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The Foundation and Principles of Human Research Protections

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Who are we?



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Agenda & Learning Objectives

Agenda

- Historical Context
- Ethical Principles
- What is a Human Research Protections Program?
- Nuts and Bolts of IRB Regulations

Learning Objectives

- Describe the foundation and principles of research ethics regulations.
- Identify ethical best practices to implement when conducting research and rules that govern human subjects research activities.

Historical Context

The New York Times

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

By HEAN HILLMAN



WASHINGTON, July 28—For 40 years the United States had its health service run amok—and it is in the line to treat the victims of one of the most heinous experiments in medical history. The study was conducted to compare the response of black and white patients to the treatment of syphilis. The study was conducted by the Tuskegee Institute, a private hospital and school of medicine in Tuskegee, Ala., which is one of the poorest of the South. The study was conducted by the Tuskegee Institute, a private hospital and school of medicine in Tuskegee, Ala., which is one of the poorest of the South. The study was conducted by the Tuskegee Institute, a private hospital and school of medicine in Tuskegee, Ala., which is one of the poorest of the South.

Tuskegee Syphilis Study

1931 – 1972



Nuclear Testing

Trinity 1945
NTS 50s-90s



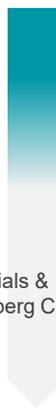
Nazi Trials & Nuremberg Code

1947



Henrietta Lacks

1951



Identical Strangers

1960s



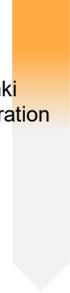
Helsinki Declaration

1964



National Research Act 45 CFR 46

1974



Belmont Report

1979



Common Rule

1991



Jesse Gelsinger

1999

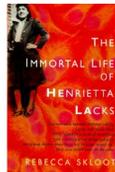


AAHRPP 2001



Revised Common Rule

2017



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 EVALI patient is 22, the researchers say that the long-term effects of vaping could be particularly concerning for young people.

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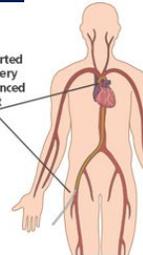
HOW TO BUILD AN ARTIFICIAL HEART

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

by 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



CAR T-cell Therapy

Remove blood from patient to get T cells

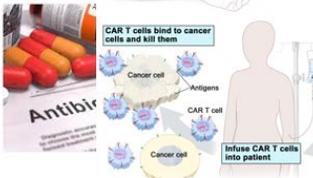
Make CAR T cells

Insert gene

Chimeric antigen receptor (CAR)

