



National Institute of
Environmental Health Sciences



Research Ethics Timeline (1932-Present)

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- **1932-1972**

The Tuskegee Syphilis Study, sponsored by the U.S. Department of Health. Studied the effects of untreated syphilis in 400 African American men. Researchers withheld treatment even when penicillin became widely available. Researchers did not tell the subjects that they were in an experiment. Most subjects who attended the Tuskegee clinic thought they were getting treatment for "bad blood."

- **1939-45**

German scientists conduct research on concentration camp prisoners.

- **1940 O.R.**

Two Nazi refugee scientists, Frisch and R.E. Peierls, warn the U.S. about Germany's nuclear weapons program. Albert Einstein writes a letter to Pres. Truman warning him about the Nazi threat.

- **1942-1945**

The U.S. begins the \$2 billion Manhattan Project to develop an atomic bomb.

- **1944-1980s**

The U.S. government sponsors secret research on the effects of radiation on human beings. Subjects were not told that they were participated in the experiments. Experiments were conducted on cancer patients, pregnant women, and military personnel.

- **1945**

The US drops two atomic bombs on Japan.

- **1945**

Led by Pres. Eisenhower and a-bomb scientist Robert Oppenheimer, the "atoms for peace" movement begins.

- **1945**

Vannevar Bush writes the report Science: the Endless Frontier for Roosevelt. The report argues for a major increase in government spending on science and defends the ideal of a self-governing scientific community free from significant public oversight. It promotes investment in science and technology as a means of promoting national security and economic development.

- **1947**

The Nuremberg Code for research on human subjects is adopted. The Allies use the document in the Nuremberg Trials to convict Nazi scientists of war crimes.

- **1948**

Research Ethics Timeline (1933-Present) [http://www.rihs.nih.gov/research/resources/bioethics/timeline/...](http://www.rihs.nih.gov/research/resources/bioethics/timeline/)
Alfred Kinsey publishes Sexual Behavior in the Human Male; Sexual Behavior in the Human Female followed in 1953. Both of these books were very controversial. Kinsey funded the research through the Kinsey Institute.

- **1949**
The Soviet Union tests a hydrogen bomb; the Cold War begins.
- **1953**
James Watson and Francis Crick discover the structure of DNA, for which they eventually would share the Nobel Prize in 1962. They secretly obtained key x-ray diffraction data from Rosalind Franklin without her permission. She was not awarded a Nobel Prize because she died in 1953 from ovarian cancer (at age 37), and the prize is not awarded posthumously.
- **1956-1980**
Saul Krugman, Joan Giles and other researchers conduct hepatitis experiments on mentally disabled children at The Willowbrook State School. They intentionally infected subjects with the disease and observed its natural progression. The experiments were approved by the New York Department of Health.
- **1950s-1963**
The CIA begins a mind control research program, which includes administering LSD to unwitting subjects.
- **1957**
The Soviets launch Sputnik, the first satellite, which triggers the U.S. government to increase its investments in science and technology to avoid falling behind in the space race.
- **1961**
John F. Kennedy commits the U.S. to the goal of putting a man on the moon by the end of the decade.
- **1961**
Rachel Carson publishes Silent Spring, which alerts people to the harmful effects on the environment of various toxins and pollutants, including DDT. Her book launches the environmentalist movement.
- **1961-1962**
Stanley Milgram conducts his "electric shock" experiments, which proved that many people are willing to do things that they consider to be morally wrong when following the orders of an authority. He publishes Obedience to Authority in 1974.
- **1964**
World Medical Association, Helsinki Declaration. Ethical principles for research on human subjects. Revised several times, most recently in 2001.
- **1964**
The U.S. Surgeon General's office issues its first of several reports on health problems related to smoking.
- **1966**
Henry Beecher publishes an article in N. Engl. J. Med. exposing 22 unethical studies in biomedicine, including the Tuskegee syphilis study and the Willowbrook hepatitis study.

The Department of Defense begins to work on a project to connect its computers scattered around the U.S. at various universities and research labs. This was followed by the development of the ARPANET (1972), BITNET and USENET (1981), NSFNET (1985), the Internet (1988), and the World Wide Web (1995).

