SRA INTERNATIONAL
ANNUAL MEETING
SEATTLE 2023
OCTOBER 14-18

The Foundation and Principles of Human Research Protections

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Michael Leavitt, MS
Intermountain Health

Agenda & Learning Objectives

Agenda

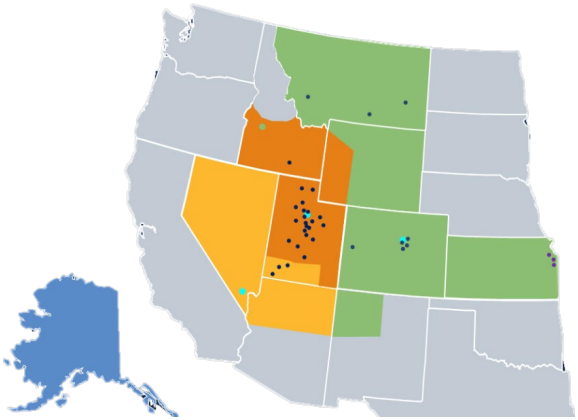
- Historical Context
- Ethical Principles
- What is a Human Research Protections Program?

Learning Objectives

- Describe the foundation and principles of research ethics regulations.
- Identify ethical best practices to implement when conducting research.

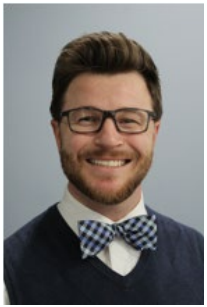
Who are we?

Intermountain Health



Shelby Moench, MLS

Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation



Michael Leavitt, MS

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Historical Context


The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

Officials of the health service who initiated the experiment have defended it in the past. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

Dr. Merlin K. DuVal, assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,

Tuskegee Syphilis Study

1931 – 1972

Nuclear Testing

Trinity 1945

NTS 50s-90s

Nazi Trials & Nuremberg Code

1947

Henrietta Lacks

1951

Identical Strangers

1960s

Helsinki Declaration

1964

National Research Act 45 CFR 46

1974

Belmont Report

1979

Common Rule

1991

Jesse Gelsinger

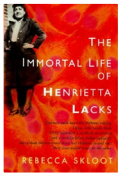
1999

AAHRPP

2001

Revised Common Rule

2017



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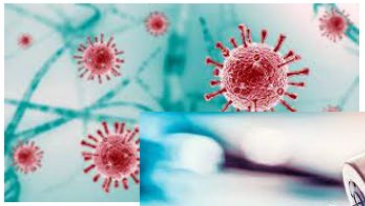
Celebrate Research!!

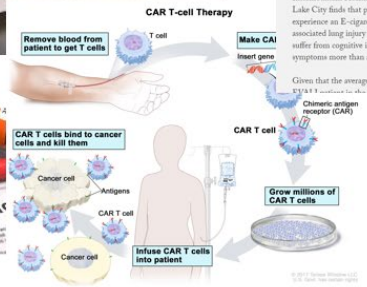


Amid COVID Pandemic, Intermountain Healthcare Study Finds Vaping Injuries Can Lead to Long-Term Cognitive Impairment, Lung Damage, and Depression

May 20

Amid the COVID pandemic, a new study from researchers at Intermountain Healthcare in Salt Lake City finds that patients who experience an E-cigarette or vaping associated lung injury (EVALI) can suffer from cognitive impairment and symptoms more than a year later.

Given that the average age of an



ANNALS OF TECHNOLOGY MARCH 8, 2021 ISSUE

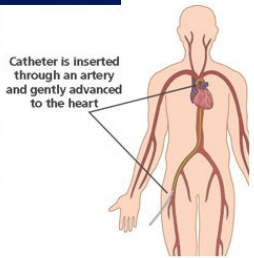
HOW TO BUILD AN ARTIFICIAL HEART

Millions of hearts fail each year. Why can't we replace them?

