BT 623: Research Methodology

Lecture 20: Ethics

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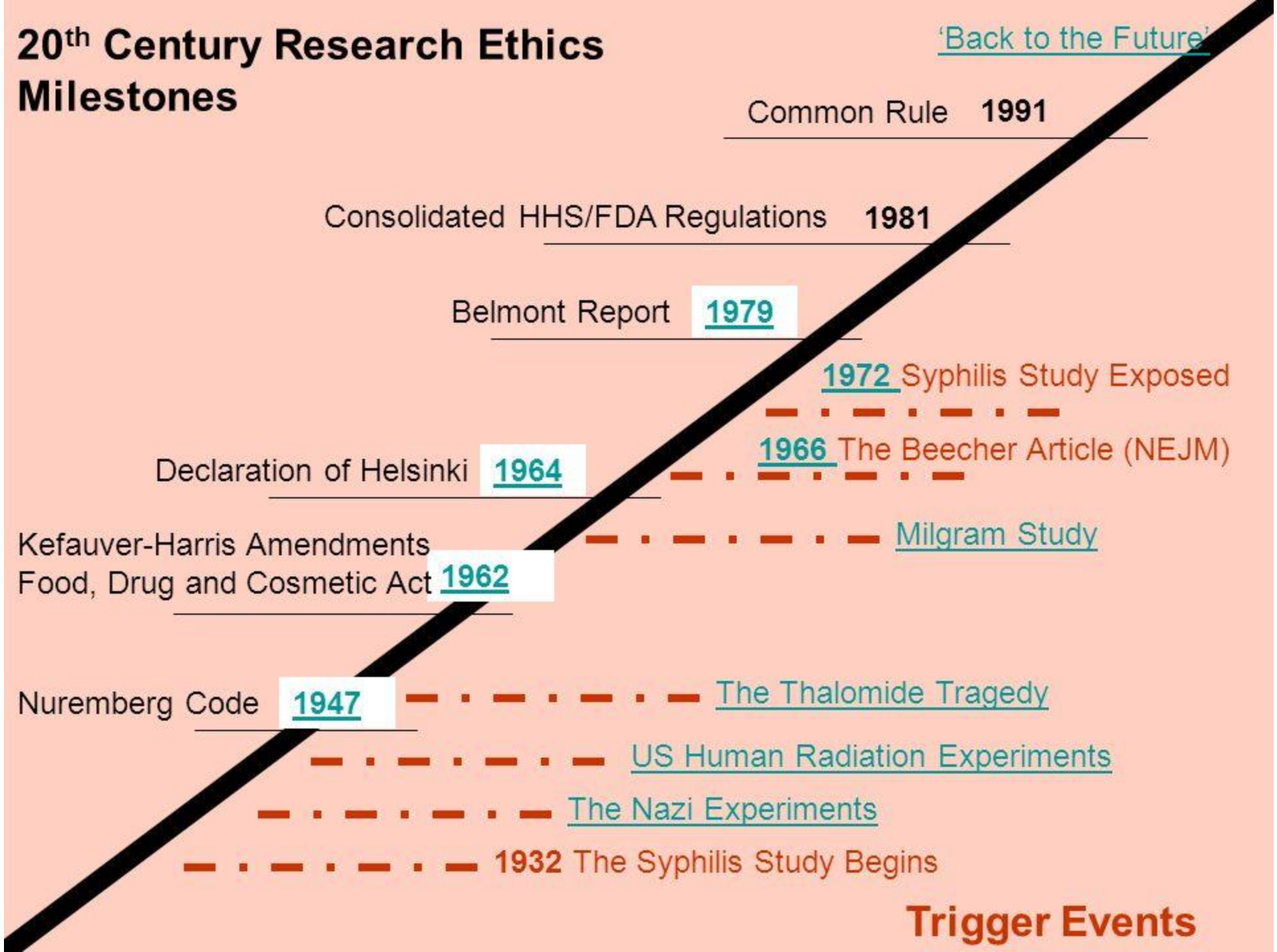
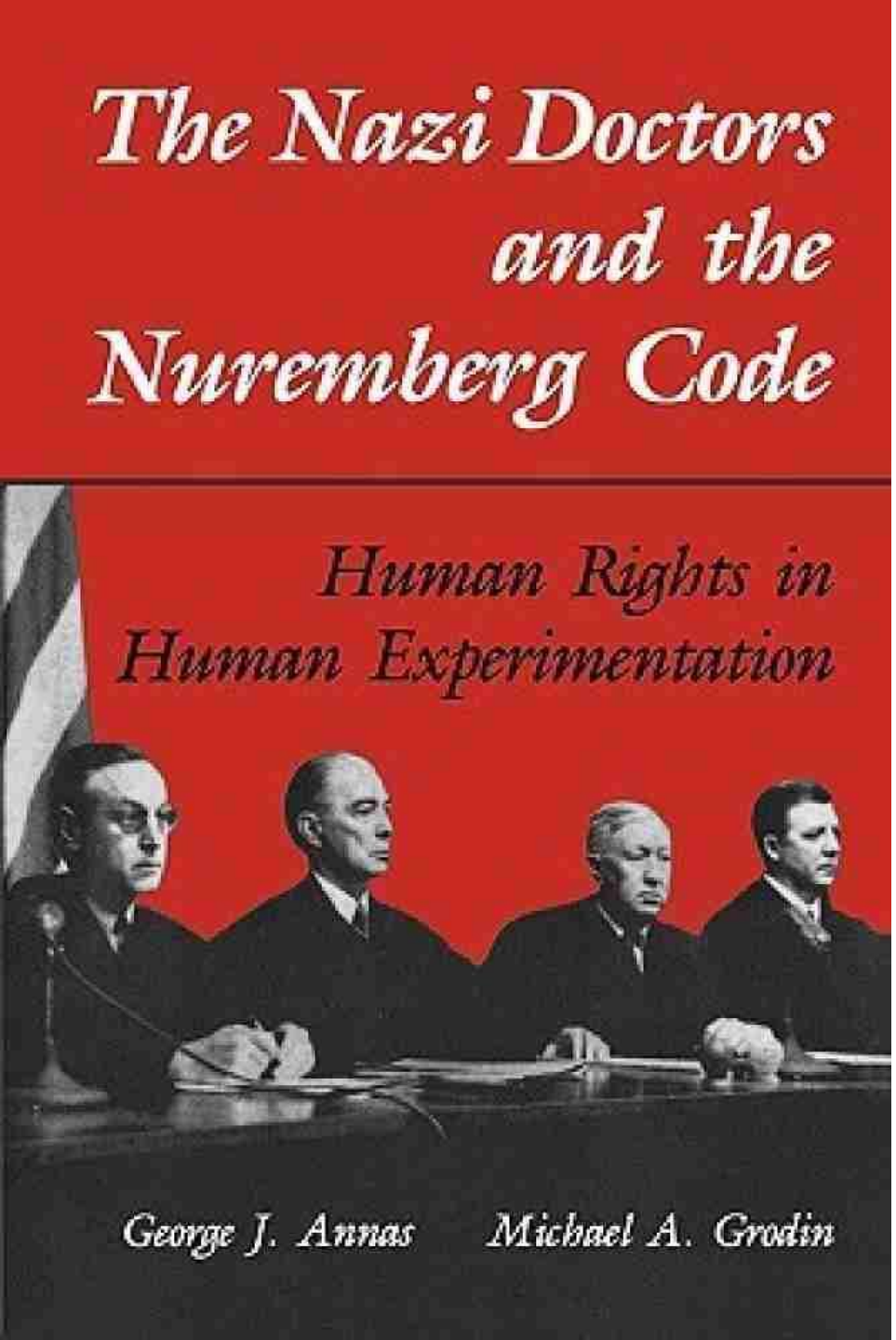
The obligations of research to society:

