

“Health Disparities: Challenges, and Contributing Factors: A Bioethics Conversation”

Community Engaged Healthcare Research Workshop: Bioscience Research Collaborative 110

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Acknowledgement



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Program Manager, RCMI



Confession!

“For we are God’s handiwork, created in Christ Jesus to do good works, which God prepared in advance for us to do”

Ephesians 2:10 (NIV)

I believe that every person is a **treasure**, every life a **sacred gift**, every human being a **unity of body, mind, and spirit**.



Historical Antecedents: 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)**



Historical Antecedents: 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: USPHS Study of Untreated Syphilis in the Negro Male at Tuskegee (1932 – 1972)



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

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

Study and Legacy:

- 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”
- **Belmont Report and Ethical Principles, 1979**
- 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
- Establishment of TU Center for Biomedical Research
- **Establishment of CRAB at Tuskegee**

Voices of Tuskegee Study Participants and Relatives

<https://www.youtube.com/watch?v=3e5VfgsGp1k>

Reference: Tuskegee’s Truths. Susan Reverby, UNC Press, 2000.



Actors Involved in the Study from the United States Public Health Service

Dr. Taliaferro Clark



*Taliaferro Clark.
(Images from History of Medicine,
National Library of Medicine)*

Dr. Oliver Wenger



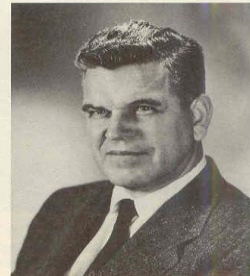
*Oliver C. Wenger.
(Images from History of Medicine,
National Library of Medicine)*

Dr. Austin Diebert



*Austin V. Diebert.
(Images from History of Medicine,
National Library of Medicine)*

Dr. John Heller



*John R. Heller.
(Images from History of Medicine,
National Library of Medicine)*



Some Tuskegee People Associated with the Study



T. M. CAMPBELL

Another Book from Tuskegee

"THE MOVABLE SCHOOL GOES TO THE NEGRO FARMER"

By Thomas Monroe Campbell
Field Agent, Extension Service
United States Department of Agriculture

A Story of the Development of a Practical Idea in Educating the Hand-to-mouth Tenant into a Thrifty Landowner

Illustrated — Approximately 200 Pages

THIS BOOK UNFOLDS one of the most stirring dramas in the development of the rural South. As a conception of the genius of Booker T. Washington, the story of the Movable School describes vividly one of the Tuskegee methods of doing a "common thing in an uncommon way."

The interest and value of the book as a panorama of the struggle of the Negro are greatly enhanced by an autobiographical sketch of the author, whose life, as a boy, represents the conditions which the Movable School has so effectively undertaken to correct. Chosen by Booker T. Washington, some twenty-nine years ago, to serve as the first Negro Agricultural Demonstration Agent in the United States and placed in charge of the Movable School, Mr. Campbell has accumulated a varied experience, so intensely human and uncommon that his book will be read with the same appealing interest as though it were the completion of an unfinished chapter from "UP FROM SLAVERY."

Price \$2.00

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Tuskegee Institute, Alabama

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**Robert R. Moton,
2nd President of
Tuskegee Institute**



Eugene H. Dibble.
Dr. Dibble was medical director of the John A. Andrew Hospital at Tuskegee Institute when the study began in 1932.
(Eugene H. Dibble Papers, Tuskegee University Archives, Tuskegee University; reprinted by permission of Tuskegee University)



Nurse Eunice Rivers and an unidentified "subject" in the cotton fields, no date.
(Centers for Disease Control Papers, Tuskegee Syphilis Study, Administrative Records, 1930-80, Box 51, negative no. 18959, National Archives-Southeast Region, East Point, Ga.)



