Diversity, Disparities, and Community Engagement in Healthcare Bioscience Research Collaborative 110

History and Ethics: Ethical Minority Engagement in Research

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Key Moments of Medical Infamy in Research and Experimentation with Humans (1 of 2)

- Experimentation on black slave women: Alabama Surgeon, J. Marion Sims, MD -- (1845 - 1849)
- ✓ United States Government Human Radiation Experiment, Lyles Station, Indiana, (1927)
- ✓ USPHS Study of Untreated Syphilis in the Negro Male (1932 - 1972)
- ✓ Guatemala Inoculation Study, John Cutler, MD – (1946 – 1948)
- The Nuremberg Nazi Doctors' Trials, Karl Brandt, MD and 22 other colleagues – (1945 - 1949)

Key Moments of Medical Infamy in Research and Experimentation with Humans (2 of 2)

- Willowbrook School, Staten Island, NY Hepatitis Experiment, Saul Krugman, MD and colleagues – (1955 – 1972)
- New York's Jewish Chronic Disease Hospital "Live Cancer Cell" Experiment, Chester Southam, MD – (1963 – 1964)
- "Ethical Violations in Clinical Research"—22 Unethical Studies, Henry Beecher, MD – NEJM, 1966

✓ Henrietta Lacks Case, 1951--

✓ The Havasupai v. Regents of Arizona State University Case, 1989 - 2010

Paradigmatic Case 1: United States Government Human Radiation Experiment Lyles Consolidated School, Lyles Station, Indiana, 1927

Mr. Vertus Wellborn Hardiman
(1922 – 2007)

- The Story: Hole in the Head: A Life Revealed
- Diagnosed with "Ringworm", 1928
- Unsuspecting parents of ten children signed permission slips for treatment misrepresented as new therapy
- Children were severely irradiated during a medical experiment conducted at the local county hospital
- All children experienced horrific side effects including necrosis of the bone and disfigurement
- Hardiman suffered the most pronounced long-term effects and wore hats, wigs, toupees for 80 years
- Hospital received a verdict of "not liable" for damage
- Hardiman bore this injustice and distress with remarkable dignity
- Hardiman donated 8 million dollars to his church and for educational scholarship
- Let me introduce you to Mr. Vertus Hardiman?
- Produced by Wilbert Smith, 2011

Reference: Hole in the Head: A Life Revealed. Wilbert Smith, Google Books, 2012

- www.imdb.com/videoplayer/vi1469423129

Paradigmatic Case 2: USPHS Study of Untreated Syphilis in the Negro Male at Tuskegee (1932 – 1972)

Voices of Tuskegee Study Participants and Relatives
https://www.youtube.com/watch?v=3e5VfgsGp1k
Reference: Tuskegee's Truths. Susan Reverby, UNC Press, 2000

The Story: What is particularly troubling to you about this Case?

Purpose: To study the natural course of syphilis in the negro male.

Study:

- 624 black men (427 with syphilis, 185 without)
- Culturally appropriate approach used
- Men were deceptively told they had "bad blood"
- Observed without treatment
- Prevented from receiving Penicillin, 1942—
- Re-evaluation of continuation of Study at CDC, 1969
- Public outrage stimulated halting Study, 1972
- Lawsuit settled "out of Court"
- The men and their families bore the injustice with dignity
- Apology given by President William Clinton, 1997
- Provision for "healing sessions" continues at Tuskegee Bioethics Center

Paradigmatic Case 3: Henrietta Lacks and The Johns Hopkins Hospital, Baltimore, MD

Mrs. Henrietta Lacks
1920 - 1951

The Story: Immortal Life (1951 --?)

- Diagnosed at Johns Hopkins Hospital with cervical cancer
- Cells taken from Henrietta Lacks were used to develop the HeLa Cell line still used in research today
- Neither Henrietta Lacks nor the Lacks Family had any knowledge of this research going on
- Advent of Informed Consent was in the 1970s
- Until recently the benefits of research was never shared with the Lacks Family
- What is particularly troubling to you about this Case?

Reference: The Immortal Life of Henrietta Lacks. Rebecca Skloot, 2011

Paradigmatic Case 4: Havasupai Indians versus ASU Board of Regents Case (2004 – 2010)

Carletta Tolousi

The Story

- Diabetes ravaged the Havasupai Tribe community
- The Havasupai Tribe gave blood to Arizona State University researchers to study the diabetes disease in 1989
- The Tribe was devastated when they found out that the blood given for diabetes research was also used for other kinds of research
- Let me introduce you to CarlettaTolousi and the Tribe
- Blood Journey (1989-2010)
- http://www.nytimes.com/video/us/124746767274 3/blood-journey.html

What is particularly troubling to you about this Case?

