

PROTECTING RESEARCH VOLUNTEERS



Regulations to Protect Volunteers in Research

Learn about the regulations that protect people who participate in research, why we have them, and who enforces them. This material is intended for public use, and we invite you to share and distribute it freely.

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Why Do We Have Regulations to Protect Research Participants?



What are the Principal Regulations that Protect Research Participants?



Which Federal Office Oversees and Enforces the HHS Regulations?



Is There Research That is Not Regulated by the Common Rule?



Protecting Humans in Research is a Shared Responsibility

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Why Do We Have Regulations to Protect Research Participants?

The regulations we have to protect people in research came about after a series of events in the twentieth century in which doctors and scientists abused the trust that society placed in them.

Examples of Unethical Research in the Past

1946 The **Nuremberg Doctors' Trial, in 1946**, was an international military tribunal that tried and convicted Nazi doctors who conducted horrific unethical experiments on concentration camp prisoners during the Holocaust. It resulted in the **Nuremberg Code**, a set of international ethical guidelines for conducting research with humans.



There also were examples of research with questionable ethics going on in the United States. **In 1966, Henry Beecher**, an anesthesiologist and researcher, published a widely cited New England Journal of Medicine article (1966; vol. 274, p.1354-1360) detailing numerous examples of unethical experiments involving human subjects that were conducted at various U.S. institutions.

1966

1972 **In 1972**, there was widespread media coverage of the **Syphilis Study in Tuskegee, Alabama**. Beginning in the 1930s and continuing for decades, U.S. government doctors studied the progression of untreated syphilis in poor African American men. The doctors did not tell the men they had syphilis, prevented them from learning their diagnosis, and did not offer treatment, even after penicillin became available.

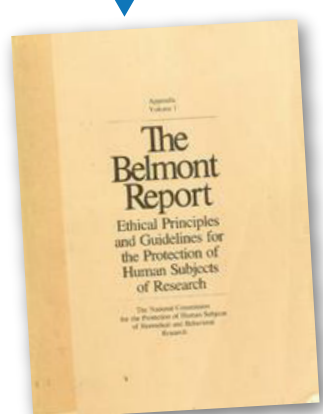


All of which resulted in

The Need for Rules to Protect Research Participants

As a result of the public outcry from publicized cases of unethical research, Congress passed a **law requiring federal rules to protect people who participate in research**. The rules rely on ethical principles that were laid out in the Belmont Report, which was written by an advisory committee created by Congress and published **in 1979**.

1979



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What are the Principal Regulations that Protect Research Participants?

The Common Rule

The Federal rules that protect people who participate in research were initially published by the Department of Health and Human Services (HHS).

The first section of the HHS rules (Subpart A) is called the **Common Rule** because it was simultaneously adopted by 15 Federal departments and agencies in 1991. The Common Rule was revised in 2017 to reflect how research has changed since 1991.

1991



One key protection in the Common Rule is the requirement for appropriate review and approval of research by **institutional review boards, or IRBs**. IRBs are committees that make sure researchers follow the HHS rules and ethical guidelines as they carry out their studies.



Additional Protections

In addition to the Common Rule, there are 4 other subparts in the HHS rules. Three of these (subparts B, C, & D) provide additional protections for certain groups of research participants that could be considered vulnerable.



The Common Rule generally requires that researchers get informed consent from volunteers who participate in research. This includes giving them information about the study, including risks and benefits.

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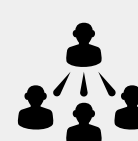
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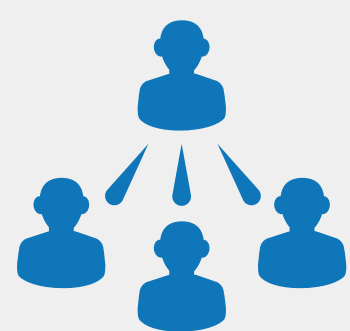
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Which Federal Office Oversees and Enforces the HHS Regulations?