Grow millions of CAR T cells

Infuse CAR T cells into patient



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Belmont Report



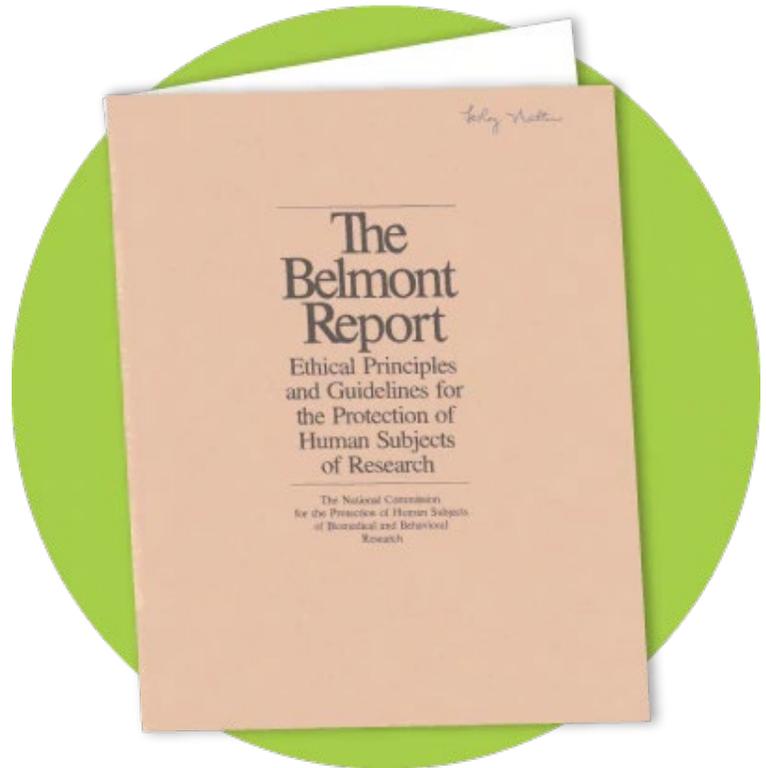
Respect for Persons



Beneficence



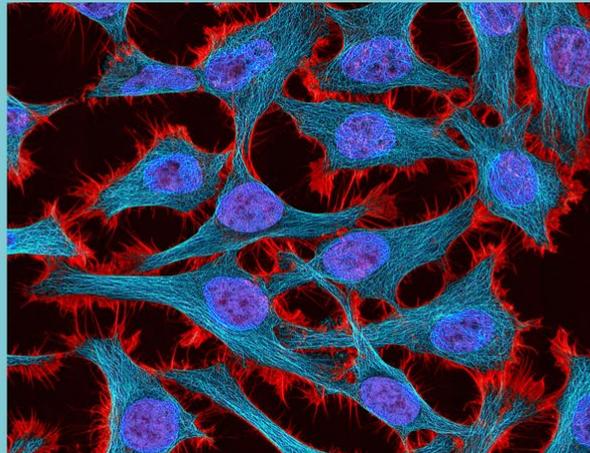
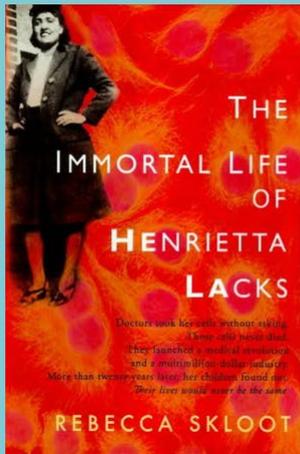
Justice





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





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



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





Belmont Principles Today

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

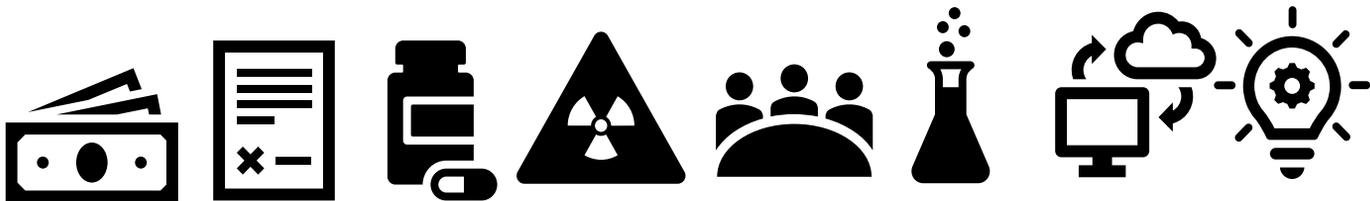
Structure of Human Research Protection Programs

- Comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research (i.e., 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
- Office of Sponsored Projects
- Compliance
- IP Office