y Joshua Rothman

March 1, 2021

Catheter is inserted through an artery and gently advanced to the heart



Insulin Pump Therapy | Medtronic Diabetes

medtronic-diabetes.com

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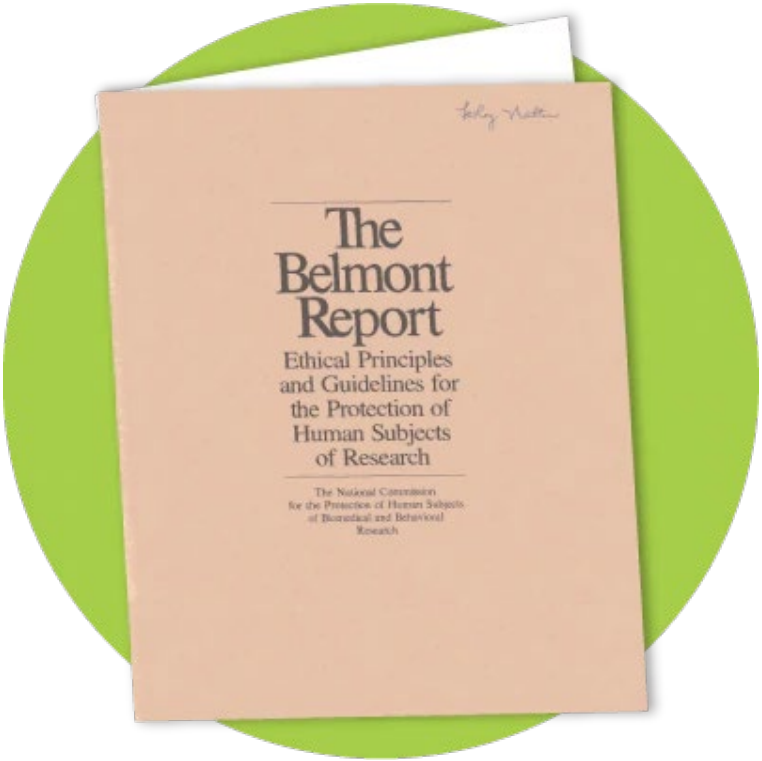
Belmont Report

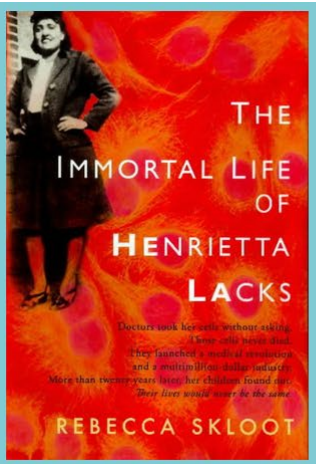
- Respect for Persons
- Beneficence
- Justice

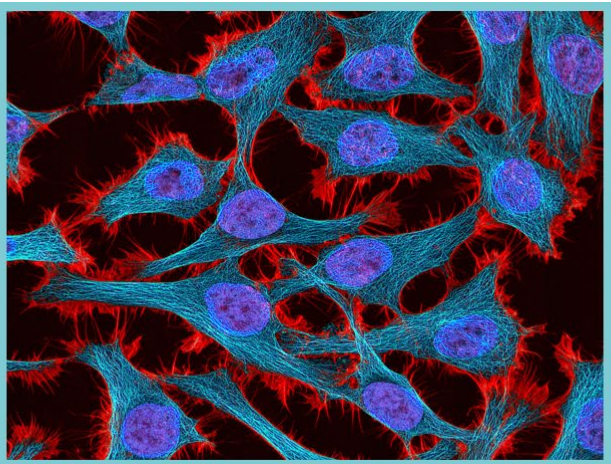


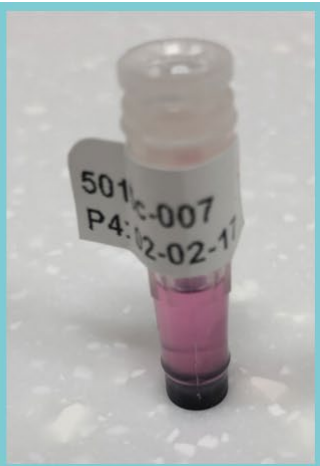
https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Respect for Persons

- Treat individuals as autonomous agents
- Protect persons with diminished capacity
- Participants voluntarily consent to participate in research
- Obtain Informed Consent
- Protect privacy and confidentiality







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https://www.nytimes.com/2021/10/13/science/henrietta-lacks-cells-who.html

Beneficence

- Means doing or producing good
- Are the risks to the research justified by the potential benefits to the individual or to society?
- Minimize the risks and maximize the benefits.

‘Three Identical Strangers’: It’s not too late to address the ethical violations

By Karen Glanz and Holly Fernandez Lynch Feb. 7, 2019 Reprints

The documentary "Three Identical Strangers" chronicles triplets born in the 1960s who were separated as infants and adopted by different families who had no idea of the other siblings' existence.

COURTESY OF NEON

https://www.pbs.org/video/three-identical-strangers-z7mjrg/

Justice

- Distribute the risks and potential benefits of research equally among those who will benefit
- Vulnerable Subjects are not targeted for convenience or because of a compromised position
- People who are likely to benefit from research participation are not categorically excluded

The New York Times

Indian Tribe Wins Fight to Limit Research of Its DNA ...

The Havasupai settlement appears to be the first payment to individuals who said their DNA was misused, several legal experts said, and came...