1.Research must contribute to society: Research should be conducted in a way that benefits society and avoids undermining human rights and democratic values. Researchers have a responsibility to ensure that research is conducted ethically and contributes to resolving global challenges.

2.Research should be compatible with sustainable development: Researchers should contribute to sustainable development and the preservation of biological diversity. The concept of sustainability encompasses economic, social, institutional, and environmental aspects.

3.Research should contribute to greater global justice: Research results and their applications should be shared with society as a whole, both nationally and globally, especially with developing countries. Research should not exacerbate global injustice, and the benefits, drawbacks, and risks associated with research activities and technological development should be shared fairly.


20th Century Research Ethics Milestones
'Back to the Future'
Common Rule 1991
Consolidated HHS/FDA Regulations 1981
Belmont Report 1979
1972 Syphilis Study Exposed
1966 The Beecher Article (NEJM)
Declaration of Helsinki 1964
Milgram Study
Kefauver-Harris Amendments
Food, Drug and Cosmetic Act 1962
Nuremberg Code 1947
The Thalomide Tragedy
US Human Radiation Experiments
The Nazi Experiments
1932 The Syphilis Study Begins
Trigger Events



The Nuremberg Trials included significant allegations against Nazi doctors, particularly during the Medical Case. They faced charges for:
1.War Crimes and Crimes Against Humanity: Conducting inhumane medical experiments on concentration camp prisoners without consent.

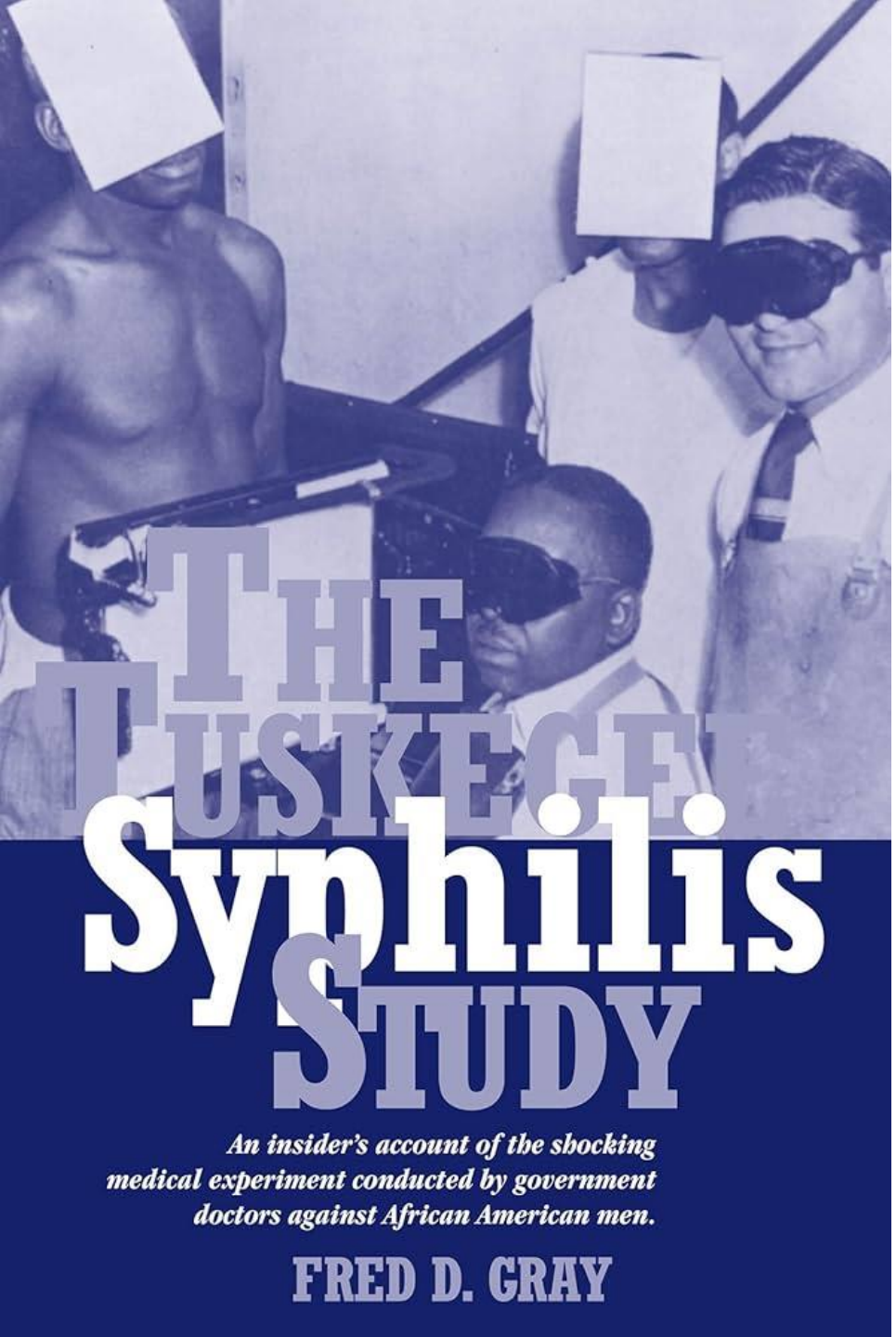
2.Euthanasia Programs: Participating in the systematic killing of individuals deemed "unfit" through certain programs.

3.Human Experimentation: Performing cruel experiments that tested human endurance and subjected prisoners to invasive procedures without anesthesia.

4.Violation of Medical Ethics: Betraying the Hippocratic Oath by prioritizing ideology over patient welfare.

5.Collaboration with the Nazi Regime: Supporting the regime’s racial purification policies.

The trials aimed to hold these individuals accountable and set a precedent for international law on medical ethics and human rights.



