the presence of the ethical guidelines put forth in the Belmont Report and implemented into the Common Rule are necessary and/or sufficient to ensure the safety of human research subjects.

Readings

Pearlman, D. (2004). Ethics in Clinical Research: A history of human subject protections and practical implementation of ethical standards. SoCRA Source - May, 2004 - pp. 37 - 41.

http://www.socra.org/pdf/200405_Ethics_Clinical_Research_History.pdf

Muhammad Ali reading a book
c. 1610

Any Questions?

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http://www.vippitbullkennels.com/images/animated-question-mark.gif