



DEPARTMENT OF HEALTH AND HUMAN SERVICES, NATIONAL INSTITUTES OF HEALTH, OFFICE OF RESEARCH ON WOMEN'S HEALTH

ISSUE: NEED FOR EXPLICIT INCLUSION OF LESBIAN, BISEXUAL, AND TRANSGENDER WOMEN IN CLINICAL TRIALS AND RESEARCH STUDIES, LEADING TO IMPROVED UNDERSTANDINGS ABOUT DIVERSITY OF NEEDS, AND THUS IMPROVED QUALITY OF CARE AND HEALTH OUTCOMES

POLICY DESCRIPTION: The Office of Research on Women's Health leads NIH efforts to monitor adherence to NIH policy on the inclusion of women and minorities in clinical research studies. The NIH policy for inclusion (Federal Register, March 1994) was strengthened in response to the NIH Revitalization Act of 1993 (Public Law 103-43) to ensure that women, and minorities and their subpopulations, are included in research involving human subjects in sufficient numbers to allow for subset analysis by sex (or race).

The ORWH Website recognizes that "Many conditions and diseases disproportionately affect women in terms of incidence, diagnosis, course, and response to treatment. Further, factors such as biology, genes, culture, education, income, access to and quality of care, and access to opportunities for inclusion in clinical trials and studies can contribute to adverse health outcomes for many populations of women. In order to better document, describe, prevent, and treat disease in women and girls, research should take into account this diversity of experience and population-specific characteristics."

However, as data is not explicitly collected about lesbian, bisexual or transgender women's sexual behaviors and attitudes, and the impact of those behaviors and identities on health and access to health care, much remains unknown about LBT health conditions, prevalence of diseases among these groups, and barriers to care.

For example, there is preliminary evidence that lesbians suffer disproportionately from breast cancer – perhaps because of nulliparity (childlessness); perhaps because of later accessing of



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diagnosis. More widespread gathering of data is necessary to determine prevalence and causality, and thus aid treatment. Similarly, researchers need broad, comprehensive data on prevalence and causality of drug and alcohol use, obesity, and mental illness among these populations of women in order to develop effective treatment.

RECOMMENDATIONS FOR CHANGE: To encourage research and data gathering that includes information about lesbian, bisexual and transgender women, the language of Title 42, Chapter 6A Public Health Service, Subchapter III National Research Institutes, Part F Research on Women's Health should be revised to include the words "sexual orientation," and "gender identity" as follows (in **CAPITAL LETTERS** below):

§ 287d. Office of Research on Women's Health

The Director of the Office shall:

- 1) identify projects of research on women's health that should be conducted or supported by the national research institutes;
- 2) identify multidisciplinary research relating to research on women's health that should be so conducted or supported;
- 3) carry out paragraphs (1) and (2) with respect to the aging process in women, with priority given to menopause;
- 4) promote coordination and collaboration among entities conducting research identified under any of paragraphs (1) through (3);
- 5) encourage the conduct of such research by entities receiving funds from the national research institutes;
- 6) recommend an agenda for conducting and supporting such research;
- 7) promote the sufficient allocation of the resources of the national research institutes for conducting and supporting such research;
- 8) assist in the administration of section 289a-2 of this title with respect to the inclusion of women as subjects in clinical research; and
- 9) prepare the report required in section 287d-2 of this title.



For purposes of this part:

1. The term ``women's health conditions", with respect to women of all age, ethnic, **SEXUAL MINORITIES, GENDER MINORITIES**, and racial groups, means all diseases, disorders, and conditions (including with respect to mental health)--
 - (A) unique to, more serious, or more prevalent in women
 - (B) for which the factors of medical risk or types of medical intervention are different for women, or for which it is unknown whether such factors or types are different for women;or
 - (C) with respect to which there has been insufficient clinical research involving women as subjects or insufficient clinical data on women.

2. The term ``research on women's health" means research on women's health conditions, including research on preventing such conditions.