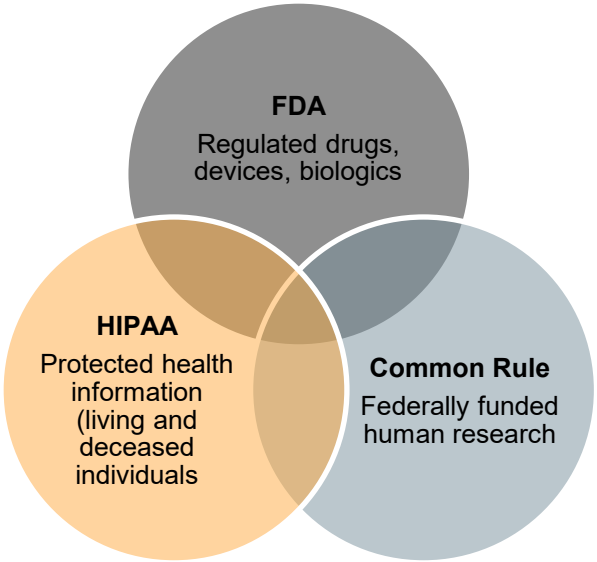
Apr 21, 2010

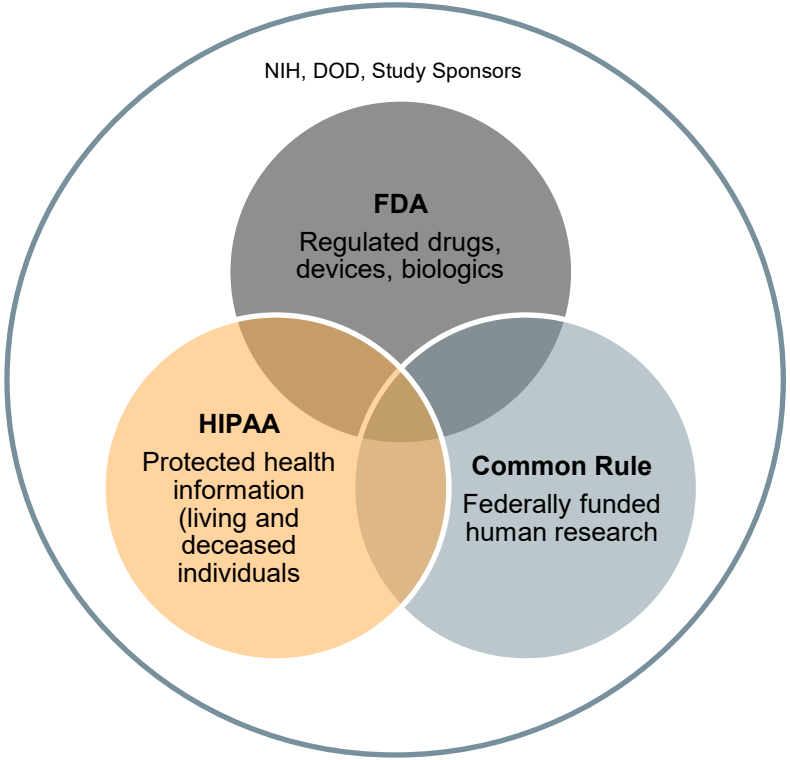
https://www.nytimes.com/2010/04/22/us/22dna.html

