In 1993, the NIH published the Revitalization Act that established guidelines for minorities’ and women’s participation in clinical research. Before the 1990s, investigators largely excluded women from their research based on the 1979 guidance from the US Food and Drug Administration, or FDA. The FDA urged investigators to exclude any woman who was or could become pregnant to protect the woman and any developing fetuses from harm. Between 1979 and 1993, several other US governmental agencies urged investigators to increase the number of women in their clinical research to improve the state of women’s healthcare. After Congress passed the National Institutes of Health Revitalization Act, hereafter Revitalization Act of 1993, investigators who used NIH funds for clinical research were required to include both women and minorities in their clinical research. The Revitalization Act established the Office of Research on Women’s Health headquartered in Washington, DC and required investigators to include women in their clinical research, thus improving the quality of women’s health research.

Biological differences between men and women cause drugs to work differently in their bodies. For example, one medication called alosetron treats a gastrointestinal disorder in women but has no effect in men. Another medication called zolpidem causes more severe side effects in women than it does in men. According to Sandra Kweder, the deputy director of the Office of New Drugs at the FDA Center for Drug Evaluation and Research, differences in patients’ weight, lifestyle, age, or other medication usage can cause patients’ bodies to process medications differently. According to Kweder, when investigators carry out drug research, they routinely look for gender specific differences.

The National Institutes of Health, or NIH, is a part of the Department of Health and Human Services, a larger government agency that works to prevent disease and improve health, headquartered in Washington, DC. The NIH is specifically responsible for biomedical and public health research. The NIH regulates and directs clinical research on foods, drugs, medical devices, diseases, and other technologies that can affect people’s wellbeing in the US. Clinical research is how investigators study the safety of drugs or medical devices in humans and other animals.

Before the women’s health portion of the Revitalization Act was passed in 1993, the FDA published a policy that urged investigators to exclude women who could potentially become pregnant from early drug research in 1979. After the FDA published that policy in 1979, scientific investigators began to exclude all women from clinical trial research, which included women taking contraception, single women, or women whose husbands had vasectomies. The policy primarily impacted researchers who performed clinical trials to get FDA approval for drugs by stopping those researchers from including women in their trials. Then, in 1985, the Public Health Service Task Force, an agency similar to the NIH that is responsible for issues of public health, published a report on women’s health. In that report, the Public Health Service Task Force establishes that there was insufficient women’s health research and establishes areas for future research. The report specifically states that investigators needed to perform more clinical research on how drugs affect women. A year later, in 1986, the NIH established a policy that encouraged investigators to include women in clinical research funded by the NIH, and in 1989, the NIH stated that any investigator who excluded women or minorities in clinical research funded by the NIH had to provide a rational reason. Between 1989 and 1993, investigators had to include women in clinical research if they wanted NIH funding, but it was not a federal law.

In 1993, the US Congress wrote the 1986 NIH policy into federal law. That policy was codified as part of the NIH Revitalization Act of 1993. Before a law is passed, an early version, called a bill, is introduced to the House of Representatives and the Senate, which make up the US Congress. Edward Kennedy introduced that bill, which was called S.1, on the Senate Floor on 21 January 1993. Then, the bill was referred to the Committee on Labor and Human Resources for a process called markup, which is when a congressional committee revises and proposes changes to the bill. During the markup process, the Committee on Labor and Human Resources made changes to wording of the section on women and minority health. The bill passed by a margin of 93 to 4 in the Senate on 18 February 1993 and 203 to 130 in the House on 25 May 1993. The bill was signed by Bill Clinton, then president of the United States, on 10 June 1993 and became a law.

The Revitalization Act is made up of twenty-one sections, and one part of a section titled “Women and Minorities as Subjects in Clinical Research” deals with the inclusion of women and minorities into federally funded clinical research. That section is Title
Sources

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**Subject**
- NIH publication
- drug law
- Legislation, Drug
- United States, National Institutes of Health Revitalization Act of 1993
- National Institutes of Health (U.S.), Clinical Center
- National Institutes of Health (U.S.), Office of Human Subjects Research
- Clinical medicine--Research
- Medical research personnel
- Decision (United States, Government Accountability Office)
- United States, Government Accountability Office
- National Institutes of Health (U.S.), Office of Extramural Research
- National Institutes of Health (U.S.), Office for Protection from Research Risks

**Topic**
- Legal

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