

[Title 1, Subtitle B, Parts I, II, and III of the “National Institutes of Health Revitalization Act of 1993” \(1993\)](#)

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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](#) ^[4], 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](#) ^[5] 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](#) ^[5], 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](#) ^[6] 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](#) ^[7], 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 1, Subtitle B, Parts I, II, and III. That section mandates that researchers include women and minorities in clinical studies funded by the NIH and that the NIH create programs to boost women's health research. The “Women and Minorities as Subjects in Clinical Research” section of the Revitalization Act is split into three parts. In the first part, the Revitalization Act establishes that

investigators must include women and minorities in clinical trials, and that if they do not abide by the act, the NIH will not approve their research proposal. In the second section, the Revitalization Act creates a new office within the NIH to identify projects on women's health throughout their lifespan. In the final part, the Revitalization Act creates another new office within the NIH to promote minority health, or the health of people in groups other than the social majority, which was Caucasian. That office, called the Office of Minority Health Research, is also responsible for researching and identifying further areas of minority health research.

The first part of the Women and Minority Health section of the Revitalization Act pertains specifically to clinical research. In clinical research, volunteer participants may take experimental medicines, test medical devices, or try new therapies that have not been approved or proven effective for use in [humans](#)^[6] yet. The Revitalization Act specifies that the Women and Minority Health section does not apply when women or minorities might be harmed by the research or are inappropriate candidates. For example, researchers do not have to include women in a study on drugs to treat [testicular cancer](#)^[8] because women do not have [testes](#)^[9], a male reproductive organ. Finally, the first part of the Act makes the director of the NIH responsible for ensuring that women and minorities are being studied in clinical trials in the same way that other groups are.

The second part of the Women and Minority Health section of the Revitalization Act establishes the Office of Research on Women's Health, or ORWH, for collecting research on women's health, appropriating funds, identifying projects for future research, and monitoring its own progress toward the goal of improving women's health. The Act defines women's health conditions in relation to diseases, disorders, and conditions including mental health conditions that may affect women. The Act holds that the director of the NIH must appoint the head of the Office of Research on Women's Health. It defines the mission of the ORWH as the identification of projects for further research on general women's health, projects for further research on menopause and aging in women, and allocation of funds to investigators who want to perform research to improve women's health.

The second part of the Women and Minority Health section of the Act establishes a committee to determine what projects the ORWH will fund. The section requires a review of the number of female researchers and physicians at the NIH and a directive to increase that number to increase women's roles in the research process. The Act specifies that projects funded by the ORWH will improve knowledge of women's health and determine how best to obtain information about women's health. The committee, called the Coordinating Committee on Research on Women's Health, is made up of directors from each of the national research institutes composing the NIH, like the National Eye Institute and the [National Cancer Institute](#)^[10]. The Act further establishes an advisory committee to monitor the Office's progress towards meeting their goals and to advise the head of the ORWH on current research on women's health.

The third part of the Women and Minority Health section of the Revitalization Act establishes the Office of Research on Minority Health, or ORMH. The third section of the Act details the purposes of the ORMH. Those purposes are to identify areas of minority health that need further research and to promote investigators' inclusion of minorities. It establishes that the director of the NIH can appoint the head of the ORMH, whose specific job is to make sure that studies on minority health are well funded by the NIH.

Although the NIH Revitalization Act attempted to legislate the inclusion of women and minorities in clinical research funded by the NIH, it is unclear whether it was successful. Before the Act was passed in 1993, the Government Accountability Office, a federal US agency that evaluates the effectiveness of other offices, determined that trials for sixty percent of FDA-approved drugs did not include a sufficient number of women. The Government Accountability Office published another analysis in 2001, in which they used a sample of ten prescription drugs that had been withdrawn from the market and found that eight of them posed greater health risks for women than men. That indicates that investigators had not studied the effects of the drugs in both men and women before releasing them to the market. More recently, in 2011, a study was performed at the Center for Research on Women and Gender at the [University of Illinois](#)^[11] at Chicago in Chicago, Illinois, in which researchers randomly analyzed 512 federally funded studies published in nine major medical journals. The researchers found that seventy-five percent of studies did not report sex-related results and only three studies mentioned a lack of diversity in participants, which indicates that sex differences were not being studied according to the Revitalization Act.

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[NIH publication](#) ^[23] [drug law](#) ^[24] [Legislation, Drug](#) ^[25] [United States. National Institutes of Health Revitalization Act of 1993](#) ^[26] [National Institutes of Health \(U.S.\). Clinical Center](#) ^[27] [National Institutes of Health \(U.S.\). Office of Human Subjects Research](#) ^[28] [Clinical medicine--Research](#) ^[29] [Medical research personnel](#) ^[30] [Decision \(United States. Government Accountability Office\)](#) ^[31] [United States. Government Accountability Office](#) ^[32] [National Institutes of Health \(U.S.\). Office of Extramural Research](#) ^[33] [National Institutes of Health \(U.S.\). Office for Protection from Research Risks](#) ^[34]

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Links

- [1] <https://embryo.asu.edu/pages/title-1-subtitle-b-parts-i-ii-and-iii-national-institutes-health-revitalization-act-1993-1993>
- [2] <https://embryo.asu.edu/keywords/national-institutes-health>
- [3] <https://embryo.asu.edu/keywords/clinical-research>
- [4] <https://embryo.asu.edu/search?text=Food%20and%20Drug%20Administration>
- [5] <https://embryo.asu.edu/search?text=National%20Institutes%20of%20Health>
- [6] <https://embryo.asu.edu/search?text=humans>
- [7] <https://embryo.asu.edu/search?text=contraception>
- [8] <https://embryo.asu.edu/search?text=testicular%20cancer>
- [9] <https://embryo.asu.edu/search?text=testes>
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- [11] <https://embryo.asu.edu/search?text=University%20of%20Illinois>
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- [13] <https://blogs.fda.gov/fdavoices/index.php/2012/02/50-years-after-thalidomide-why-regulation-matters/>
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- [22] <https://www.gao.gov/assets/220/216966.pdf>
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- [33] <https://embryo.asu.edu/library-congress-subject-headings/national-institutes-health-us-office-extramural-research>
- [34] <https://embryo.asu.edu/library-congress-subject-headings/national-institutes-health-us-office-protection-research-risks>
- [35] <https://embryo.asu.edu/topics/legal>
- [36] <https://embryo.asu.edu/formats/articles>