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Ethical Recruitment

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VIRGINIA COMMONWEALTH UNIVERSITY

School of Nursing

Community Engaged Research: Ethical Recruiting

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ETHICS

The process of examining moral standards and looking at how we should interpret and apply such standards in real world situations

Conduct of Unethical Research

- **Tuskegee Experiment** (1932-1972): US Public Health Service studied 399 African-American males with syphilis for the sole purpose of studying the long term effects of the disease. Thought they were being treated and once effective treatment was discovered in 1940's, they were not given treatment.
- **Holmsburg Prison Experiments** (1951-1974). Inmates were subjected to multiple inhumane experiments including exposure to malaria, typhoid, herpes, TB, syphilis, cancer.
- **Zimbardo's Stanford Prison Experiment** (1971). Study had to be ended prematurely because of abusive behaviors to participants by those who where assigned as guards over those subjects that were assigned as prisoners.
- **Countless others**

Protection of Human Subjects

- Nuremberg Code (1949)
- Declaration of Helsinki (1964)
- National Research Act of 1974
- Belmont Report (1979)

Protection of Human Subjects

- Nuremberg Code (1949)- developed following Nuremberg war crime trials (1945-1947)-initially ignored in the U.S.

- Declaration of Helsinki (1964, amended six times; 2008 current version)-expanded from Nuremberg Code to differentiate **Therapeutic** versus **Non-Therapeutic Research**

Protection of Human Subjects

- National Research Act of 1974

  Institutional Review Boards (IRB) established

- 1975-1978 – National Commission for Protection of Human Subjects of Biomedical and Behavioral Research

- April 1979 – Belmont Report

The Belmont Report

- Respect for Persons
- Beneficence
- Justice

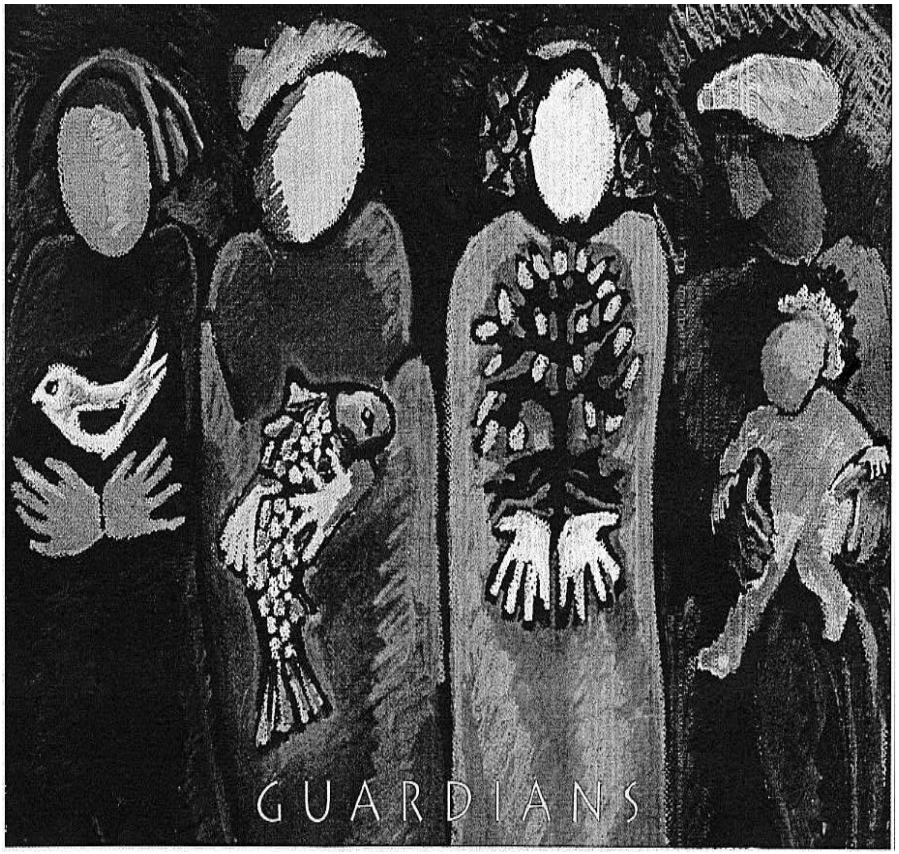
- http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Guiding Documents-Protection of Human Subjects

Belmont Report (1979) Major ethical document guiding human research in the U.S.

