

1 AN ACT in relation to health.

2 Be it enacted by the People of the State of Illinois,
3 represented in the General Assembly:

4 Section 1. Short title. This Act may be cited as the
5 Inclusion of Women and Minorities in Clinical Research Act.

6 Section 5. Definitions. In this Act:

7 "Grantee" means any qualified public, private, or
8 not-for-profit agency or individual, including, but not
9 limited to, a college, university, hospital, laboratory,
10 research institution, local health department, voluntary
11 health agency, health maintenance organization, corporation,
12 student, fellow, or entrepreneur, conducting clinical
13 research using State funds. A grantee may also be a
14 corporation that is headquartered in Illinois and that
15 conducts research using State funds.

16 "Minority group" is defined as in the 1993 National
17 Institutes of Health guidelines.

18 "Project of clinical research" includes a clinical trial.

19 Section 10. Inclusion of women and minorities. Except as
20 provided in Section 15 or 30, in conducting or supporting a
21 project of clinical research, a grantee must do all of the
22 following:

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

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

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

1 Section 15. Exceptions. The requirements established in
2 Sections 10 and 25 regarding women and members of minority
3 groups do not apply to a project of clinical research if the
4 inclusion of women and members of minority groups as subjects
5 in the project is inappropriate because of either of the
6 following:

- 7 (1) The health and safety of the subjects.
- 8 (2) The purpose of the research.

9 Section 20. Manner of conducting trial. In a clinical
10 trial in which women or members of minority groups will be
11 included as subjects as required under Section 10, a grantee
12 must ensure that the trial is designed and carried out in a
13 manner sufficient to provide for a valid analysis of whether
14 the variables being studied in the trial affect women or
15 members of minority groups, as the case may be, differently
16 than other subjects in the trial.

17 Section 25. Grantee bound by terms of Act. In any grant,
18 or in any contract by a grantee under a grant, the grantee or
19 contracting party must acknowledge, agree to, and be bound by
20 the terms of this Act.

21 Section 30. Grantee's compliance with 1993 National
22 Institutes of Health guidelines. If a grantee is in
23 compliance with the 1993 National Institutes of Health
24 guidelines, the grantee shall be deemed to be in compliance
25 with this Act.