Ethical Conduct in Research

July 2013

Background on Research Ethics

* Milgram's obedience study (1963)
* Tuskegee syphilis study (1932-1972)
* Humphrey's (1970) 'tearoom study'
* Stanford Prison Experiment (1971)

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

The Commission was created in 1974

In 1979, the commission released the **Belmont Report** on basic ethical principles of research, which determines Boundaries between biomedical and behavioral research and accepted routine practice of Medicine.

Practice vs. Research

* Practice: interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success.
* Research: an activity designed to test an hypothesis, permit conclusions to be drawn to develop or contribute to generalizable knowledge

Basic Ethical Principles

* Respect for Persons:
  * Individuals should be treated as autonomous
    * The right to be knowledgeable of all information necessary to make an informed decision that is in participant's best interest
  * Persons with diminished autonomy are entitled to protection
    * Not all individuals are capable of self-determination and, must therefore be protected (ie infants, children, mentally impaired, prisoners)

Beneficence

An obligation to:

1. Not harm
2. Maximize possible benefits and minimize personal harms

This extends both to individuals and society at large

Justice

* When is it an injustice?
* Who receives the benefits and bears the burdens of the research?
* RCT's- placebo versus treatment group

Institutional Review Board (IRB)

* Purpose: to assure participant rights and welfare are protected, risks are minimized, and benefits maximized to the best of investigator's ability without compromising study design and results.

* All institutions receiving federal research funding must have an IRB certified with a Federal Wide Assurance number.

* Who makes up IRB's committees?
  * Lay people
  * People representative of the population looking to be investigated
  * Priests, religious figures
  * Not just doctors, nurses, or scientists

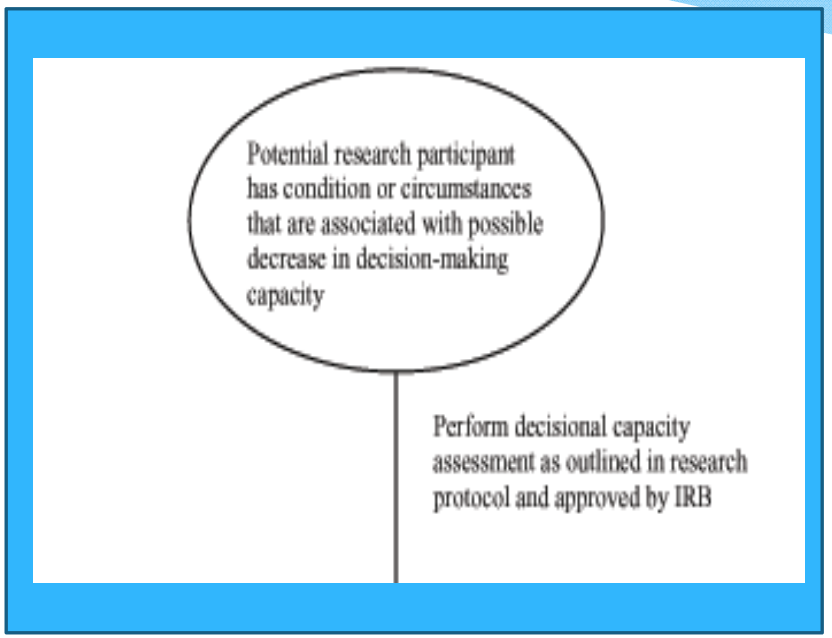
Informed Consent

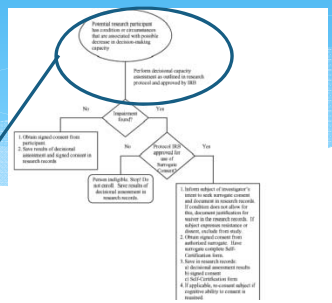
* Tool for providing autonomy to participants.
* Clear and complete information must be given.
* Voluntary aspect of participation must be emphasized, with provided opportunity to opt out at any time.
* A time to allow for questions and to assess participant comprehension of what is being asked of them, the risks involved and alternative treatments if available.

Risk/Benefit Analysis

* Investigators' role: To put optimum effort in the research design as to reduce risk and maximize benefits to participants
* Review committees' role: To weigh the risks and determine if they are justifiable.
* Aids in participants' decision to participate or not.