Office for Human Research Protections (OHRP)

OHRP is part of the U.S. Department of Health and Human Services (HHS). OHRP oversees and enforces the Common Rule and other HHS regulations for protecting people in research that is funded with HHS money.

HHS agencies include, for example, the **National Institutes of Health (NIH)** and the **Centers for Disease Control and Prevention (CDC)**. Human research funded by these agencies falls under OHRP's oversight. Research funded by other Federal departments that follow the Common Rule is overseen by the respective departments.



OHRP
Office for Human
Research Protections



OHRP works with institutions to ensure compliance with the regulations, and **responds to complaints about potential violations.**

OHRP **provides clarification and guidance** about the regulations.



OHRP **educates researchers and institutional staff** on ethical expectations for conducting research with humans, Common Rule requirements, and the additional requirements in subparts B, C, and D of the HHS regulations.

OHRP **provides the general public information** about research participation.



Potential research participants can find useful questions to ask researchers and learn about research protections and general research concepts at www.hhs.gov/about-research-participation.



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Is There Research That is Not Regulated By the Common Rule?

There are many research activities that do not come under the Common Rule.

An example is research funded by private money such as research paid for by private companies, charitable foundations, or wealthy individuals. Some state or even federally funded research may not come under the Common Rule as well.

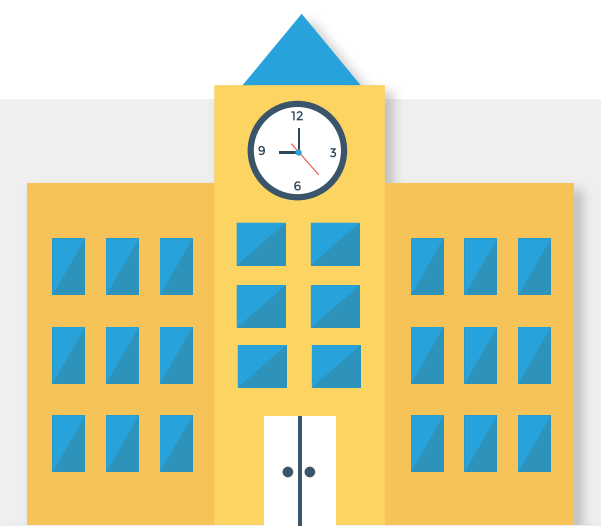
Some Research is Outside of OHRP's Oversight



Even when research is not required to follow the Common Rule, **there may be other regulations that provide protections.**

For example, pharmaceutical companies that do research on new drugs that they plan to sell in the U.S. must comply with the ***U.S. Food and Drug Administration (FDA)*** rules to protect humans in research. The FDA's rules are very similar to the Common Rule. The FDA protects public health by ensuring the safety and efficacy of drugs, biological products, and medical devices such as artificial heart valves. It is also responsible for advancing public health by helping the public get the accurate, science-based information they need to use medical products to maintain and improve their health.

Finally, many institutions voluntarily apply the protections laid out in the Common Rule, even if their research does not fall under OHRP oversight.



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Protecting Humans in Research is a Shared Responsibility

 OHRP Office for Human Research Protections	 Funding Organizations	 Research Institutions	 IRBs	 Researchers	 Individuals
Responsible for the rules that protect volunteers in HHS-funded research	Ensure that human research is conducted ethically and complies with appropriate rules and standards of protections	Agree to comply with the rules and educate research personnel about appropriate conduct toward research volunteers	Review and oversee research to ensure that research volunteers are adequately protected according to ethical standards and relevant rules	Carry out scientifically valid and ethical research. Often this includes providing information to help people make an informed decision about participating	Learn about the risks and benefits associated with a research study through the informed consent process, and make an informed decision about whether to participate

Talk to the research team for questions about a research study. OHRP has created a list of [Questions to Ask](#) to help participants when meeting with the research team. The institution's **human research protection office** and the **IRB** are also able to address concerns. Contact information for these resources should be in the consent documents for the study.

