

**Assembly Bill No. 2038**

CHAPTER 250

An act to add Article 1.5 (commencing with Section 100237) to Chapter 2 of Part 1 of Division 101 of the Health and Safety Code, relating to health research.

[Approved by Governor August 25, 2000. Filed with Secretary of State August 28, 2000.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2038, Alquist. Health research: women's health.

Under existing law, the State Department of Health Services administers various public health programs.

This bill would enact the Inclusion of Women and Minorities in Clinical Research Act, which would require a grantee, as defined, in conducting or supporting a project of clinical research, as defined, to ensure that women of all ages, and members of minority groups, as defined, are included as subjects in the clinical research projects, except under prescribed circumstances. The bill would also require state agencies to, and would declare legislative intent that the University of California include in specified progress reports, data on the extent to which state funds administered by state agencies and the University of California are used by grantees for research on diseases, disorders, and health conditions, that includes women and minorities in the research trials, and that studies diseases, disorders, and health conditions of particular concern to women and minorities. This bill would state legislative intent that research include, but not be limited to, specified diseases, disorders, and health conditions.

*The people of the State of California do enact as follows:*

SECTION 1. Article 1.5 (commencing with Section 100237) is added to Chapter 2 of Part 1 of Division 101 of the Health and Safety Code, to read:

Article 1.5. Inclusion of Women and Minorities in Clinical Research Act.

100237. (a) This article shall be known, and may be cited as, the "Inclusion of Women and Minorities in Clinical Research Act."

(b) For purposes of this article, the following definitions and descriptions shall apply:

(1) "Grantee" means any qualified public, private, or nonprofit agency or individual, including, but not limited to, colleges,



universities, hospitals, laboratories, research institutions, local health departments, voluntary health agencies, health maintenance organizations, corporations, students, fellows, entrepreneurs, and individuals conducting clinical research using state funds. A grantee may also be a corporation that is headquartered in California and that conducts research using state funds.

(2) “Minority group” shall be defined pursuant to the definition in the 1993 National Institutes of Health guidelines.

(3) “Project of clinical research” includes a clinical trial.

100238. (a) In conducting or supporting a project of clinical research, a grantee shall, except as provided in subdivision (b) or (e), do all of the following:

(1) Ensure that women, including, but not limited to, women over the age of 40 years, are included as subjects in each research project.

(2) Ensure that minority groups are included as subjects in each research project.

(3) Conduct or support outreach programs for the recruitment of women and members of minority groups as subjects in projects of clinical research.

(b) The requirement established in subdivisions (a) and (d) regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and minority groups is inappropriate for either of the following reasons:

(1) With respect to the health and safety of the subjects.

(2) With respect to the purpose of the research.

(c) In the case of any clinical trial in which women or members of minority groups will, under subdivision (a), be included as subjects, a grantee shall ensure that the trial is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

(d) In any grant, or in any contract by a grantee under a grant, the grantee or contracting party shall acknowledge, agree to, and be bound by, the terms of this section.

(e) If a grantee is in compliance with the 1993 National Institutes of Health guidelines, the grantee shall be deemed to be in compliance with this section.

100239. (a) Pursuant to Section 439.904, state agencies shall, and it is the intent of the Legislature that the University of California, include, in appropriate periodic progress reports required under existing law, data on the extent to which state funds administered by those agencies and the University of California, or both, are used by grantees to support research on diseases, disorders, and health conditions that includes women and minorities in the research trials,



and that studies diseases, disorders, and health conditions of particular concern to women and minorities.

(b) It is the intent of the Legislature that research shall include, but not be limited to, cardiovascular diseases, cancer, Alzheimer's disease, HIV and AIDS, sickle-cell anemia, obesity, mental illness, arthritis, and osteoporosis.