1. **Respect for Persons**: autonomy, informed consent, and protection of the vulnerable
2. **Beneficence**: Acts of kindness or charity that go beyond duty; benefits exceed risk; minimize risk
3. **Justice:** fair distribution of benefits and burdens; fair participant selection; research population is expected to benefit

Research Ethics-Human Subjects



- Scientific integrity
- Consent
- Assessment of risk
- Privacy and confidentiality
- Protection of vulnerable populations
- Equity and fairness

Scientific Integrity

This covers all of the researcher's decisions and actions from conceiving of the idea to reporting the results.

Ethical Researcher Ensures

- Do No Harm
- Respect autonomy in the consent process
- Justice in subject selection
- Fully explain research procedures
- Obtain proper and informed consent
- Ensure confidentiality
- Maintain documentation throughout process
- Adhere to research protocols
- Report results fairly and factually

Vulnerable Populations

- Vulnerable subjects are not targeted for convenience
- People are not selected as subjects because of their ease of availability or compromised position
- People who are likely to benefit are not excluded

Vulnerable Populations

- Children
- Pregnant women
- Students
- Prisoners
- Cognitive impairment
- Others

Diminished autonomy

and/or

Incapable of making their own decisions

(cannot fully participate in the consent process)

Informed Consent

- Information about the purpose, methods, demands, risks, and possible outcomes of the research
- Voluntary choice to participate; may opt to not participate at any time for any reason
- Informed Assent for minors

Components of Informed Consent

- Information
  - ✓ Extent and nature sufficient for a reasonable person to decide whether to participate
- Comprehension
  - ✓ Must be written at 5th grade reading level. Potential subjects can balance the risks and benefits
- Voluntariness

The Belmont Report

Clarifies the Boundaries Between Practice and Research

- ✓ IRB must determine that the researcher (and through informed consent, the subject) distinguishes *practice* from *experiment*

Voluntary Informed Consent

Informed Consent should include:

- Description of the research
- Statement that the research is voluntary and participants can withdraw at any time
- Identification of Risks and Benefits
- Description of how confidentiality will be protected
- Description of compensation
- Description of what data researchers will share with participants
- Identification of who is responsible for research including contact information

Health Literacy: The New Vital Sign

- 27 studies: 13 RCT with interventions; 14 descriptive
- 78% used investigator developed tools to assess participant comprehension
- 74% did not assess literacy
- 89% did not assess readability of consent form

(Montalvo & Larson, 2014)

Ethical Recruiting

- https://www.youtube.com/watch?v=jWHmJC8-TEk
- https://www.youtube.com/watch?v=_lB6oNpyAU4

Community Engaged Research: Ensuring Ethical Recruitment

- Community involvement:

1. Recruitment advertisement

2. Simplify language to explain study

(Johnson et al., 2015)

Community Engaged Research: Ensuring Ethical Recruitment

Strategies

1. Community liaison
2. Contact from trusted community organizations
3. Display and distribute study materials in the community
4. General community outreach and engagement activities

(Samus et al., 2015)

References

- Johnson, D., Joosten, Y., Wilkins, C. & Shibao, C. (2015). Case study: Community engagement and clinical trial success: Outreach to African American women. *Clinical and Translational Science,* 1-3. doi10.1111/cts.12264
- Montalvo, W. & Larson, E. (2014). Participant comprehension fo research for which they volunteer: A systematic Review. *Journal of Nursing Scholarship, 46,* 423-31.
- Samus, Q., Amjad, H., Johnston, D., Black, B., Bartels, S. & Lyketsos, C. (2015). A multi-pronged, adaptive approach for the recruitment of diverse community-residing elders with memory impairment: The MIND at home experiment. *Journal of Geriatric Psychiatry.*
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In Closing