The Tuskegee Syphilis study, conducted from 1932 to 1972, is now a key example of unethical medical research, leading to reforms in research ethics and regulations. It involved several key allegations and violations:

1.Lack of Informed Consent: Participants were not informed they were part of a study on syphilis and were misled about their treatment.

2.Deception: Researchers falsely claimed participants were being treated for "bad blood," without disclosing their syphilis diagnosis.

3.Withholding Treatment: After penicillin became available, it was deliberately withheld to observe the disease's natural progression.

4.Racial Exploitation: The study exploited vulnerable African American men, reflecting systemic racism in medical research.

5.Ethical Violations: It violated ethical principles such as respect for persons, beneficence, and justice.


DENTAL
SNUFF

Herman Shaw speaks as President Bill Clinton looks on, during ceremonies at the White House on May 16, 1997. Clinton apologized to the survivors and families of the victims of the Tuskegee Syphilis Study.

JOURNAL ARTICLE

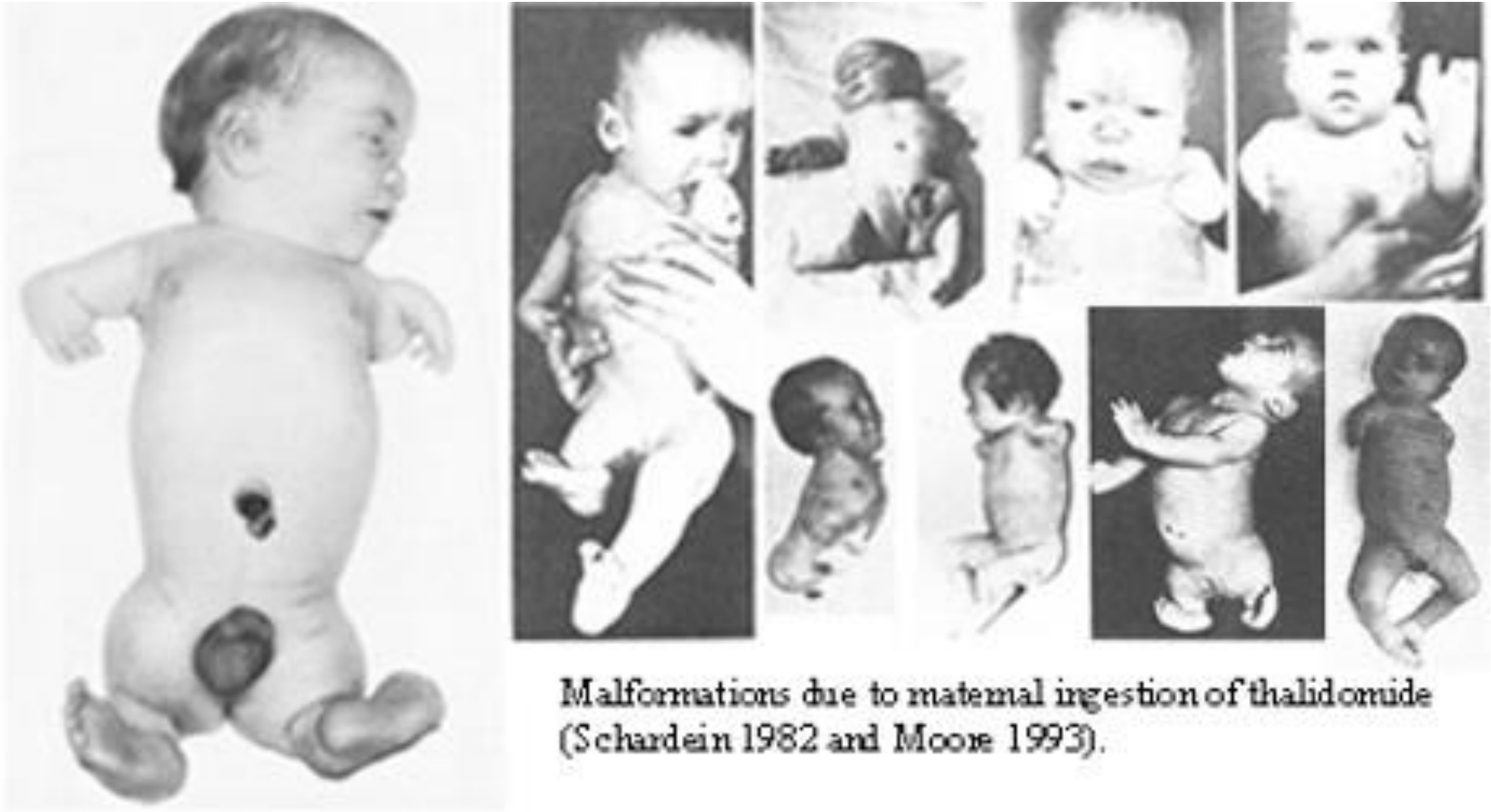
Thalidomide: The Tragedy of Birth Defects and the Effective Treatment of Disease FREE

