The progress of safety and participant rights in clinical research

Click to continue

Clinical trials have come a long way. In the 1900s, many protections for volunteers like you didn’t exist. Because safety wasn’t always a focus of clinical research, thousands of people—mostly communities of color—were harmed in the name of medical progress.

We know we can’t erase this history. We also know that repairing trust broken from the early years of clinical research takes time.

The clinical trial process is constantly changing, and steps have been taken to make sure medical injustices like the Tuskegee Study never happen again. Read on to learn more about this event and others that have shaped the progress of safety and participant rights in clinical research.

This timeline focuses mainly on people in the US and is only a sample of the events that happened in the history of clinical research. We hope it will be a starting point in understanding the evolution of your rights and how they are protected today.

See timeline

Interactive timeline

Explore this timeline to learn more about the historic events that led to laws and actions that protect participants' rights today.

- **Click on each event and response to learn more**
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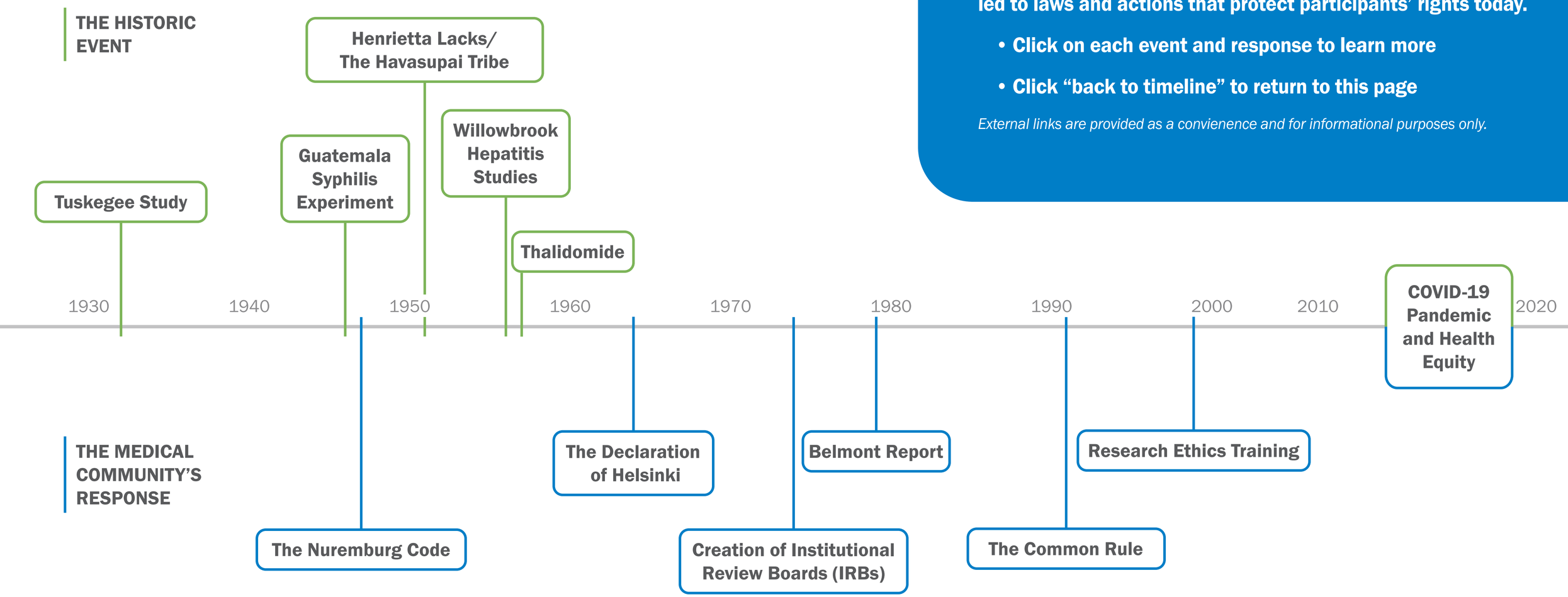

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THE MEDICAL COMMUNITY'S RESPONSE

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Creation of IRBs

Belmont Report

THE HISTORIC EVENT

Learn more about the Tuskegee Study

1932–1973

The Tuskegee Study

A study researching syphilis* in 600 African American men (399 men with the disease and 201 men without) recruited participants with the promise of free healthcare. However, medical researchers didn't treat participants on purpose, leaving many of the surviving men with major health problems, including blindness and mental impairment.

After the study ended and all the survivors were given the recommended treatment for syphilis (penicillin), the National Research Act was signed into law in 1974, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (NCPHS). The NCPHS develops guidelines for research involving humans to make sure all research is conducted ethically. These include the creation of **IRBs** and the **Belmont Report**.

