

AN ACT in relation to health.

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

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

Section 5. Definitions. In this Act:

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

"Minority group" is defined as in the 2000 National
Institutes of Health guidelines.

"Project of clinical research" includes a clinical trial.

Section 10. Inclusion of women and minorities. Except as
provided in Section 15 or 30, in conducting or supporting a
project of clinical research, a grantee must 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 members of 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.

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

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

Section 20. Manner of conducting trial. In a clinical trial in which women or members of minority groups will be included as subjects as required under Section 10, a grantee must 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.

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

Section 30. Grantee's compliance with 2000 National Institutes of Health guidelines. If a grantee is in compliance with the 2000 National Institutes of Health guidelines, the grantee shall be deemed to be in compliance with this Act.