Capacity Assessment





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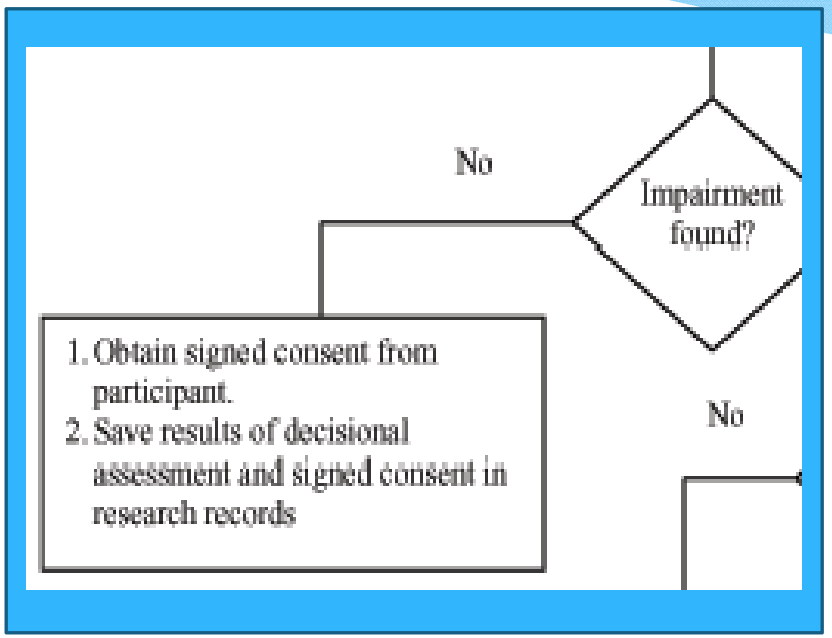

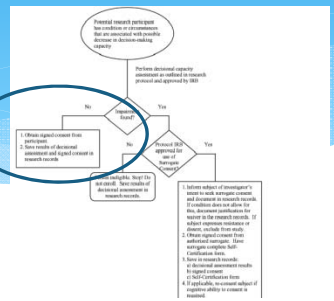

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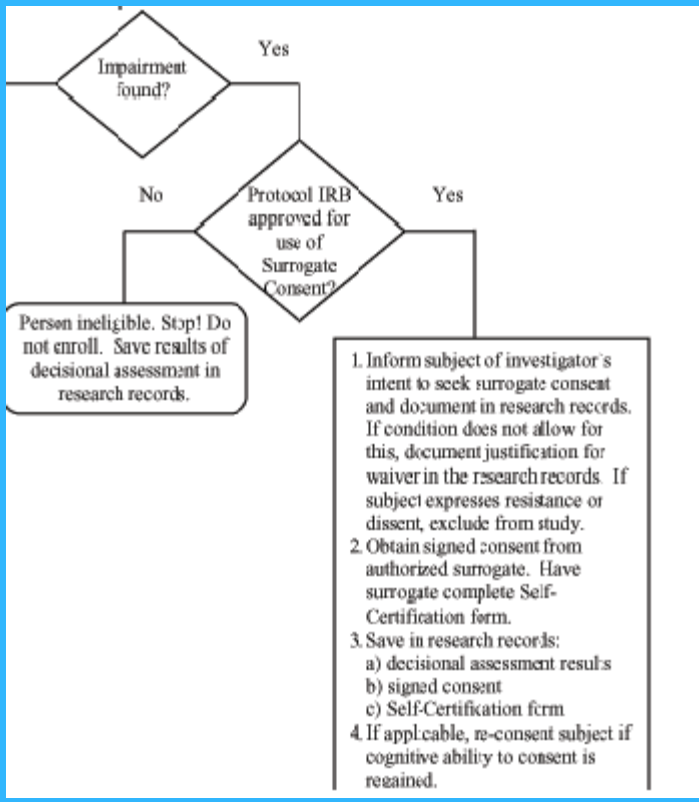
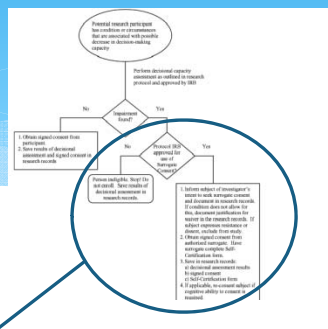




Surrogate Consent

What do you do when the subject is not able to provide informed consent?

* **Who can serve as a surrogate?**
  1. person's agent designated by an advance health care directive
  2. Conservator or guardian of person having authority to make health care decisions for the person
  3. Spouse of the person
  4. The domestic partner of the person as defined in Section 297 of the Family Code
  5. An adult son or daughter of the person
  6. A custodial parent of the person
  7. Any adult brother or sister of the person
  8. Any adult grandchild of the person
  9. An available adult relative with the closest degree of kinship to the person

Vulnerable Populations

* Infants and Children
* Ethnic minorities
* Non-English speaking participants
* Economically disadvantaged populations
* Cognitively, developmentally or physically impaired
* Elderly