As a participant, your health and safety are the main priority. Every part of the clinical trial process is monitored by IRBs; their main goal is to protect your rights and health.

*A sexually transmitted disease that can be life-threatening if left untreated.

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THE MEDICAL COMMUNITY'S RESPONSE

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The Nuremburg Code

THE HISTORIC EVENT

Learn more about the Guatemala Syphilis Experiment

1946–1948

The Guatemala Syphilis Experiment

During the Guatemala syphilis experiment, researchers infected a number of Guatemalan people from vulnerable populations with sexually transmitted diseases. At the time, there were no laws that researchers had to get informed consent* and more than 5,500 people were forced into the study without their permission.

This study ended up shaping US informed consent regulations and international legal and ethical standards for clinical research. These include making sure informed consent forms are clear and easy to understand. IRBs have the power to approve or disapprove proposed studies or to completely shut down studies that are already happening if they don't meet certain standards.

Your health and safety is always more important than the research. Clinical trial participation is voluntary and it can't happen without your permission. You're free to leave a trial at any time and for any reason.

*A vital part of the clinical trial process that helps potential participants make an informed decision about taking part. This includes providing you with everything you need to know about the study drug, study assessments, and other things that happen during your time in the trial.

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THE MEDICAL COMMUNITY'S RESPONSE

Learn more about the Nuremburg Code

1947

The Nuremburg Code

Formed in response to the horrors of Nazi war crimes during World War II, the Nuremburg Code contains a set of 10 principles for ethical clinical research, including requiring researchers to act in your best interest.

The first principle is about voluntary consent. This means participants have the power to make their own decisions freely. The Nuremburg Code also requires researchers to properly prepare the study site to make sure there are no chances of anyone getting hurt.

If at any point, researchers decide it isn't safe for you to continue, they must end your participation in the trial.

THE MEDICAL COMMUNITY'S RESPONSE

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The Common Rule

THE HISTORIC EVENT

Learn more about Henrietta Lacks | Learn more about the Havasupai Tribe

1951

Henrietta Lacks/The Havasupai Tribe

While being treated for cervical cancer, Henrietta Lacks' cells were kept by researchers without her permission. Her cells were later cloned and sold for profit.

During a 1994 study among members of the Havasupai tribe, researchers intentionally misled participants with an overly broad informed consent document. While participants agreed for their blood samples to be used to research diabetes, they didn't know it would also be used to study inbreeding, alcoholism, and syphilis among members of their community.

Informed consent means that you are fully aware of what will happen during the study, including all the risks and benefits of taking part, and what happens to your samples after the study ends. This also led to revisions to the **Common Rule**, a rule of ethics that guides researchers if they take and use patient samples. So after the study ends, researchers may not keep your samples without your consent.

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THE MEDICAL COMMUNITY'S RESPONSE

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Research Ethics Training

THE HISTORIC EVENT

Learn more about the Willowbrook Hepatitis Studies

1956

The Willowbrook Hepatitis Studies

Willowbrook State School, a home for children with severe mental disabilities, infected children with a mild form of hepatitis* on purpose to study the progression and treatment of viral hepatitis. While the results led to the development of a successful hepatitis vaccine, researchers took advantage of new families desperate to enroll their children in the school.

To avoid unethical clinical trial conduct, clinical trial staff are required to complete human research protection and good clinical practice training, including a lesson on protecting people in research.

Good clinical practice was developed to protect your health and safety. It's a standard for designing, conducting, monitoring, recording, reporting, and performance of all clinical research involving people.

*A term used to describe inflammation of the liver. While there are different types of hepatitis, they all affect how your liver functions and can lead to liver disease.

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THE MEDICAL COMMUNITY'S RESPONSE

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The Declaration of Helsinki

THE HISTORIC EVENT

Learn more about Thalidomide

1957–1961

Thalidomide

In the past, scientists didn't know that the effects of drugs could be passed on to developing fetuses. Thalidomide* could be bought without a doctor's prescription in Germany without any safety testing during pregnancy.

More than 10,000 babies worldwide were affected before scientists understood Thalidomide could harm developing fetuses. Half died within months of birth.

The US Food and Drug Administration (FDA) responded by creating pregnancy categories for medication. It drove the passage of the 1962 Kefauver–Harris Amendment to the Federal Food, Drug, and Cosmetic Act requiring drug manufacturers to show that a drug is safe and effective before marketing it.

Before potential treatments are studied in clinical trials, the FDA must give approval for the trial to take place. If they think any clinical trial materials are misleading or if the person who is running the research (the investigator) seems unqualified, they can delay or stop the research from happening.

*A drug used to treat nausea, morning sickness, and conditions like the flu.

