

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH HANDBOOK

1. **REASON FOR ISSUE.** This Veterans Health Administration (VHA) Handbook defines the requirements regarding the inclusion of women and minorities in Department of Veterans Affairs (VA) research.
2. **SUMMARY OF MAJOR CHANGES.** This is a recertification; no major changes have been made to this Handbook.
3. **RELATED DIRECTIVE.** VHA Directive 1200.
4. **RESPONSIBLE OFFICE.** The Office of Research and Development (12) is responsible for the contents of this VHA Handbook. Questions may be addressed to 202-254-0183.
5. **RESCISSION.** VHA Handbook 1200.9, dated June 1, 2001, is rescinded.
6. **RECERTIFICATION.** This VHA Handbook is scheduled for recertification on or before the last working date of March 2013.

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INCLUSION OF WOMEN AND MINORITIES IN RESEARCH

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides information regarding the requirement for the inclusion of women and minorities in Department of Veterans Affairs (VA) research. *NOTE: This requirement extends to all research proposals reviewed and funded by the Office of Research and Development (ORD), including Biomedical Laboratory Research & Development Service (BLR&D), Clinical Science Research and Development Service (CSR&D), Rehabilitation Research and Development Service (RR&D), and Health Services Research and Development Service (HSR&D).*

2. DEFINITION OF RACIAL AND ETHNIC MINORITY

This category of racial and ethnic minority applies to any subset of the United States (U.S.) population that is distinguished by racial, ethnic, and/or cultural heritage.

a. VA research adopts the classifications defined by the Office of Management and Budget (OMB), which include the following categories for data on race:

- (1) American Indian or Alaska Native,
- (2) Asian,
- (3) Black or African American,
- (4) Native Hawaiian or Other Pacific Islander, and
- (5) White.

b. The OMB categories for data on ethnicity are:

- (1) Hispanic or Latino, and
- (2) