The Institutional Review Board: What Is it and Why Should I Care?

LSSU IRB

Faculty Development Day, 8/23/2012

IRB Committee

- Ron Hutchins, *IRB Chair* and Associate Dean of Nursing
- Kathleen Kalata, School of Mathematics and Computer Sciences *
- Kirk Mauldin, School of Social Sciences
- Britt Ranson-Olson, School of Biology
- Mary Reynolds-Keegan, School of Nursing
- Russ Searight, School of Psychology *
- Jody Susi, School of Recreation and Exercise Sciences *
- Jason Swedene, School of Communication Studies & Fine and Performing Arts
- Derek Wright, School of Physical Sciences

Background

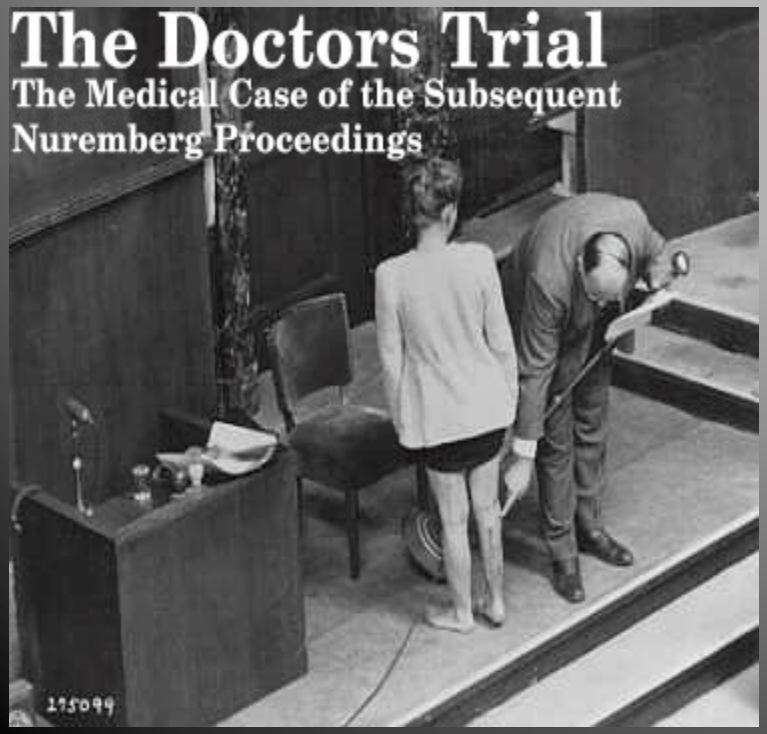
- Nuremberg War Trials (1946)
- Use of prisoners for cruel medical experiments
- Active programs of harmful research in concentration camps

Nazi Medical Atrocities

- High altitude experiments
- Use of a chamber with reduced oxygen to simulate high altitude flying

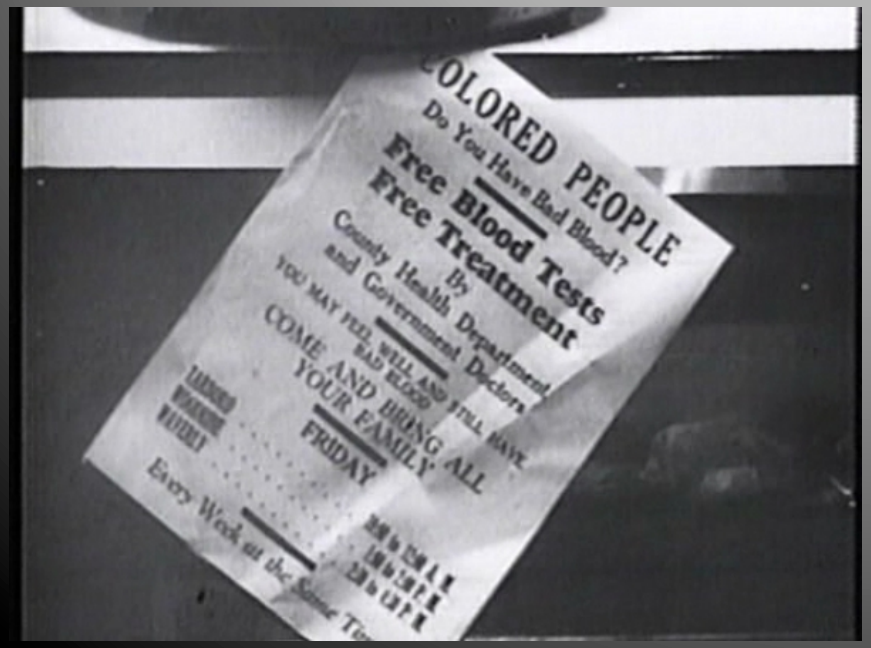
The Nuremberg Code, Aug. 19, 1947

- *10 rules for "Permissible Medical Experiments":*
  - voluntary consent, without coercion,
  - good science, done by good scientists,
  - potential benefits justify experiment,
  - harms minimized,
  - degree of risk less than potential benefit,
  - subjects can end their participation, …



US Public Health Service Syphilis Study

- *Natural history of **untreated** syphilis in*
  405 African American men
  impoverished sharecroppers around Tuskegee, AL 1932-72
- *Researchers lied to the men*
  - said they treated them for "bad blood"
- *Highly "successful"*
  - dropout rate only 1% over 40 years



Tuskegee Syphilis Study

Scientific Publications

The Tuskegee Study of Untreated Syphilis

The 30th Year of Observation

DONALD H. ROCKWELL, MD; ANNE ROOF YOBS, MD;
AND M. BRITTAIN MOORE, JR., MD, ATLANTA

year 1963 marks the 30th year of the
m evaluation of the effect of un-
syphilis in the male Negro conducted

tion such as this offered an unus
tunity to follow and study the dise
long period of time. In 1932, a tot

Henry K. Beecher's (1966) NEJM Article

- 22 examples of published studies in respected journals violating basic guidelines for treatment of human subjects

- Examples:
  - Live hepatitis virus given to residents of Willowbrook State School
  - Withholding penicillin from patients with streptococcal respiratory infections
  - Ingestion of ammonia by patients with active liver disease
  - Injecting live cancer cells into hospitalized patients
  - Infants less than 48 hrs old given x-rays to study bladder function

Behavioral Research Raising Ethical Concerns

- *Milgram (1963)*
  - Behavioral study of obedience
  - a few participants still quite distressed when queried well after the experiment
  - not medical
- *Humphries (1970)*
  - Tearoom Trade: Impersonal Sex in Public Places
  - concerns of confidentiality and privacy
  - neither medical nor experimental

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

- *By the 1974 National Research Act*
- *First, it **proposed regulations:***
  - required Institutional Review Boards (IRBs)
  - for research done or conducted by HEW (now DHHS)

Independent Review

- Institutional Review Boards (IRBs)
  - independent review is mandated by federal regulation for most research with human subjects
  - IRBs review studies at inception
    - Privacy of participants' information, risk/benefit ratio, informed consent
  - IRBs also monitor studies as they proceed
    - continuing reviews at least annually
    - reporting of adverse events, unanticipated problems

Ethical Principles Underlying Human Research per DHHS

- *Respect for persons*
  - Informed Consent
- *Beneficence*
  - Assessment of potential risks [harms] and benefits
- Non-maleficence
  - Do no harm
- *Justice*
  - Selection of people to be in the research

Respect for Persons (Autonomy)

- *"Individual autonomy"*
- *Informed consent*
  - full information
  - full comprehension ???
  - voluntary
    - without coercion
  - Protect individuals with reduced capacity to exercise autonomy

Non-maleficence: Harm

- There is no prespecified level for the unethical threshold of harm (e.g., 36 degrees or 12 pounds)

- Consideration is in the cost/benefit ratio
  - In general, make sure the benefits (from the study) outweigh the costs (to individual participants)