Ethical Issues that Can Impact Engagement and Recruitment into Research Studies

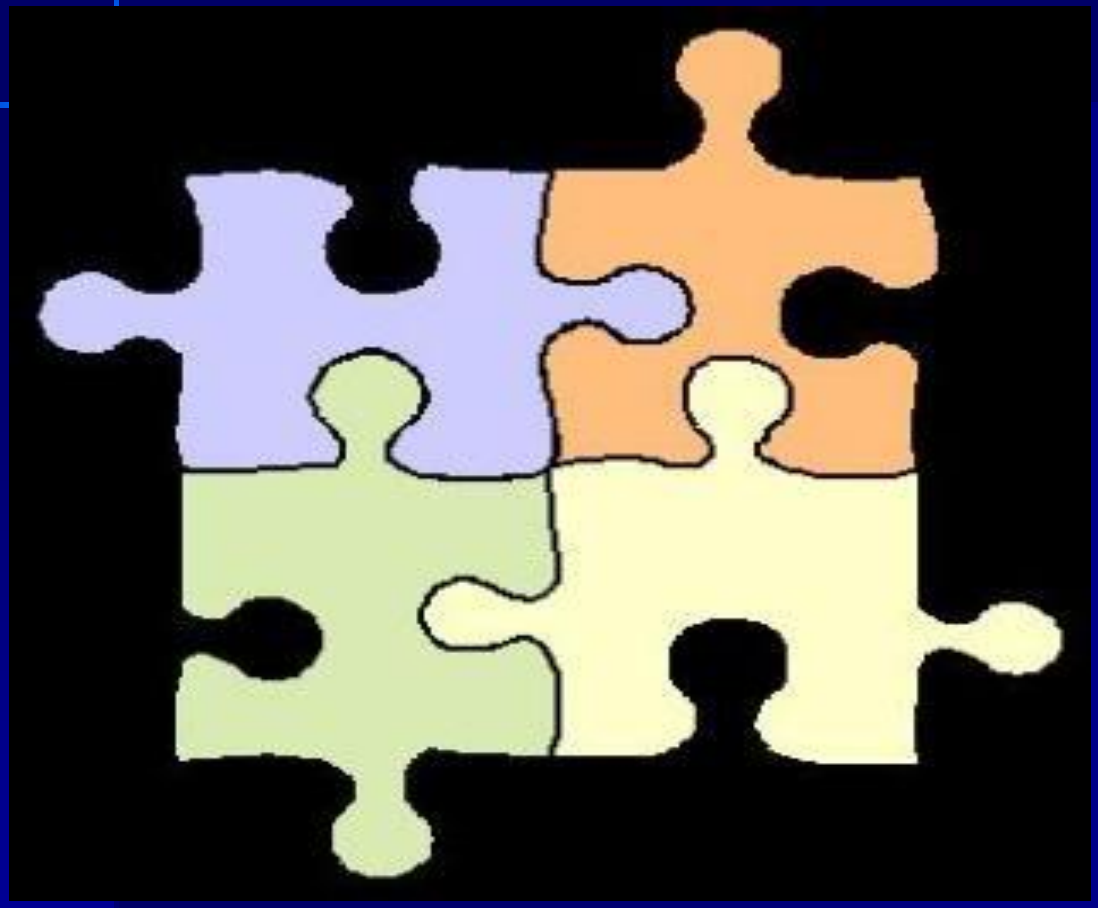
- Respect for patient or participant autonomy and community values and culture
- Deception by research investigators
- Use of research terms unfamiliar to participants or communities
- Trust of participants in doctors betrayed
- Trustworthiness of doctors and research investigators
- Mistrust and distrust of the medical establishment
- Suspicion of the motives and intensions of research investigators
- Dignitary harm imposed on participants
- Emotional harm experienced by participants
- Reluctance to trust the research establishment
- Reluctance to be engaged or be recruited for medical research
- Question of stigmatization associated with inappropriate use of research data
- Questions of privacy, security, and confidentiality of research data

Human Subject Protections: Research Regulations and Oversight

- Nuremberg Code (1949)
- Declaration of Helsinki (1964)
  - Adopted by the World Medical Association
  - Modified 1975, 1983, 1989, and 1996
- USA: National Research Act, 1974
- USA: Belmont Report (1979)
- USA: DHHS: 45 CFR 46 Code of Federal Regulations
- USA: FDA 21 CFR 50 Code of Federal Regulations
- HIPAA Privacy Protections
- Certificate of Confidentiality
- Establishment of Independent Review: IRBs /ERC to provide oversight
- International CIOMS Guidelines (1982, 1993)

Take-Home Lessons: What Makes Clinical Trials as Research Ethical?

- Value: Enhancement of knowledge from the research
- Scientific validity: Methodology must be rigorous
- Fair selection of subjects and distribution of benefit and burden
- Favorable risk-benefit ratio: Risks must be minimized, and potential benefits enhanced
- Reasonable compensation or incentive
- Independent review and oversight: IRB
- Informed consent: Individuals must be informed about the research, and they should provide voluntary consent.
- Respect for persons enrolled in the research: Persons should have their privacy protected, have the opportunity to withdraw without penalty, and have their well-being monitored.
- Reference: (Emmanuel, Wendler, Grady, JAMA 2000)



We Can Do This Together!

Each one of us is a “piece” of the Jigsaw Puzzle when identifying and resolving bioethical issues in Clinical Research and Clinical Trials for the benefit of all of us.

We are dependent on one another for our health and wellness!

Can you hear me now? Good!

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COMMENTS AND QUESTIONS?