- **1960s/1970s**

Animal rights movement; Congress adopts the Animal Welfare Act (1966, 1970, 1976, 1985), which excludes rodents and birds. States adopt animal welfare laws; US Public Health Service, Policy on the Humane Care and use of Laboratory Animals; American Association for the Accreditation of Laboratory Animal Care (AAALAC).

- **1969**

The US lands the first man on the moon.

- **1972**

The national media and Congress focus on unethical research practices with human subjects, including the Tuskegee study.

- **1974**

Congress passes the National Research Act, which authorizes federal agencies to develop human research regulations, e.g. 45 CFR 46, 21 CFR 50,54,56.

- **1974**

William Summerlin **admits to fabricating data** by using a marker to make black spots on white mice at Sloan Kettering Cancer Institute. He was developing a technique for transplanting skin grafts.

- **1974**

Monsanto and Harvard reach a deal for the first major corporate investment in a university.

- **1975**

Scientists gather at Asilomar, CA to discuss the benefits and risks of recombinant DNA research; the NIH forms the Recombinant DNA Advisory Committee.

- **1975**

Peter Singer publishes Animal Liberation.

- **1975**

E.O. Wilson publishes Sociobiology, which re-ignites centuries-old "nature vs. nurture" debate. His book proposes biological and evolutionary explanations of human behavior and culture.

- **1978**

Louise Brown, the world's first test-tube baby, is born.

- **1979**

The National Commission releases The Belmont Report, principles of ethical research on human subjects. The Report becomes a key document in human research ethics regulations in the U.S.

- **1980**

Congress passes the Bayh-Dole Act, which allows researchers to patent inventions developed with government funds; the Act

- **1980**

In *Diamond v. Chakrabarty* the U.S. S. Ct. rules that a genetically modified bacterium can be patented because it is the product of human ingenuity. This sets a precedent for patents on other life forms and helps to **establish solid intellectual property protection** for the new biotechnology industry.

- **1981**

The Whitehead Institute is established at MIT, another major private investment in a university.

- **1981**

The DHEW conducts major revisions of the federal human research regulations on human subjects research.

- **1981**

John Darsee, a postdoctoral fellow at Harvard, is **accused of fabricating data.**

- **1982**

William Broad and Nicholas Wade publish *Betrayers of Truth*, **claiming that there is more misconduct in science than researchers want to admit. Their book helps to launch an era of "fraud busting" in science.**

- **1984-1993**

Luc Montagnier accuses Robert Gallo misappropriating an HIV strain. **Gallo is found innocent of misconduct.** Gallo and Montagnier also have a dispute about who should be credited with discovering HIV and who can patent a test for the virus. The U.S. and French governments reach an agreement to settle the controversy.

- **1986**

Roger Boisjoly **warns NASA about possible O-ring failure**, due to cold weather, in the space shuttle Challenger. NASA decides to go ahead with the launch, and the Challenger explodes, killing the entire crew.

- **1987**

A NIMH panel concludes that Steven Breuning **fabricated and falsified data in 24 paper.** Breuning is convicted of defrauding the federal government in 1988.

- **1987**

Martin Luther King is accused of plagiarizing his Ph.D. dissertation.

- **1987-1996**

Margot O'Toole, a post-doctoral student at the Whitehead Institute, has some questions about a data presented in a paper authored by six of her colleagues published in the journal *Cell* in 1986. She asks to examine Thereza Imanishi-Kari's lab notebooks, which seem to be inconsistent with published results. She accuses Imanishi-Kari of **fabricating or falsifying data.** The ensuing investigation leads to inquiries by M.I.T. and Tufts as well as the N.I.H. and a Congressional committee chaired by Rep. John Dingell. Nobel Prize winner David Baltimore is one of the co-authors on the disputed paper. Although he was not accused of misconduct, Baltimore resigned as President of Rockefeller University. He described the investigation, which was covered by the New York Times, as a "witch hunt." **An appeals board at the DHHS eventually exonerated Imanishi-Kari, who admitted only to poor record keeping.**

• 1988

Harvard and Dow Chemical patent a genetically engineered mouse used to study cancer.

• 1989

The PHS forms two agencies, the Office of Scientific Integrity and the Office of Scientific Integrity Review to investigate scientific misconduct and provide information and support for universities. It also amends its definition of misconduct. The two agencies are reorganized in 1992 as the Office of Research Integrity (ORI).