James H. Kim ✉, Anthony R. Scialli

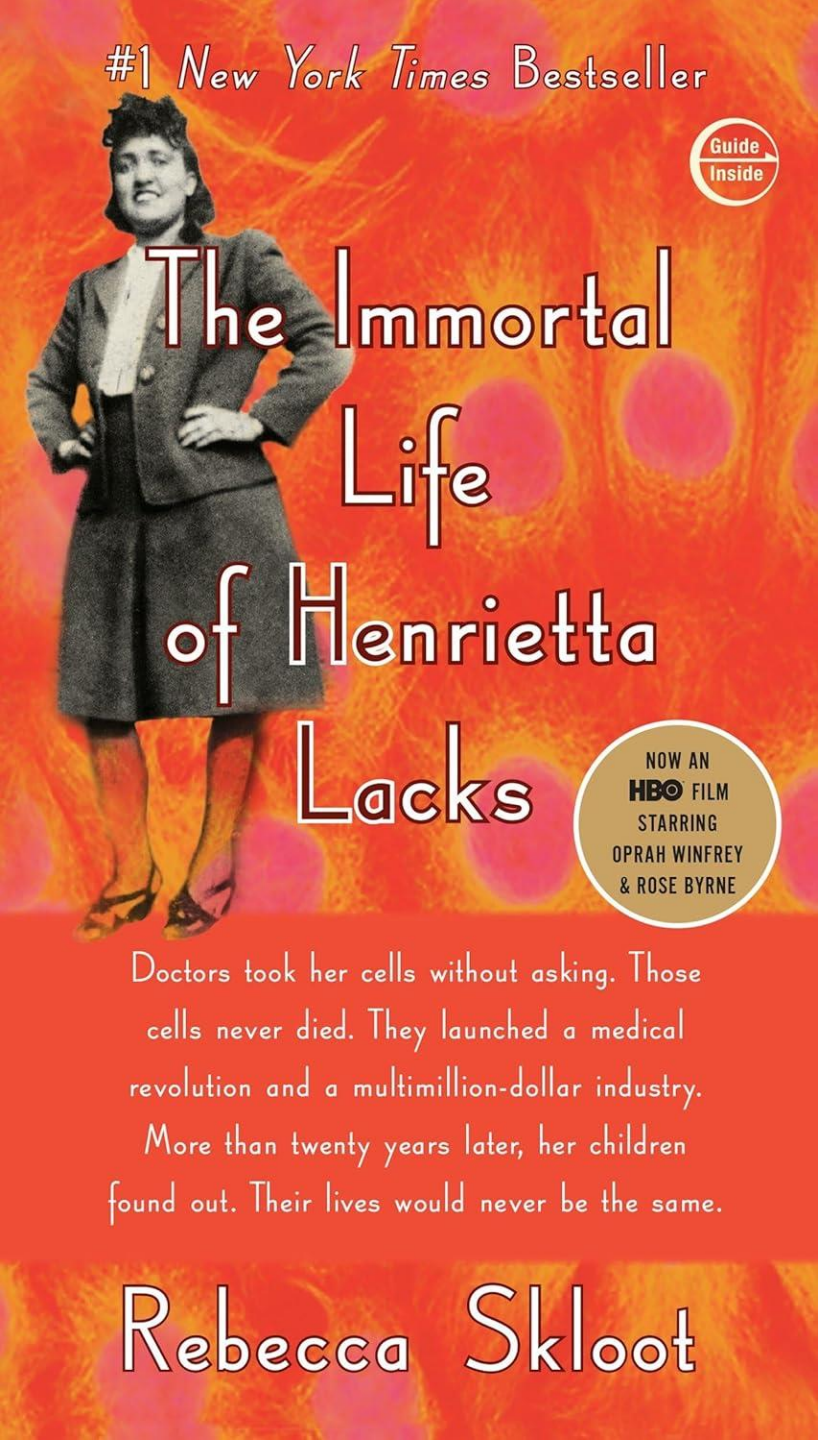
Toxicological Sciences, Volume 122, Issue 1, July 2011, Pages 1–6,
https://doi.org/10.1093/toxsci/kfr088
Published: 19 April 2011 **Article history** ▾

Abstract

Thalidomide was a widely used drug in the late 1950s and early 1960s for the treatment of nausea in pregnant women. It became apparent in the 1960s that thalidomide treatment resulted in severe birth defects in thousands of children. Though the use of thalidomide was banned in most countries at that time, thalidomide proved to be a useful treatment for leprosy and later, multiple myeloma. In rural areas of the world that lack extensive medical surveillance initiatives, thalidomide treatment of pregnant women with leprosy has continued to cause malformations. Research on thalidomide



Malformations due to maternal ingestion of thalidomide (Schardein 1982 and Moore 1993).



The case of Henrietta Lacks and her HeLa cells involves several key violations and allegations:

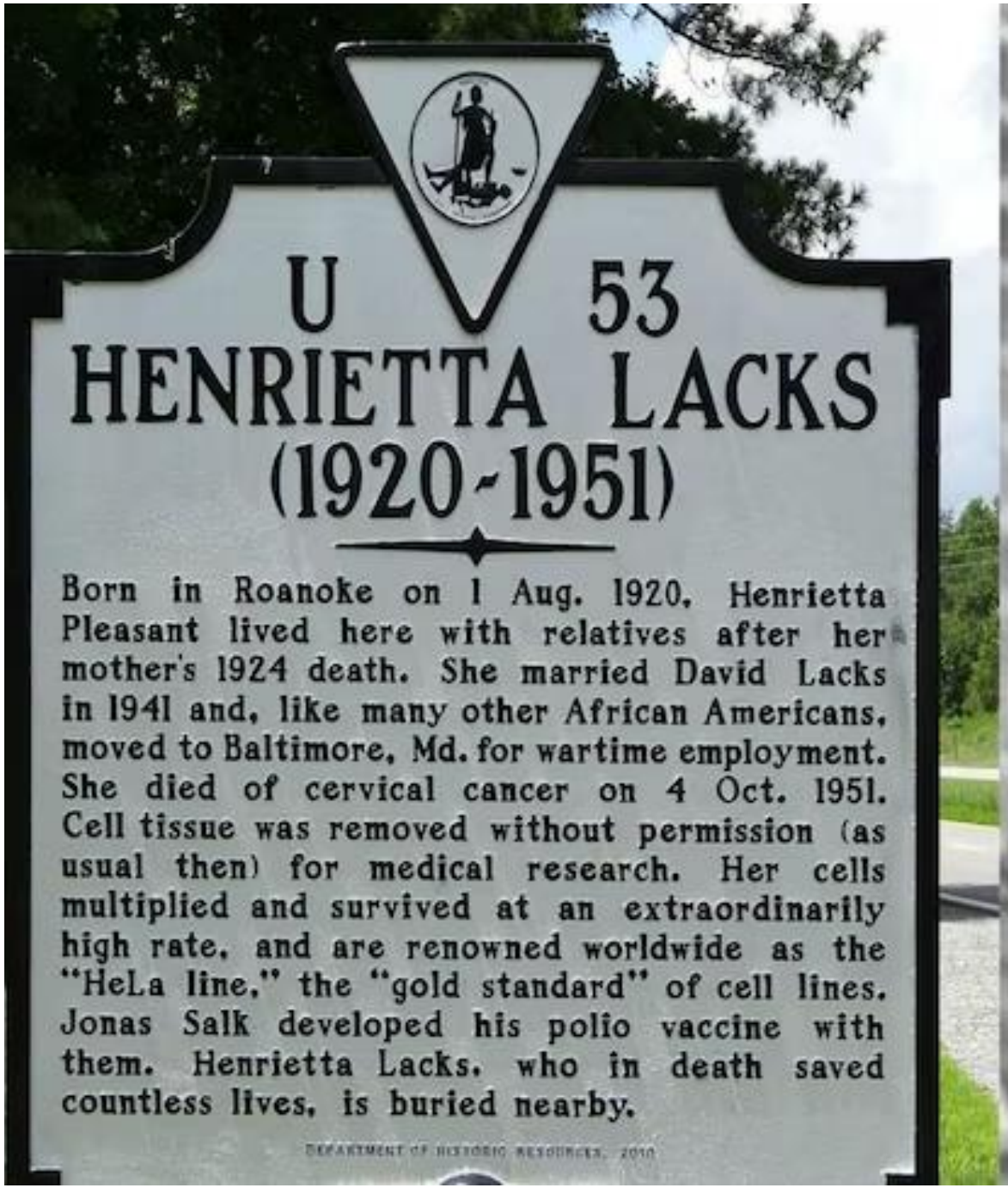
1.Lack of Informed Consent: Her cells were taken without her knowledge or consent during cancer treatment.

