

Department of Veteran Affairs
Veterans Health Administration
Washington, DC 20420

M-3, Part I
Chapter 14

July 24, 1992

1. Transmitted is a new chapter to the Department of Veterans Affairs, Veterans Health Administration Manual M-3, "Research and Development in Medicine," Part I, "General," Chapter 14, "Inclusion of Women and Minorities in Clinical Research."

2. The principal purpose of Chapter 14 is to set policy for the inclusion of women and minorities.

3. Filing Instructions:

Remove Pages	Insert Pages
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4. RESCISSION: VHA Circular 10-91-056, dated May 28, 1991.

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Distribution: RPC: 1041
FD

Printing Date: 7/92

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CHAPTER 14. INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

14.01 PURPOSE

This chapter provides VHA (Veterans Health Administration) policy regarding the inclusion of women and minorities in clinical research. Such inclusion is needed to assure that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study.

14.02 SCOPE

a. VHA policy applies to all applicants for VA (Department of Veterans Affairs) Central Office support for clinical research, e.g., all applicants for funding from:

- (1) Medical Research Service.
- (2) Health Services Research and Development Service.
- (3) Rehabilitation Research and Development Service.

b. Since similar policies exist for other funding sources, e.g., National Institutes of Health, it is appropriate that applicants for extra-VA funding familiarize themselves with all relevant policies.

14.03 POLICY

a. Applicants for VA Central Office research support will include minorities and women in their study population whenever possible and scientifically desirable.

b. Special efforts will be made to include members of minority groups and women in studies of disease, disorders, and conditions that disproportionately affect such groups.

c. If women or minorities are excluded or inadequately represented in a proposed clinical research study, particularly in a proposed population-based study, an exception to the policy must be approved by the Associate Chief Medical Director for Research and Development, or designee.

14.04 BACKGROUND

The policy stated in this chapter results from a Congressional directive "that VA make every effort to provide for adequate representation of women and minorities, within the constraints imposed by the characteristics of the population served by the VA, in VA-funded medical research projects, and to develop a policy to ensure such representation." (Ref: Report 101-474 from the Senate Committee on Appropriations, p. 21.)

14.05 PROCEDURES

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a. Medical center Directors will ensure, through their research offices, that all potential applicants for clinical research support are familiar with the policy stated in this chapter.

b. Research and development committees and human studies subcommittees will review all proposals for compliance with this policy.

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c. Scientific peer review groups, in VA Central Office, will evaluate all applications for clinical research support for compliance with this policy.

d. Projects that do not comply with this policy will not be funded by:

(1) Medical Research Service.

(2) Health Services Research and Development Service.

(3) Rehabilitation Research and Development Service.

14.06 DEFINITIONS

Clinical research includes human studies of the etiology, treatment, diagnosis, prevention, or epidemiology of diseases, disorders, or conditions, including but not limited to clinical trials.

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