• 1989

The NIH requires that all graduate students on training grants receive education in responsible conduct of research.

• 1989

Stanley Pons and Martin Fleischmann hold a press conference at the University of Utah to announce that they have discovered a way to produce nuclear fusion at room temperatures. **Dozens of labs across the world fail to reproduce their results.** They are accused of fraud, sloppiness, and self-deception.

• 1989

The NAS publishes *On Being A Scientist* (revised in 1994), which is a free, short book on research ethics for scientists in training.

• 1990

The US launches the Human Genome Project, a \$20 billion effort to map and sequence the human genome.

• 1990

W. French Anderson begins the first human gene therapy clinical trial on patients with ADA deficiency, a genetic disease that affects the immune system.

• 1990

In *Moore v. Regents of the University of California*, the **California S. Ct. rules that researchers have intellectual property rights in a cell-line derived from Moore's tissue but that Moore did not have any property rights in his own tissue.** The Court also rules that **the researchers violated Moore's right to informed consent** by not disclosing their commercial interests in his tissue sample to him.

• 1990

Congress investigates conflicts of interest involving Pharmatec and the University of Florida.

• 1990s-present

Europeans oppose the introduction of genetically manipulated foods and crops. Consumers in the US are more receptive to GM plants and animals. Europeans finally allow GM foods but require them to be labeled as such.

• 1991

Revision/unification of human research regulations. All U.S. government agencies, except the EPA, now accept one basic regulatory framework, known as "the common rule" (45 CFR 46).

• 1992

NAS publishes *Responsible Science*: Ensuring the Integrity of the Research Process. The book estimates the incidence of

- **1993**
In Daubert v. Merrell Dow Pharmaceuticals the US S. Ct. rules that judges serve as the gatekeepers for admitting scientific testimony in court and that they can use a variety of criteria, including testability, reliability, peer review, and general acceptance.
- **1993**
Fertility researchers successfully clone human embryos.
- **1994**
Harvard psychologist Richard Herrnstein and Charles Murray publish The Bell Curve, a controversial book that re-ignites the centuries old debate about biology, race and intelligence.
- **1994**
Roger Poisson admits to fabricating and falsifying patient data in breast cancer clinical trials in order to qualify his patients to participate in research and have access to experimental treatments.
- **1994**
The NIH applied for patents on thousands of gene fragments in order to undercut private efforts to patent gene fragments. The Patent Office rejected the NIH's applications.
- **1994-1995**
The Ryan Commission, convened by the NIH, holds meetings on scientific misconduct.
- **1994**
The Clinton Administration declassifies information about secret human radiation experiments conducted from the 1940s-1980s and issues an apology.
- **1994**
Two scientists who worked at Philip Morris, Victor DeNobel and Paul Mele, testify before Congress about secret research on the addictive properties of nicotine. If the research had been made public, the FDA or Congress might have taken additional steps to regulate tobacco as a drug. Many states and individuals brought litigation against tobacco companies, which led to a \$206 billion settlement between tobacco companies and 46 states. The scientific community also publishes more data on the dangers of second-hand smoke.
- **1995**
Boots Pharmaceuticals pressures Betty Dong to withdraw a paper from publication in JAMA showing that its drug, synthroid, is not more effective than generic equivalents at treating hypothyroidism.
- **1995-2003**
Dozens of studies are published in biomedical journals which provide data on the relationship between the source of research funding and the outcomes of research studies, the financial interests of researchers in the biomedical sciences, and the close relationship between academic researchers and the pharmaceutical and biotechnology industries.

• **1995**
The NIH and NSF revise their conflict of interest policies.

• **1995**

Scientists and defense analysts become concerned about the use of chemical or biological weapons by a terrorist group after Aum Shinrikyo, a Japanese doomsday cult, releases sarin gas in a Tokyo subway, killing 12 people and sending 5,500 to hospitals. The group also attempted (unsuccessfully) to spray anthrax spores over Tokyo. In 1998, terrorism experts warn about the use of biological or chemical weapons by Osama bin Laden and Saddam Hussein.