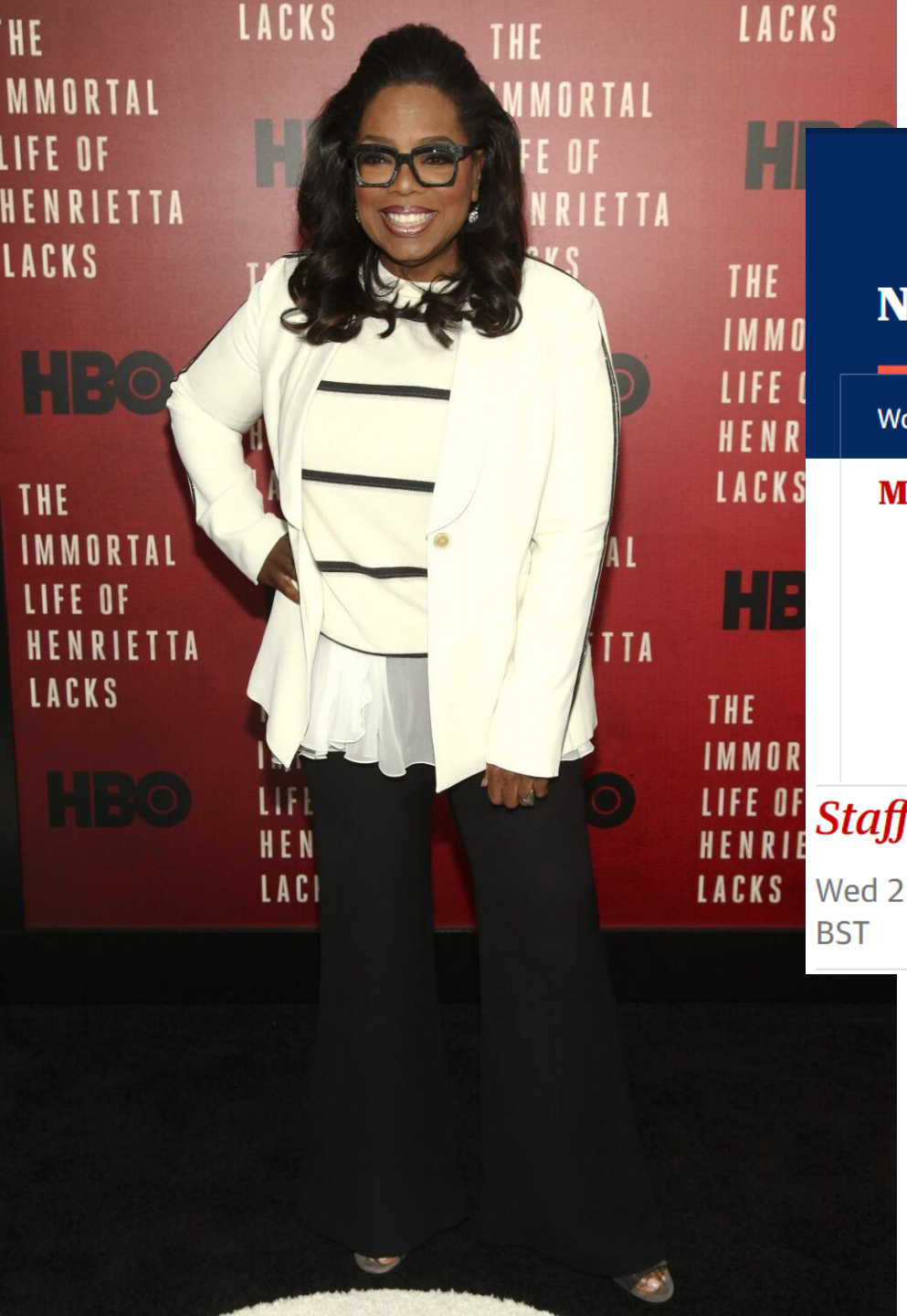
2.Exploitation: HeLa cells became crucial in research, yet Lacks and her family received no compensation or recognition.

3.Racial Discrimination: As an African American woman, Lacks's case highlights systemic racism in medical research practices.

4.Lack of Family Awareness: Her family was unaware of the significance of her cells and the ongoing research for decades.
5.Privacy Violations: Concerns arose regarding the privacy and autonomy of Lacks and her family, especially as her medical history became public.

Her case has sparked important discussions about ethics, informed consent, and individual rights in scientific research.


U 53
HENRIETTA LACKS
(1920-1951)
Born in Roanoke on 1 Aug. 1920, Henrietta Pleasant lived here with relatives after her mother's 1924 death. She married David Lacks in 1941 and, like many other African Americans, moved to Baltimore, Md. for wartime employment. She died of cervical cancer on 4 Oct. 1951. Cell tissue was removed without permission (as usual then) for medical research. Her cells multiplied and survived at an extraordinarily high rate, and are renowned worldwide as the "HeLa line," the "gold standard" of cell lines. Jonas Salk developed his polio vaccine with them. Henrietta Lacks, who in death saved countless lives, is buried nearby.



Medical research

This article is more than 1 year old

Immortal cells: Henrietta Lacks' family settle lawsuit over HeLa tissue harvested in 1950s

Staff and agencies

Wed 2 Aug 2023 01.03 BST

ells taken without consent from cancer victim can eproduce indefinitely and were sold for unjust profit by hermo Fisher Scientific, relatives argued

SCIENCEINSIDER | PEOPLE & EVENTS

What does the historic settlement won by Henrietta Lacks's family mean for others?

A legal expert says Thermo Fisher agreement could help some patients whose tissues were commercialized win redress, but they still face obstacles

7 AUG 2023 • 11:45 AM ET • BY MEREDITH WADMAN

EUROPEAN CENTER FOR CONSTITUTIONAL AND HUMAN RIGHTS

ECCHR

CASE SUMMARY

Human rights violations in clinical trials in India, the case of the HPV vaccination project

In 2009, the States of Andhra Pradesh and Gujarat launched a research project for the vaccination against the human papilloma virus (HPV) which can cause cervical cancer. Adolescent girls between the ages of 10 – 14 in the States of Andhra Pradesh and Gujarat were to be vaccinated. The vaccines were provided by GlaxoSmithKline and Merck. The project was designed and executed by PATH (Program for Appropriate Technology in Health) and funding was received from the Bill & Melinda Gates Foundation. In April 2010, however, the Government of India suspended the program as several violations of ethical standards by PATH were widely reported by human rights organizations. However, by that time, 24,000 girls were already vaccinated.

In 2011, a parliamentary enquiry committee found that the process of informed consent was inadequate (especially questioning the fact that school head masters signed consent forms on behalf of the children, calling it "wrongful authorization"). Informed consent is the process in which trial volunteers are informed about the nature, significance, implications and risks of the trial. Informed consent is crucial to protect people against unwanted experimentation. Also, in the absence of personal physical injury, Article 7 of the International Covenant on Civil and Political Rights (ICCPR) recognizes that a lack of informed consent constitutes a human rights violation: *"No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation."* The parliamentary committee further criticized that the monitoring system did not report all adverse events. Monitoring of clinical trials is, however, essential to identify injuries and respond promptly and adequately.