Reflection Questions

- What is most troubling to you about the study?
- Should the Study have been conducted? Why? Why not?
- What did we learn from the study, if anything?
- How are the lessons learned used to curtail unethical research now?
- Do you have any sympathy for those who conducted the study? Why? Why not?
- What **valuable insight did you gain** from watching the video-clip: **“The Voices of Tuskegee Study Participants and Relatives”**?
- Can a study like this happen again? Should it?
- What are you prepared to do to ensure that a study like this does not happen again.
- How would you reduce the likelihood of the health inequity consequences of the study?



Legacy of the Syphilis Study

Is there anything praiseworthy or blameworthy?

■ Negative

- Harm done to Tuskegee University and community
- Suffering of the people involved (Men, women, Children)
- Class action against the US Government was led by Mr. Charles Pollard and Attorney Fred Gray of Tuskegee
- **Mistrust of medical establishment and distrust of research**
- HIV in 1990 to most African Americans surveyed was a genocidal plot by the government
- **Level of distrust of the government and health personnel very high**
- The wound of humiliation through deception is still fresh

■ Positive

- Establishment of legally binding ethical framework for conducting research
- National Research Act, 1974
- Kennedy Hearings—**Belmont Report, 1979**
- National Commission for the Protection of Human Subject of Biomedical and Behavioral Research—**Vulnerability surfaced!**
- **Federal Regulations on Oversight for Research: Informed Consent Requirement**
- **Institutional Review Board**
- President William Jefferson Clinton's **Apology, 1997**
- **Bioethics Centers and Graduate Programs**
- Health benefit for descendants of study participants
- Efforts to support healing from the wounds of the study continues at the Tuskegee University Center for Bioethics



Looking Back to Move Forward: Human Subject Research Protections 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)

From the Belmont Report to the Code of Federal Regulations

Evolution of research ethics in the United States

- **The United States Study of Untreated Syphilis in the Negro Male (1932-1972)**
 - Ethical problems with research are identified
- **The Belmont Report**
 - Fundamental principles for the ethical conduct of research are advocated
- **The Code of Federal Regulations**
 - Specific regulations are adopted

Belmont Report

- **Three important basic principles for biomedical research:**
 - 1. Respect for persons (treating individuals as autonomous agents and protecting persons with diminished autonomy)**
 - 2. Beneficence (minimizing harms and maximizing benefits)**
 - 3. Justice (fairness in the distribution of benefits and burdens of research).**