• **1995**

Over 200 religious leaders, led by biotechnology critic Jeremy Rifkin, protest the patenting of plants, animals, and human body parts in Washington, DC.

• **1996**

Dolly, the world's first cloned sheep, is born; her birth is announced in 1997. Several European nations ban human cloning. Congress considers a bill to ban all human cloning but changes its mind after scientists argue that the bill would undermine biomedical research.

• **1997**

the ICMJE, representing over 400 biomedical journals, revises its authorship guidelines.

• **1997**

In an article published in N. Engl. J. Med., Peter Lurie and Sidney Wolfe accuse the NIH, WHO, UN and CDC of designing unethical studies on the prevention of mother-child transmission of HIV in developing countries. The dispute spurs a reexamination of international research ethics codes.

• **1998**

Scientists perfect methods for growing human embryonic stem cells. Some countries ban the research; others promote it.

• **1998**

Craig Venter forms Celera Genomics and begins a private effort to sequence the human genome, using dozens of automated sequencing machines.

• **1998-1999**

Apotex forces Nancy Olivieri, a clinical researcher at the University of Toronto, to withdraw a paper that exposes safety concerns about its drug deferiprone, which is used to treat thalassemia. The company tries to discredit Olivieri and have her fired.

• **1999**

Jessie Gelsinger dies in a human gene therapy experiment at the University of Pennsylvania. The event triggers heightened scrutiny of conflicts of interest in human subjects research, including institutional conflicts of interest. Penn settles with the Gelsinger family for an undisclosed amount of money.

• **1999-present**

Human research lawsuits increase dramatically. Alan Milstein, from the law firm Sherman, Silverstein, Kohl, Rose & Podolsky, P.A., instigates 13 lawsuits against researchers, universities, pharmaceutical companies, and Institutional Review Boards.

- **1999**

The NIH and the OHRP require all people conducting or overseeing human subjects research have some training in research ethics.

- **2000**

The Office of Science and Technology Policy finalizes a federal definition of misconduct as "fabrication, falsification or plagiarism" but not "error honest error or differences. The policy is still not effective.

- **2000**

ORI proposes mandatory training in responsible conduct of research for all researchers on PHS grants, including junior senior investigators, students, and technicians. Several scientific associations and universities oppose the policy as an unnecessary and un-funded mandate. The Bush Administration suspends the ORI proposal in 2001 on the grounds that the agency failed to follow proper procedures for proposing new government regulations. To ORI proposal is still in limbo.

- **2001**

Celera and the Human Genome Project both complete 99% complete drafts of the human genome and publish their results in Science and Nature.

- **2001-present**

Congress debates legislation on human cloning.

- **2001**

Several journals, including Nature and JAMA, experiment with requiring authors to describe their responsibilities when publishing research.

- **2001**

The Bush Administration announces that the NIH will fund research on approximately 64 embryonic stem cell lines created from leftover human embryos.

- **2001**

Terrorists hijack 3 airplanes on September 11 and kill over 5,000 people. Several weeks later, an unknown terrorist sends 4 letters containing anthrax, killing 5 people and infecting 23.

- **2002**

Bell Labs determines that Jan Hendrick Schon, a rising star working in condensed matter physics and nanotechnology who published dozens of articles in a short period of time in prestigious journals, had committed misconduct. So far, 28 papers authored by Schon have been withdrawn.

- **2002**

The President's Council on Bioethics recommends that the U.S. ban reproductive cloning and enact a moratorium on research cloning.

- **2002**

Historian Stephen Ambrose is accused of plagiarism.

- **2002**

A panel of independent investigators finds that Jan Hendrick Schön, a physicist at Bell Labs, fabricated or falsified data in 17 papers published in Science, Nature, and Physical Review Letters.

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- **2002**

The NAS publishes Integrity in Scientific Research, which recommends that universities develop programs for education in responsible conduct of research (RCR) as well as policies and procedures to deal with research ethics.

- **2002**

North Korea admits that it has a secret nuclear weapons program and warns that it has other "more powerful" weapons.

- **2002**

Scientists publish several papers in prominent journals with direct implications for bioterrorism. A paper published in the Journal of Virology described a method for genetically engineering a form of mousepox virus that is much deadlier than the naturally occurring strain. A paper published in Science show how to make poliovirus by obtaining supplies from a mail-order company. In 2003, the American Society for Microbiology (ASM), the National Academy of Sciences, and the Center for Strategic and International Studies held a meeting to discuss the censorship biological research that poses security risks. Journals agree to self-censor some research.