Privacy

- Sensitivity of topic &/or data
  - Can responses/results affect the subject's life if known by others
- How public/private is the setting?
- Public display of the data
  - Personally identifiable information should be removed or changed

Principle: Justice

- *"Treat individuals fairly"*

- *Selection of subjects / participants*
  - Equitable distribution of research harms and benefits
  - Equitable selection of subjects / participants within a population
  - Equitable selection of population

Informed Consent--Defined

- Process by which one person allows another to intrude upon his/her bodily integrity or rights
- Agreeing party is considered competent
- Consent is voluntary
- Agreeing party has reasonable knowledge of the situation
- (Schouten, 2004)

Important Elements of Informed Consent

- Statement that the study involves research
- Statement that participation is voluntary
- Visual protocol schema
- Description of foreseeable risks
- Description of any benefits
- Disclosure of appropriate alternatives
- Explanation of whether compensation for injury is available
- Statement describing the degree to which identifiable records will be kept confidential
- Name of person to contact for answers to questions

- These should all be covered in the consent document or verbal recruitment – each subject should be provided with a full copy of the signed consent document

45CFR46.116(a)

Additional Elements of Informed Consent

- May include information about
  - Risks to the participant that are unanticipated
  - Circumstances when participation may be terminated by the investigator
  - Consequences of the decision to withdraw
  - Significant new finding and whether and/or when they will be shared with participants
  - Approximate number of individuals in the study
- Internet-Based Research: Confidentiality is maintained to the degree permitted by the technology utilized (no guarantees of confidentiality should be provided)

45CFR46.116(b)

Types of IRB Review

- Exempt—Rare; Maybe some educational research or program evaluation; probably under-used
- Expedited—Little to no risk; May be approved by IRB chair alone
- Minimal risk— More than "No Risk;" Typically reviewed by 2-3 members and Chair
- Full Review— More risk or concerns regarding informed consent; Entire Committee meets—common issues are conflicts of interest; greater level of potential harm to participants

LSSU's IRB

- Our knowledge of your study is based upon the clarity of your proposal
- Committee members are often outside the applicant's discipline—they need to be able to understand proposal
- Key element is how human subjects are treated—should be focus of proposal (i.e.—no need for detailed literature reviews, statistical procedures to be employed, etc.)

Issues: Guidelines are Open to Interpretation

- Conflicts of Interest—Often unavoidable; transparency
- Use of Consent Documents—Participant privacy vs. record of informed consent
- Minors as Participants—Parental approval
- Coercion—Are college students a vulnerable population ?
- Genetic testing—Do research participants have a right to know their status ?
- Research Outside LSSU—Who is responsible ?
- Assessment—Does evaluation of course or program outcomes = applied research requiring IRB review ?

LSSU HSIRB Requirements

- 1. Cover sheet to Protocol
  - Include exemption # if applying for exempt status
- 2. Human Subjects Questionnaire
- 3. Abstract to Protocol – Part One
  - 1-page summary of project
- 4. Protocol – Part Two
  - Outline Format
    - Subjects
    - Procedures
    - Risk/Deception
    - Safeguarding Subjects Identity
  - Informed Consent Form
  - Cooperating Institutions
    - Sample Affiliation Letter (original signed affiliation letter)

Suggestions for Successful IRB Proposals

1. Clear description of how participants are recruited
2. Copy of survey, research protocol
3. Clear description of what participants actually do
4. Assessment of risk: benefit ratio
5. Privacy concerns and how they are addressed
6. All elements of informed consent covered in consent form or rationale for not having a consent form
7. Letter of agreement from outside settings when appropriate
8. Justification for any unusual risks or procedures and how the risks are minimized
9. Use the literature related to study, when relevant, to support your procedures

LSSU HSIRB Website

- Home Page
  - http://www.lssu.edu/irb/
- Submission Forms (PDF and Word):
  - http://www.lssu.edu/irb/forms.php
- Tutorials
  - http://www.lssu.edu/irb/tutorials.php