The Belmont Report

Ethical Principles

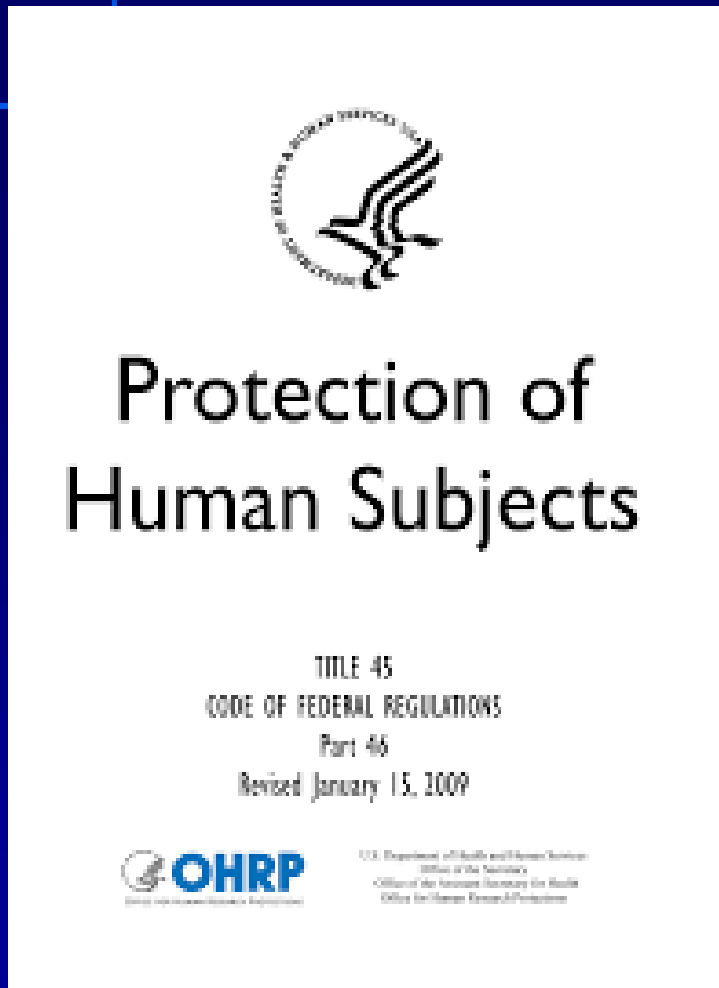


Applications

- Respect for Persons
- **Beneficence**
- **Justice**

- Informed Consent
- **Assessment of Risks and Benefits**
- **Selection of Subjects**

Code of Federal Regulations: What is in it?



Title 45 Public Welfare, Department of Health and Human Services, Part 46 Protection of Human Subjects

Subpart A (The Common Rule): IRB review of Human Subjects Research

Subpart B: Additional Protections for Pregnant Women, Human Fetuses, Neonates involved in research

Subpart C: Additional Protections for Prisoners as Research Subjects

Subpart D: Special Protections for Children, mentally, disabled or economically and educationally disadvantaged persons as Research Subjects

Subpart E: IRB Registration

www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm



Challenges: 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 intentions 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**



Contributing Factors: What Makes Clinical Trials as Biosciences 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)



Paradigmatic Case 2: United States Government Human Radiation Experiment Lyles Consolidated School, Lyles Station, Indiana, 1927



Mr. Vertus Wellborn Hardiman
(1922 – 2007)

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

- 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
- **Mr. Vertus Hardiman left us a message that we must remember!**
- **Produced by Wilbert Smith, 2011**
- www.imdb.com/videoplayer/vi1469423129



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 Carletta Tolousi and the Tribe
- Blood Journey (1989-2010)
- <http://www.nytimes.com/video/us/1247467672743/blood-journey.html>

What is particularly troubling to you about this Case?

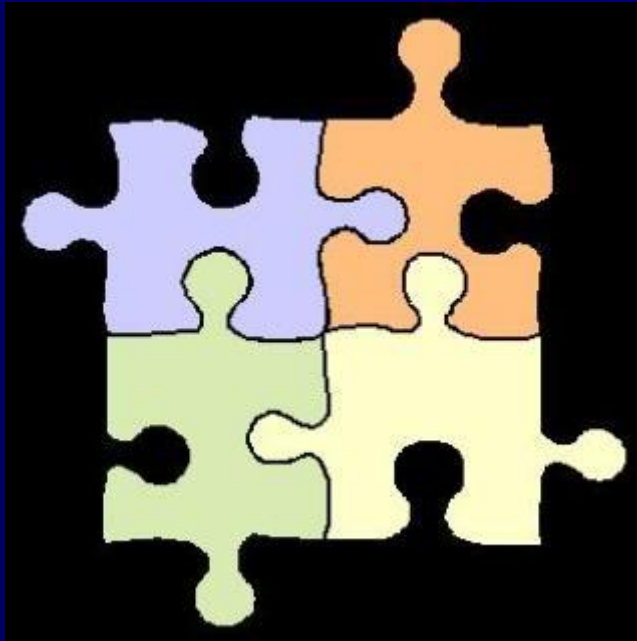


Partners in Community-Engaged Health Research: An Ethically-Sensitive and Collaborative Model



- **The Community**
 - Research Participants
 - Other Community Members
- **The Research Staff**
 - Study Investigators
 - Other Study Personnel
- **The Ethics Committee (EC);
Institutional Review Board (IRB);
OR
Community Research Advisory Board
(CRAB)**
- **Sponsors of the Study**

Making a Symbolic Commitment!



- **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!**
ssodeke@tuskegee.edu



COMMENTS AND QUESTIONS?