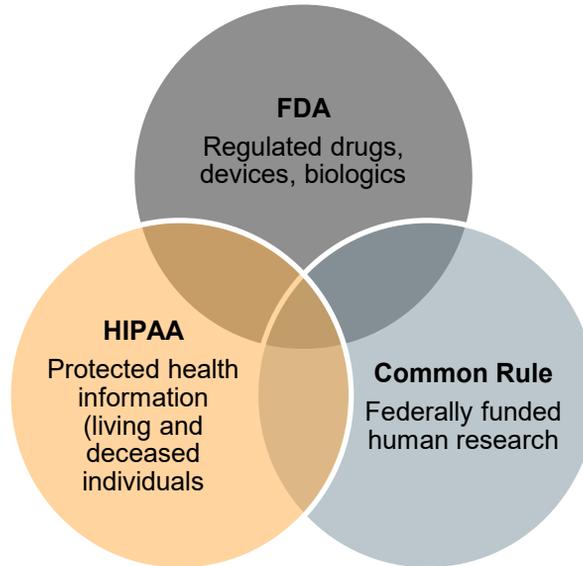
HRPP Purpose

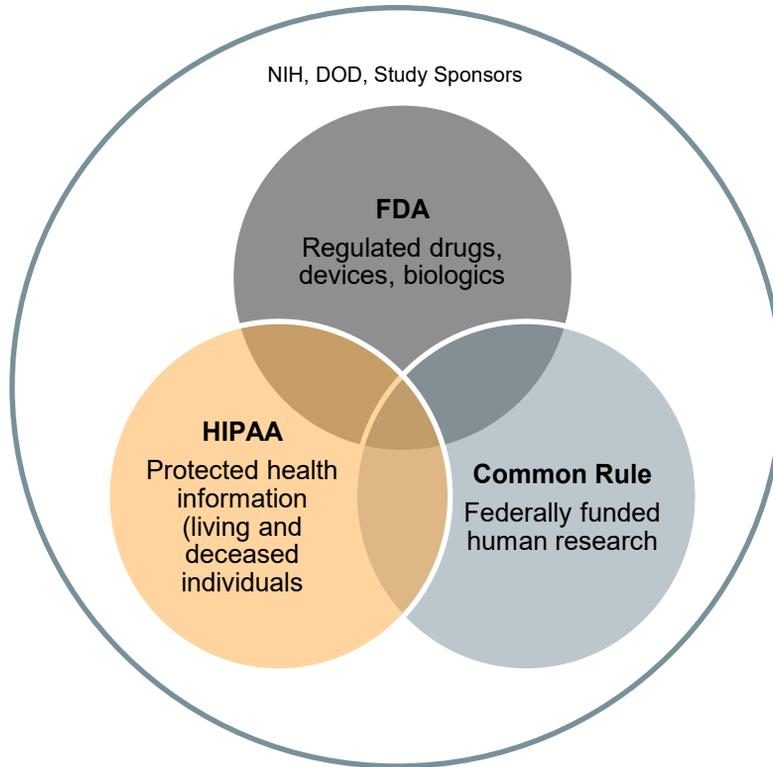
- The Human Research Protections Program protects the rights and welfare of human participants in research being conducted at an institution.
- The HRPP promotes high quality, ethical research by:
 - Requiring IRB review and approval for all research involving human subjects prior to initiating any research 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

Nuts and Bolts of IRB Review



Rules and Regulations





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



IRB Rules and Regulations

- **Common Rule (45 CFR 46)**
 - Federal Policy for the Protection of Human Subjects
 - Applies to federally funded research
 - Assurances of Compliance
 - Outlines the basic provisions for IRBs – including membership and IRB functions and operations
 - IRB Review of Research
 - Criteria for IRB Approval
 - Suspension/Termination
 - Informed consent
 - Includes additional protections for pregnant women, human fetuses, neonates, prisoners, and children



IRB Rules and Regulations

- **FDA Regulations (21 CFR Parts 50 and 56)**
 - Outlines the regulations set forth by the FDA to protect human subjects involved in clinical investigations
 - Informed Consent (part 50), including
 - Allowable exceptions
 - Elements of Informed Consent
 - Documentation of Informed Consent
 - Additional safeguards for children
 - Describes the functions and operations of IRBs (Part 56), including
 - Membership
 - Procedures for review
 - Outlines the criteria for IRB approval
 - Suspension or termination



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.



Questions?

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 the regulatory foundation and your organization’s system helps research administrators facilitate/manage the research process

Thank You!

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