Subject Recruitment: The Best Approach

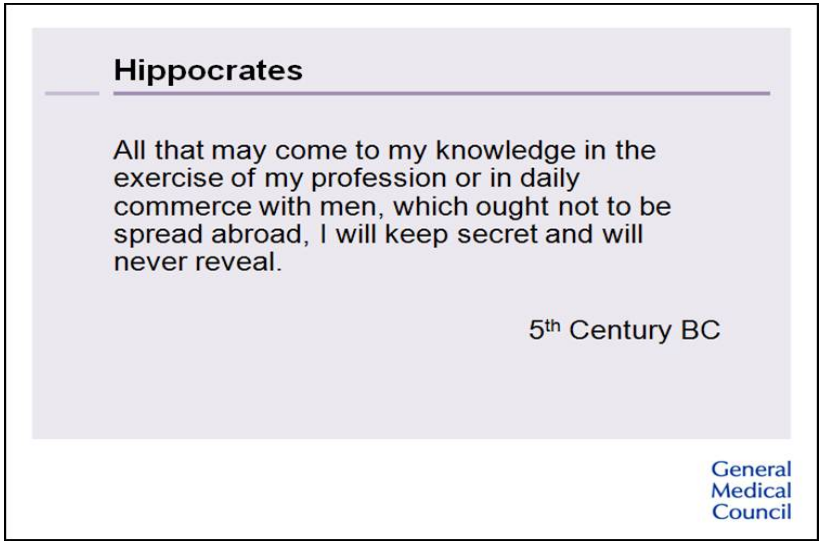
* Identify your study population and recruitment method most appropriate for that population
* Use neutral language in fliers, on phone screeners, and all recruitment material
* Be as transparent as possible regarding the study when first talking with prospective subjects

Subject Recruitment: What not to do

* Coercion
  * Emphasizing financial compensation, insisting their participation is necessary for their health, threatening that health services may be cut.
* Deceptive marketing or advertising
  * "You will receive free treatment" (possibility of being in a placebo group, no guarantee that the treatment will work)
  * 'Therapeutic Misconception'
* Withholding information to manipulate into volunteering
  * Misquoting length of visit, needed time commitment, unclear disclosure or undermining of possible risks.
* Peer pressure
  * Especially within researchers, between PI and staff/students

Confidentiality

* HIPPAA: Health Insurance Portability and Accountability Act of 1996
* Patient ID: De-identify data before sharing with collaborators and colleagues
* Maintain patient records and documents in secure spaces (locked cabinets, offices)
* Password protect and encrypt all documents containing PHI



NIH Certificate of Confidentiality

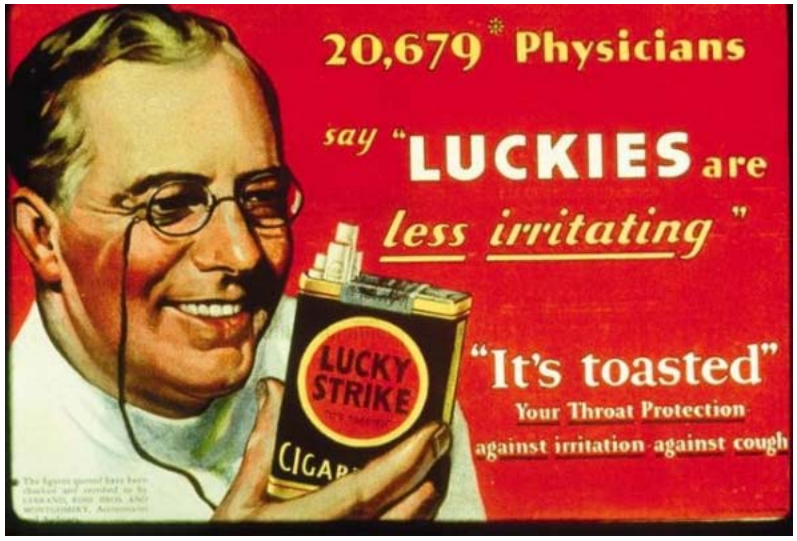
* Protects researchers and institutions from being subpoenaed to disclose information that could be used to identify research study participants.
* Allows researchers and institutions to refuse to disclose identifying information in any civil, criminal, administrative, or legislative case whether at federal, state or local level

Research Participant Compensation

* ‘Payment’ versus ‘compensation’
* The term ‘payment’ is reserved for money given to subjects in order to offset time and inconvenience, and/or to provide incentive to participate.
* Want to avoid subjects from perceiving payment for participation as a means of income.
* Amount should be determined by investigator based on demands of participation and ultimately approved by IRB.

Conflicts of Interest

* "Situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting or reporting research." –UCSF CHR Guiding Principles on Conflicts of Interest



Reporting Data and Results

* It is the responsibility of investigators to report results in an honest and accurate manner.
  * Ensure accurate and consistent data collection through checking RA work periodically
  * Cannot massage data to fit hypothesis
  * Must report results, whether they were expected or not
  * Proper credit (authorship) should be given to all collaborators and contributors

3 Tenets of the Belmont Report

* What are they?
* How do we abide by them in practice?
* Challenges and Dilemmas?

Ethics Case 1: Have you contacted my partner yet?

* While a participant is here for their research visit they inquire if we have contacted their partner for participation?
  * What are the ethical considerations here?
  * What aspects must you be aware of?
  * How do you respond?

Ethical Case 2: Acute HIV Treatment

* A research group would like to identify newly HIV infected patients within a week of infection and treat them.
* WHO guidelines require symptoms of diseases, visible viral load, low CD4 count in order to initiate treatment.
* Is this ethical? Why or why not?

Ethical Case 3: Untreated HIV+ Children

* A current study has proposed to follow HIV infected children longitudinally without treating them
* Is this unethical? Should we be treating them, even if no signs of symptoms?
* What are implications of treating versus not treating?