Research with Vulnerable Populations

Virginia Commonwealth University

What is a “Vulnerable Population?”

- Examples

Special Populations

- Vulnerable populations require extra protection:
  - Children
  - Decisionally Impaired
  - Prisoners
  - Pregnant Women
  - Fetuses *in utero*
  - Economically or Educationally disadvantaged
  - Employees, Students

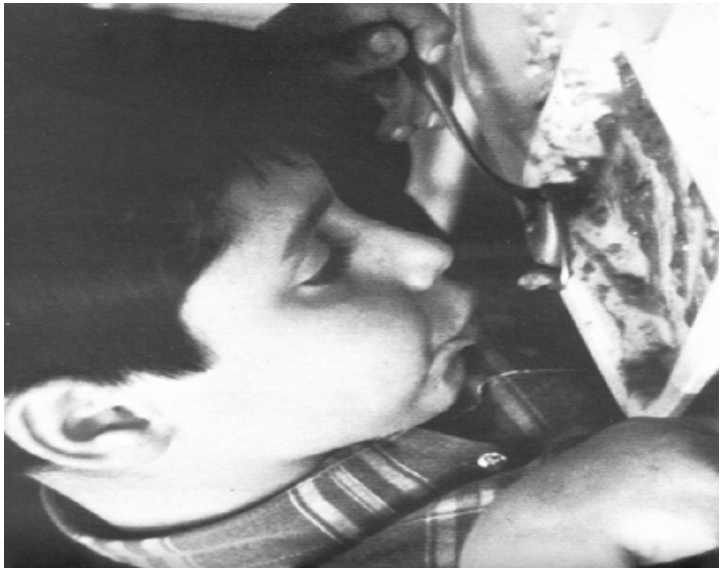
Vulnerable Populations

- Vulnerable to coercion or undue influence in a research setting
- Relatively or absolutely incapable of protecting their own interests.
- Requires detailed justification & additional safeguards

Tuskegee Syphilis Study
Macon Co., AL 1932-1972

- 400 African-American men, many who were **illiterate**
- Researchers tested the men for syphilis
- Recruited with promise of "special free treatment"
- **Enrolled without consent**

Willowbrook State School Hepatitis



- Inoculation and injection of hepatitis
- Institutionalized children

Subpart B: Pregnant Women, Fetuses, & Neonates

- Mother & fetus will be placed at **risk only to the minimal extent** to meet the health needs of the mother or risk to the fetus is minimal.
- The father's signature is required unless:
  - The purpose of the study is to meet the mother's health needs, or
  - The father is not reasonably available, or
  - The pregnancy was the result of sexual assault

Subpart B: Pregnant Women, Fetuses, & Neonates

- Risk to the fetus is caused solely by interventions or procedures that hold out the **prospect of direct benefit** for the woman or the fetus
- Least possible risk
- If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A.
  - Father's consent may not be needed

Subpart B: Pregnant Women, Fetuses, & Neonates

- For **children who are pregnant**, assent and parental permission are obtained in accord with the provisions of subpart D of this part
- No rewards to terminate a pregnancy
- No part in deciding timing, method, or procedures used to terminate a pregnancy
- No part in determining the viability of a neonate

45 CFR 46.205 Research Involving Neonates (a)

- Neonates of **uncertain viability** and **nonviable neonates** may be involved in research if all of the following conditions are met:
  - Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
  - Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
  - No part in determining the viability of a neonate.
  - The requirements of paragraph (b) or (c) of this section have been met as applicable.

45 CFR 46.205 Research Involving Neonates of Uncertain Viability (b)

- Prospect of increasing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective
- The purpose = development of biomedical knowledge which cannot be obtained by other means
  - No added risk to the neonate resulting from the research;
- The legally effective informed consent of either parent of the neonate

45 CFR 46.205 Research Involving Non-Viable Neonates (c)

- After delivery, a non-viable neonate may only be involved in research if all of the following are met:
  - ***Vital functions*** of the neonate ***will not be artificially maintained;***
  - The research will ***not terminate the heartbeat or respiration*** of the neonate;
  - There will be ***no added risk to the neonate*** resulting from the research;
  - The ***purpose = development of biomedical knowledge*** that cannot be obtained by other means
  - The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part *

45 CFR 46.205 Research Involving Viable Neonates (d)

- A neonate may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§46.206 Research Involving After Delivery, the Placenta, or Fetal Material:

- (a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.
- (b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

Subpart C: Prisoners

- Prisoner: Any individual involuntarily confined or detained in a penal institution. 45 CFR part 46.303(c)
  - Person who enters into a study and at a later time becomes a prisoner.
  - Rules are designed to prevent coercion (intentional or not).
  - People with certain freedoms are not considered research participants for whom Subpart C applies.

Subpart C: Prisoners

- Full review & approval by the IRB (including a prisoner representative).
- Research must fit into one of the allowable categories for Prisoner Research.
- Participation cannot be used to influence sentencing or parole decisions.

Subpart C: Prisoners

- The risks must be as acceptable to non-prisoner participants as to prisoners.
- Selection of prisoners as subjects must be fair.
- Adequate follow-up care must be provided if needed.

Subpart D: Children

- A child is a person less than 18 years of age
- Children cannot legally give consent.
  - Signed Assent
  - Understandable language to child
- Parental permission
- Re-consent once they reach 18 years old

Subpart D: Children

- Fit into one of the following categories:
  - **Category 404 - Minimal Risk**
  - **Category 405 - Greater than Minimal Risk (with Prospect of Direct Benefit)**
  - Category 406 - Greater than Minimal Risk (with No Prospect of Direct Benefit)
  - Category 407 - Not Otherwise Approvable (w/ potential to understand, prevent, pain mgmt.)
    - If research is under category 406 or 407, 9 conditions must be met.

Decisionally Impaired to Consent

In order to give fully INFORMED consent, participants need to fully understand the research they are consenting to.

Decisionally Impaired to Consent

- Vulnerable populations with limited decision making capacity may include:
  - Psychiatric disorders
  - Neurological conditions
  - Substance abuse
  - Traumatic brain injury
  - Emergency illness/injury
  - Stroke

Decisionally Impaired to Consent

- A legally authorized representative (LAR) may grant permission
  - Legal guardian or person with validly designated power of attorney.

Decisionally Impaired to Consent

- Special precautions:
  - Use of a LAR
  - Use of patient advocates
  - Renewing consent at specific stages of the research
  - Limiting time period for approval

Vulnerable Populations: Students

- Concern is that student participation in research may not be truly voluntary for numerous reasons including the student's desire to appear cooperative or motivated.

Vulnerable Populations: Students

- Various procedures may be used to reduce the possibility of unintentional coercion:
  - Posting IRB approved advertisements throughout the campus to recruit from a broad base of students
  - Avoiding personal solicitations of students by any person
  - Providing a number of research projects from which to choose if participating as a research subject is used a course requirement
  - Providing alternative and equal methods for meeting course requirements other than participating as a research subject.