Project Launch: 2009. Vaccination project against HPV, targeting girls aged 10-14, funded by the Bill & Melinda Gates Foundation and executed by PATH.

Suspension of Program: The Indian government suspended the program in April 2010 due to reported ethical violations by PATH, despite 24,000 girls already vaccinated.

Informed Consent Issues: A 2011 parliamentary inquiry found that informed consent was inadequate, particularly criticizing school headmasters for signing consent forms on behalf of the girls.

Human Rights Violations: The lack of informed consent was deemed a violation of Article 7 of the ICCPR, which protects against unwanted medical experimentation.

Monitoring Failures: The monitoring system failed to report all adverse events, which is essential for ensuring participant safety in clinical trials.

Criticism of PATH: In 2013, a second parliamentary committee condemned PATH for prioritizing the commercial interests of HPV vaccine manufacturers over the well-being of the Indian population, suggesting profit motives influenced the project.

Global Bioethics Enquiry 2021;9(2)

Review Paper

Ethics Dumping and India's Unfortunate History

Sharon Gracia Glenn[1], Sneha Sonavane[2], Natasha Sharma[3]

[1]Second Year Medical Student, Sri Muthukumaran Medical College, Hospital and Research Institute, Tamil Nadu, India
[2]Second Year Medical Student, Grant Medical College, Sir J.J. Hospital, Maharashtra, India
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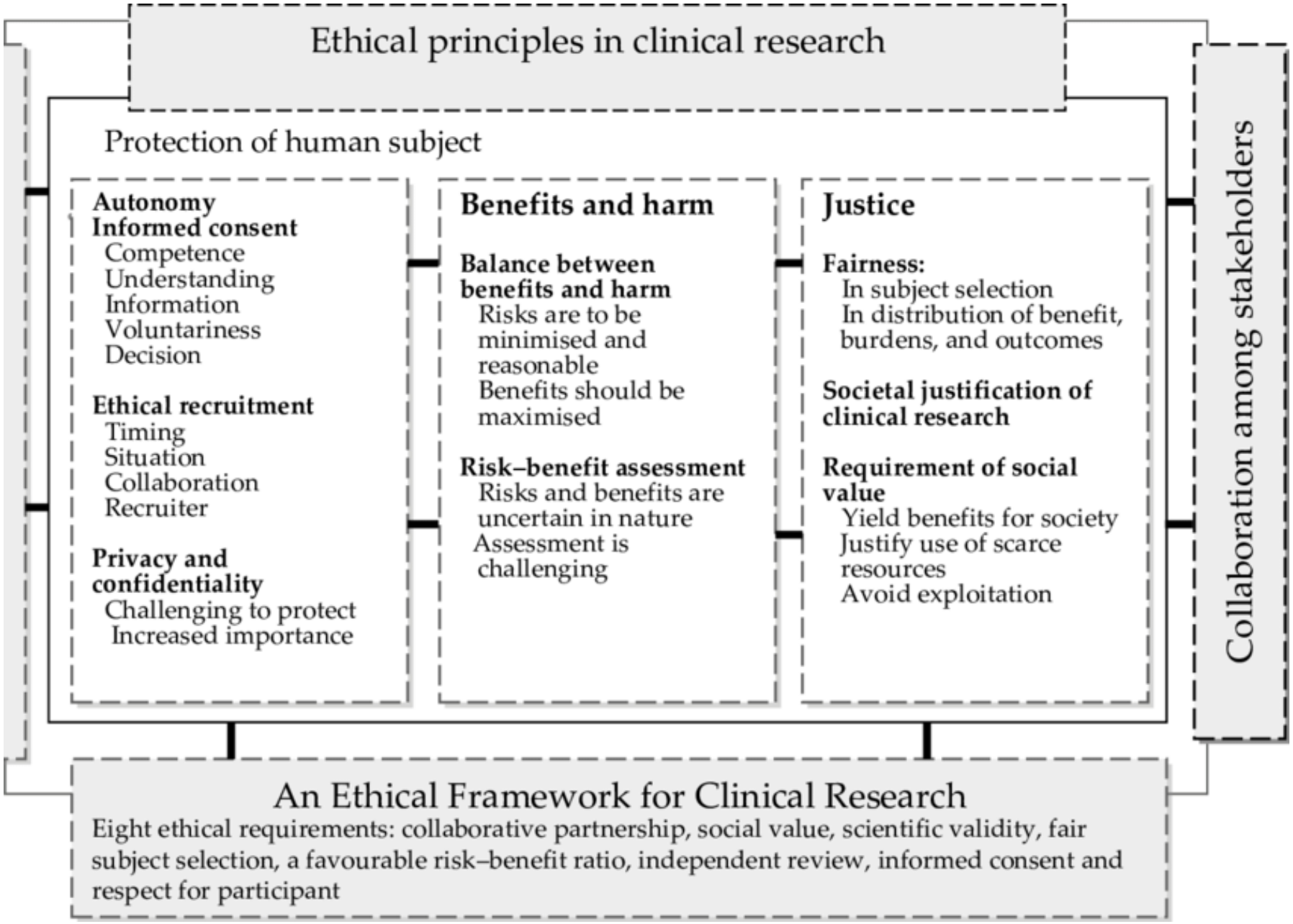
Download this and similar papers and prepare a note on the "Violations of Bioethics in India".

Protection of Research Subjects
Specific requirements for protecting the rights and well-being of research subjects.

Freely Given, Informed Consent: Researchers must obtain informed consent from participants, ensuring they understand the purpose of the research, can evaluate their situation, make an independent decision, and freely communicate their consent.

Protection: Researchers must protect the privacy of research subjects, particularly when sensitive information is collected. Information should be handled with care, and participants should be informed about how their information will be protected.