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THE MEDICAL COMMUNITY'S RESPONSE

Learn more about the Declaration of Helsinki

1964

The Declaration of Helsinki

A statement of ethical principles adopted by the World Medical Association.* For physicians, this means protecting their patient's life, health, dignity, integrity, privacy, confidentiality, and right to make their own decisions. This statement also makes sure that even the best treatments or procedures are continually evaluated for safety, effectiveness, accessibility, and quality.

The Declaration of Helsinki also includes a rule requiring access to research opportunities for underrepresented populations.

*An international organization dedicated to ensuring physicians meet the highest possible standards of ethical behavior.

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THE MEDICAL COMMUNITY'S RESPONSE

Learn more about the Creation of IRBs

1974

The Creation of Institutional Review Boards (IRBs)

Before a trial begins, IRBs look over the protocol and other study-related materials and can approve or deny the planned research. You can think of them as gatekeepers of clinical research. As long as there are interactions between the study team and participants, IRBs will continue to monitor the trial to make sure appropriate steps are taken to protect all participants. If any new information comes up about the trial risks, IRBs will make sure all participants are informed and reminded that they can leave the trial at any time.

The scientists, non-scientists, and community representatives on the IRB are your advocates and they work to make sure trials are designed to keep participants safe.

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THE MEDICAL COMMUNITY'S RESPONSE

Learn more about the Belmont Report

1979

The Belmont Report

A response to the **Tuskegee Study**, the Belmont Report identified three important things related to the process of informed consent: information, comprehension, and the voluntary nature of participation. The information part of the Belmont Report makes sure all study materials contain detailed information about the trial purpose, assessments, and known risks and benefits. Comprehension means that all study materials are presented in a clear way. The last part of the process focuses on the participant's decision to take part and makes sure it's completely voluntary without any kind of influence.

Like the Nuremburg Code, the Belmont Report makes sure that any research involving people is done in an ethical manner. It also makes sure your ability to make your own decisions is respected and protected.

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THE MEDICAL COMMUNITY'S RESPONSE

Learn more about the Common Rule

1991

The Common Rule

The US Congress passed the Common Rule as another regulation designed to protect research participants. It requires all government-funded research institutions to gain IRB approval and outlines the criteria for IRB review. In 2017, updates to the Common Rule reflected changes in research including making informed consent forms easier to understand. Important details about the study are now at the top of the form, so participants don't have to search through an entire document.

The Common Rule includes additional protections for people considered vulnerable (eg, children, pregnant women, or individuals with impaired decision-making abilities). This means extra rules to further protect vulnerable participants.

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THE MEDICAL COMMUNITY'S RESPONSE

Learn more about Research Ethics Training

1999

Research Ethics Training

Based on the revised Common Rule, the US National Institutes of Health (NIH) and the Office for Human Research Protections (OHRP) now require that all people conducting or overseeing human subjects research be trained in research ethics to protect the integrity of the research.

After taking different classes about human research protections, clinical research in general, and IRBs, they will receive a certificate for completing the training.

Everyone involved in the trial is required to protect participants' health and safety and to act in their best interest.

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THE EVENT AND THE MEDICAL COMMUNITY'S RESPONSE

Learn more about the COVID-19 Pandemic | Learn more about Health Equity

2019

COVID-19 Pandemic and Health Equity

Pre-existing health disparities in marginalized communities and other vulnerable populations have only become more clear during the COVID-19 pandemic. In order to address this inequity, organizations like the American Medical Association created a series of **COVID-19 health equity*** resources dedicated to identifying and eliminating these disparities through advocacy, community leadership, and education.

Since 2010, the FDA's Office of **Minority Health and Health Equity** has been working to close the health equity gap among communities of color. Their COVID-19 initiatives include the creation of a communications toolkit, available in six languages to assist individuals with limited English proficiency.

*Equal access to healthcare for all.

Moving forward

Improving the clinical trial process for volunteers is a constant effort, including making sure all patients are accurately represented in order to help scientists and researchers better develop effective treatments for all.

That's why when you take part in a clinical trial, you're supporting your family, friends, and entire community. Your participation provides unique and important information that can help researchers take steps toward developing a healthier world. So, thank you for making a difference for people in your community and beyond.

Listening and learning

Clinical research wouldn't be the same without community contribution. We value your input, and developed this timeline with the help of patients and caregivers to create something we hope is meaningful for readers everywhere.

Clinical trials today

We've made big strides in protecting study participants since the medical injustices of the 20th century, and now we continue to fight for accurate representation of all people in clinical research.

Click here to learn more about clinical trials and how you can contribute to the greater good of medicine:

Biogen Trial Link

For more information about Biogen and our commitment to boosting clinical trial diversity and representation:

About Biogen

Our commitment to clinical trial transparency