- **2003**

The US invades Iraq with the stated purpose of eliminating its chemical, biological, and nuclear weapons programs. So far, the US has found evidence of weapons programs but no actual weapons.

- **2004**

The EPA suspends the CHEERS study due to criticism from advocacy groups and members of Congress, who claimed that the study was intentionally exposing children to pesticides. The EPA revised its human subjects rules in response to a Congressional mandate to strengthen protections for children and pregnant or nursing women.

- **2004**

The NIH and other agencies adopt the OSTP misconduct definition.

- **2004**

Ronald Reagan, Jr. makes a presentation in support of federal funding for embryonic stem cell research to the Democratic Convention. Stem cell research (and therapeutic cloning) become hot issues in the 2004 Presidential election.

- **2005**

In response criticism from Congress, the NIH revises its conflict of interest rules for intramural research. NIH researchers cannot hold stock in pharmaceutical or biotech companies or consult with these companies (and other affected entities) for pay.

- **2005**

Seoul University research Woo Suk Hwang **admits to fabricating data in two papers published in the journal Science**. In the papers, Hwang claimed that he had used nuclear transfer techniques to develop patient-specific human embryonic stem cells.

- **2005**

University of Vermont researcher Eric Poehlman **admits to fabricating or falsifying data in 15 federal grants and 17 publications**.

- **2009**

Someone hacked into the email server at the University of East Anglia's Climatic Research Unit (CRU) and posted on the internet thousands of emails exchanged between climate change researchers at the CRU and researchers around the world. The emails showed that the **researchers refused to share data and computer codes with climate change skeptics, who called the incident "climategate."**

- **2009**

The Obama Administration announces it will significantly expand NIH funding of human embryonic stem cell research which had been restricted under the Bush Administration.

- **2010**

The National Science Foundation (NSF) announces RCR training requirements for funded investigators, students, and trainees. The NIH expands and strengthens its RCR training requirements.

- **2010**

While doing research on the Tuskegee Syphilis Study, Susan Reverby, Professor of Women's Studies at Wellesly College, uncovered documents concerning unethical research experiments on human subjects conducted by the US government in Guatemala from 1946 to 1948. The research involved intentionally infecting over 1300 subjects with venereal diseases to test the effectiveness of penicillin. Only 700 subjects were given penicillin and 83 died as a result of the study. The subjects were not informed that they were participating in an experiment.

- **2010**

Lancet retracts **a fraudulent paper, published in 1998 by Andrew Wakefield and colleagues, linking autism to the measles vaccine.**

- **2011**

The NIH and NSF revise their conflict of interest rules for funded research.

- **2011**

The Office of Human Research Protections announces proposed changes to the Common Rule to enhance human subject protections and reduce investigator burden. The Common Rule has not been changed significantly since 1981.

- **2012**

Two papers embroiled in controversy were published in *Science* and *Nature* after several months of debate about their implications for bioterrorism. The papers reported results of NIH-sponsored research conducted by a team working in the Netherlands, led by Ron Fouchier, and a team working at the University of Wisconsin, led by Yoshihiro Kawaoka. The researchers were able to genetically modify an H5N1 avian flu virus so that it can be transmitted between mammals, including humans. Currently, avian flu can only be contracted through contact with birds. The virus is highly lethal, with a mortality rate of 60%. Over 300 people have died from the virus since 1997. The National Science Advisory Board for Biosecurity (NSABB)

initially recommend that the papers be published in redacted form, with key details removed and only made available to responsible scientists, so the terrorists or others could not use the information to make deadly bioweapons. However, the NSABB changed its mind and recommended full publication of both papers after learning more about the value of the research for monitoring bird populations for dangerous avian flu mutations and the difficulties with redacted publication.

- **2013**

The NIH launches the **reproducibility initiative in response to problems with the reproducibility of scientific research.**

- **2014**

Nature retracts a fraudulent paper, published earlier in the year by Haruko Obokata and colleagues, claiming to describe a method for deriving pluripotent human stem cells from somatic cells.

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