Confidentiality and Anonymity: Researchers must provide confidentiality or anonymity to participants who desire it. Confidentiality means that information is de-identified, while anonymity means that even the researcher does not know who provided the data.



https://www.researchgate.net/figure/The-theoretical-basis-for-protection-of-human-subjects-in-clinical-research_fig1_328685156/actions#reference

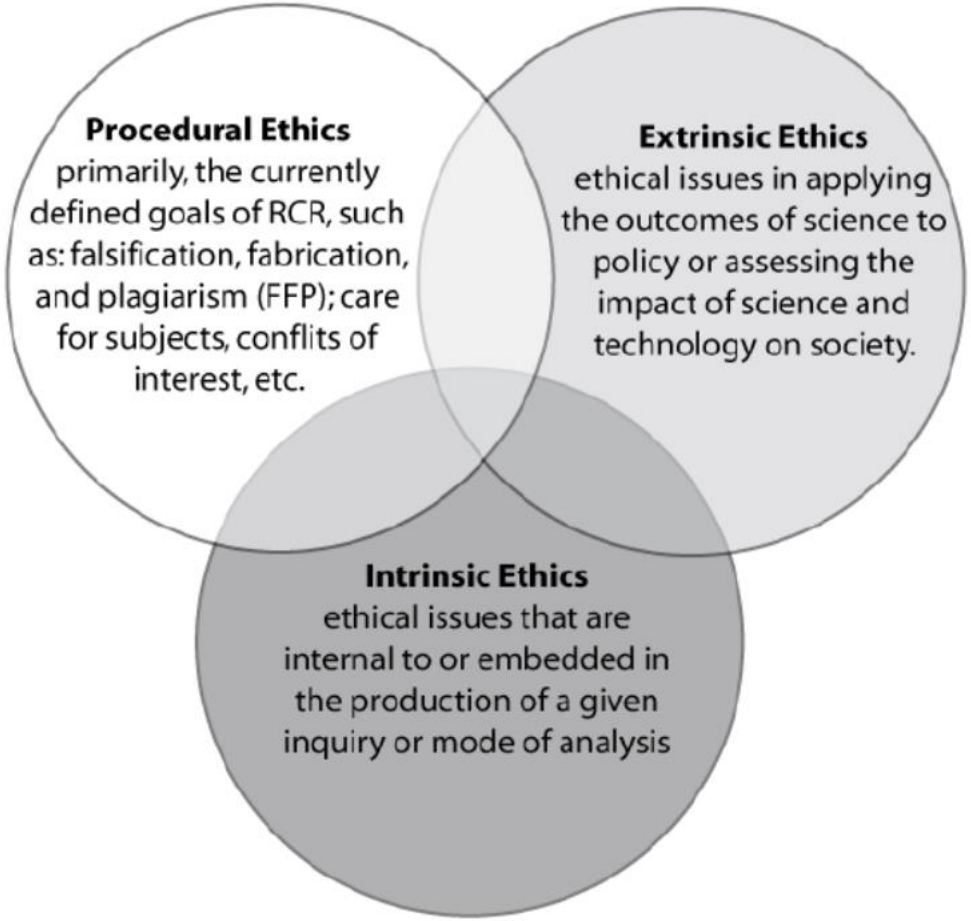
Training in Research Ethics that emphasizes only Responsible Conduct of Research (RCR) fails to acknowledge the necessity of science being both responsible and responsive. A study by Eric and colleagues identified two key issues: traditional RCR pedagogy overlooks important ethical dimensions of scientific research, and the Broader Impacts Criterion (BIC) is underutilized because current training does not provide the necessary knowledge and skills for scientists and social scientists.

They advocate for institutions to adopt a more comprehensive approach to research ethics, termed the Ethical Dimensions of Scientific Research (EDSR), which encompasses a broader range of ethical issues relevant to scientific inquiry, including the implications of research.



While Responsible Conduct of Research (RCR) is important, it does not encompass the full range of ethical aspects of scientific inquiry. RCR is particularly inadequate in addressing ethical issues arising from specific scientific content or the broader implications of scientific knowledge. In light of these shortcomings, Erich et al. (2009) proposed recognizing three distinct components of research ethics. These components form a new model, the Ethical Dimensions of Scientific Research (EDSR), which they advocate as a successor to traditional RCR pedagogical approaches to research ethics.

REFER TO THIS PAPER FOR FULL DETAILS:
Social Epistemology, 2009, 23(3-4): 317-336



Domain diagram of the Ethical Dimensions of Scientific Research model of a broaderconception of “research ethics.

1) **Procedural ethics**: ethical aspects of the process of conducting scientific research, such as: falsification, fabrication, and plagiarism; care for subjects (human and non-human animal); responsible authorship issues; analysis and care for data; and conflicts of interests. Procedural ethics is contained almost entirely within the currently defined goals of RCR .

2) **Intrinsic ethics:** ethical issues intrinsic to the production of scientific research, i.e. ethical issues embedded in the research, such as: the use of certain equations, constants, and variables; analysis of data; handling of error and degree of confidence in projections; and choice of a cost-benefit analysis paradigm.

3) **Extrinsic ethics:** ethical issues extrinsic to the production of scientific research, i.e. ethical issues in how the outcomes of science research impact society, such as: policy making; lawsuits; changes in social norms; and education and entertainment

Bioethics is the interdisciplinary study of ethical, legal, and social issues arising from advances in biology and medicine. It encompasses a range of topics, including the moral implications of medical practices, biomedical research, biotechnology, and the treatment of living organisms. Bioethics aims to address complex questions about human rights, informed consent, equity in healthcare, and the ethical treatment of animals, ensuring that scientific progress aligns with societal values and ethical principles.

Four Basic Principles of Bioethics

Bioethics, the study of ethical issues arising from advances in biology and medicine, is guided by four fundamental principles:

1.Autonomy: This principle respects the individual's right to make informed decisions about their own healthcare. It includes the right to refuse treatment, participate in research, and make choices about end-of-life care.

2.Beneficence: This principle requires healthcare providers to act in the best interests of their patients. It involves promoting good and preventing harm.

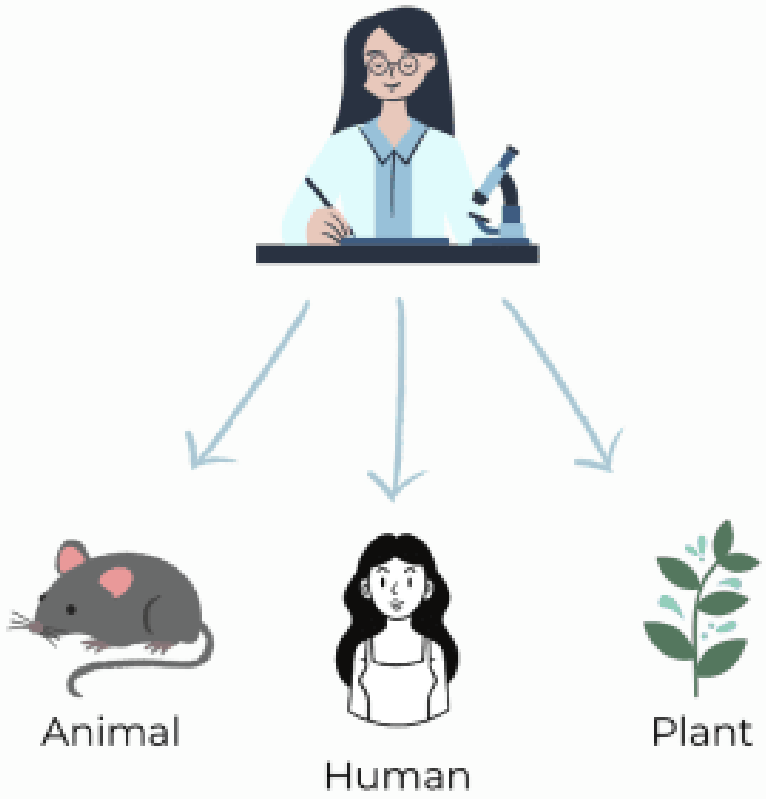
3.Non-maleficence: This principle prohibits causing harm to others. It is often summarized as "do no harm.“

4.Justice: This principle requires fairness in the distribution of healthcare resources and services. It involves ensuring that individuals are treated equally and without discrimination.