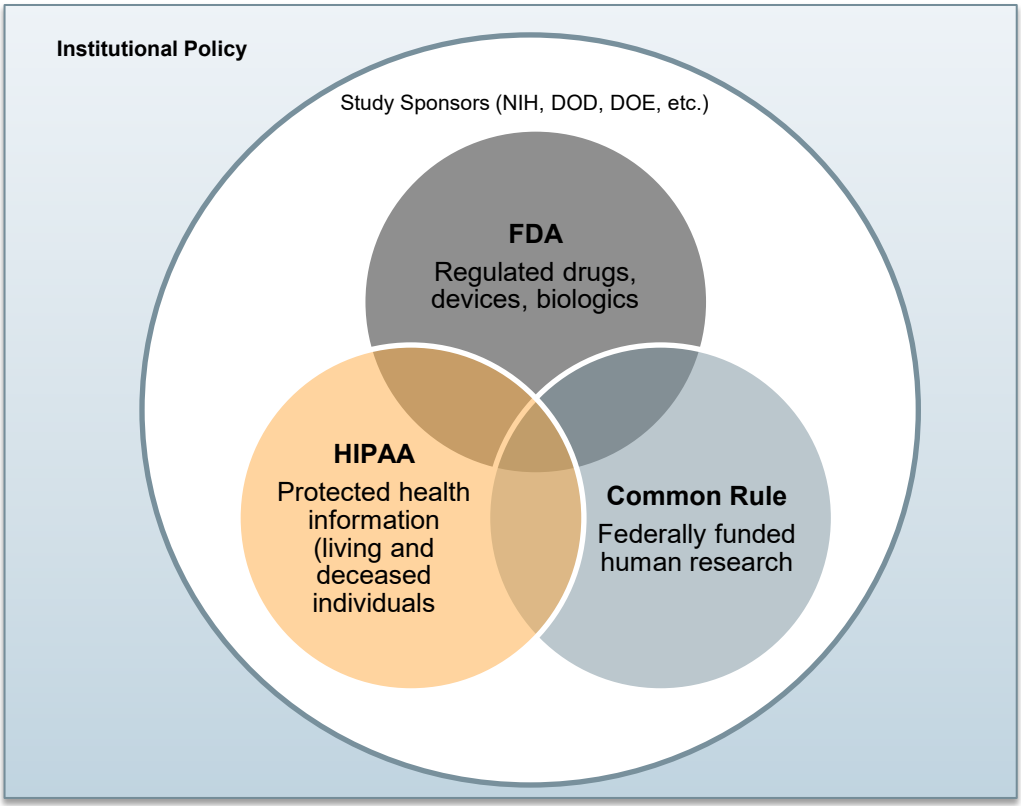
Belmont Principles Today

- **What kinds of ethical issues face researchers and research administrators in 2022?**

Rules and Regulations




NIH, DOD, Study Sponsors
FDA
Regulated drugs, devices, biologics
HIPAA
Protected health information (living and deceased individuals
Common Rule
Federally funded human research


Institutional Policy
Study Sponsors (NIH, DOD, DOE, etc.)
FDA
Regulated drugs, devices, biologics
HIPAA
Protected health information (living and deceased individuals
Common Rule
Federally funded human research

Criteria for Approval

- **Before the IRB can approve a study it must document that the following criteria are met:**
  - ✓ **Risks** to the subject are **minimized**
  - ✓ **Risks** are **reasonable** in relationship to the anticipated benefits
  - ✓ Selection of subjects is **equitable**
  - ✓ **Informed consent** will be sought and document from each subject (unless IRB grants a waiver of consent)
  - ✓ Provisions will be made to **monitor the data** collected to ensure the **safety** of subjects
  - ✓ Provisions will be made to **protect the privacy** of subjects and maintain confidentiality of data.
  - ✓ Additional protections are required for subjects likely to be **vulnerable** to coercion or undue influence, such as prisoners, children, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons.

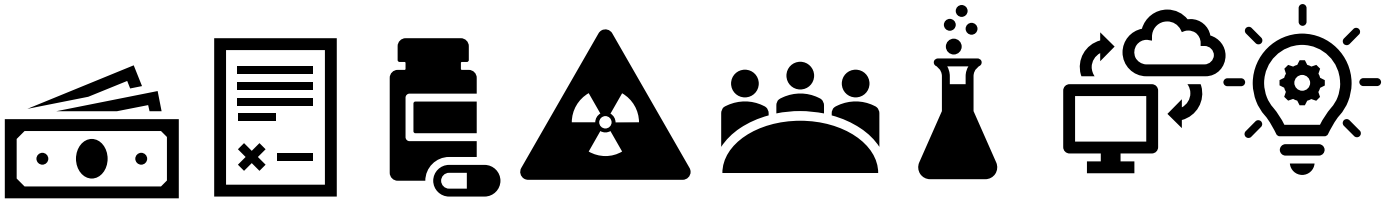
Structure of Human Research Protection Programs

- Comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research (ie, more than IRB)
  - Research Compliance/Integrity, Biosafety, Conflict of Interest, IRB, etc.
- IRBs reside as part of an organization's Human Research Protection Program (HRPP)
  - IRBs make independent decisions, an institution cannot approve research that an IRB has denied.

HRPP Components

- IRB
- Privacy
- Cybersecurity
- Radiation Safety
- Institutional Biosafety Committee
- Conflict of Interest Committee
- Pharmacy

- Researchers
- Institutional Leaders
- Legal
- OSP
- Compliance
- IP Office



HRPP Purpose

- The Human Research Protections Program protects the rights and welfare of human participants in research being conducted at an institution.
- The HRPP promotes high quality, ethical research by:
  - Requiring IRB review and approval for all research involving human subjects prior to initiating any research at Intermountain Healthcare
  - Monitoring, evaluating and continually improving the protection of human subjects
  - Promoting compliance with research regulations, institutional policies and professional and ethical standards
  - Responding to concerns of research participants
  - Responding to needs and concerns from researchers and research teams
  - Educating researchers and research teams of their responsibilities to protect research participants

Summary

- Past has help build foundation – we have learned much and have many things to celebrate
- Human research protections is more than an IRB review
- Many processes and programs involved in protecting human subjects
- Understanding your organization's system helps research administrators facilitator/manage process (to get the pieces and see the connections between all programs)

Thank You!

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Questions