These four principles provide a framework for ethical decision-making in a variety of healthcare settings. However, they may sometimes conflict with one another, requiring careful consideration and balancing of competing interests.

Bioethics

Subjects of bioethic questions



4 bioethics principles

Beneficence

Non-maleficence

Autonomy

Justice

Protection of Animals Used in Research

By adhering to following principles while using animals in research, researchers can ensure the ethical treatment of animals used in research and minimize any harm or suffering.

Animals as moral objects: Animals deserve respect and ethical treatment.

Animal welfare considerations: Ethical considerations apply to both laboratory animals and animals that are the subject of research.

Justification of experiments: Researchers must justify the necessity of experiments involving animals, considering the three R's (reduce, refine, replace).

Compliance with regulations: Researchers must cooperate with supervisory authorities and comply with relevant legislation and guidelines for using laboratory animals.

Avoidance of harm: Research on animal breeding must not compromise animal welfare. Exceptions may be justified in rare cases for important veterinary or human medicine purposes.

The principles of the 3R in animal research

Research with animals

Replace

Achieve a research objective by avoiding or replacing the use of animals.

Reduce

As many experiments as necessary, but as few laboratory animals as possible.

Refine

Minimize the potential suffering and stress of laboratory animals and enhance their wellbeing.

The Relationship Between Research and Other Forms of Knowledge

It is important to acknowledge and respect other forms of knowledge, such as traditional knowledge and local knowledge for a comprehensive and inclusive understanding of the world.

- **Diverse forms of knowledge:** Societies have a multitude of knowledge types, including experience-based knowledge, local knowledge, and traditional knowledge.

- **Respect and protection:** These forms of knowledge and their bearers should be treated with respect and protected from exploitation.

- **Acknowledge economic and cultural value:** Researchers using or building on other forms of knowledge should acknowledge their economic and cultural value.

- **Fair and equitable sharing:** When research results in financial gains, the bearers of traditional knowledge should receive a fair share.

- **Dialogue with knowledge-bearers:** Researchers should engage in dialogue with local and traditional knowledge-bearers to gain insights and potentially apply relevant knowledge in their research.

Access and Benefit-Sharing

Ensuring the fair and equitable sharing of benefits from the utilization of genetic resources

ABS refers to the agreement between user and provider in the access of genetic resources and how benefits are shared between them.

- **Prior and Informed Consent (PIC)**
  seeks permission from appropriate representatives and shares information on the purpose for accessing genetic resources and traditional knowledge.
- **Mutually Agreed Terms (MAT)**
  states monetary and non-monetary benefits in exchange for access as agreed between user and provider.
- **Traditional Knowledge**
  refers to knowledge of indigenous peoples and local communities that are rich sources of information for bio-product development.
- **Compliance**
  is observance of obligations to ensure sharing of benefits when genetic resources leave a provider.

Opportunities

Research and Development:
Advances in biotechnology

Potential Income Generation:
Creation of products worth billions

Development of ABS Frameworks:
More ASEAN Member States are acceding to the Nagoya Protocol and/or developing national ABS policies.

Ways Forward

Raise public awareness and increase stakeholders' participation

Promote regional cooperation and capacity building

Implement legislation and administrative or policy measures on ABS

Formulate national regulatory and institutional frameworks on ABS

Protect genetic resources from misappropriation and misuse

Scientific Integrity, Truthfulness, and Accountability in Research

These guidelines emphasize the importance of good scientific practice based on integrity, truthfulness, and accountability. Here are the key points:

1. Responsibilities of Researchers and Institutions:
Researchers must conduct high-quality research with integrity, truthfulness, and accountability.
Research institutions must create an environment that encourages these practices.
Researchers and institutions must be familiar with relevant research ethics guidelines.

2. Scientific Integrity:
Researchers must be honest in all aspects of research, from planning to reporting.
Falsifying, misrepresenting, or concealing data is unacceptable.
Plagiarism is forbidden.
Researchers must report errors in their research and correct them.

3. Authorship and Collaboration:
Researchers must acknowledge the contributions of others.
Good publication practices should be followed.
Authorship should be based on substantial contribution to the research.
All authors must be accountable for the work.

4. Peer Review:
Researchers reviewing the work of others must be impartial and qualified.
Reviewers should recuse themselves from conflicts of interest.

5. Compliance with Rules and Regulations:
Researchers must comply with national and international regulations for ethical research and safety.
Research should adhere to national safety standards.
Ethical standards should not be compromised for the sake of foreign regulations.
Researchers must inform funding institutions of any ethical or safety issues encountered abroad.

Uncertainty, Risk, and the Precautionary Principle in Research

It is important to address uncertainty and risk in research, especially when the findings may have significant consequences.

Clarify uncertainty and risk: Researchers must be transparent about the degree of uncertainty in their research and evaluate the potential risks associated with their findings.

Communicate uncertainty: Researchers should present their findings critically and in context, highlighting any uncertainties or risks that may affect interpretation or application.

Observe the precautionary principle: When there is a potential for harm, even if it is uncertain, researchers should contribute knowledge that supports the precautionary principle. This means working with others to avoid or minimize harm.

The precautionary principle emphasizes the importance of taking action to prevent harm, even when scientific certainty is limited. Researchers have a shared responsibility to ensure that evaluations are based on this principle to avoid or minimize potential risks.

- **Citizen participation:** Researchers should involve affected parties in the research process through appropriate methods.
- **Democratic corrective:** Citizen participation can help ensure that research focuses on relevant and important topics.
- **International conventions:** The Aarhus Convention and other international conventions support the participation of users, citizens, and social actors in research.

By involving affected parties, researchers can ensure that their work is relevant, responsive, and contributes to democratic decision-making.

Commissioned Research, Openness, and Conflicts of Interest

The importance of openness, transparency, and managing conflicts of interest in commissioned research is emphasized to maintain the integrity and trustworthiness of the work.

- **Openness and scientific quality:** Research institutions and researchers must ensure openness and scientific quality in commissioned research. This includes transparency in methods, data acquisition, interpretation, and reporting.

- **Conflict of interest disclosure:** Researchers must disclose any potential conflicts of interest that could influence their research or its communication.

- **Whistleblower protection:** Institutions must protect whistleblowers who raise concerns about ethical issues or misconduct in research.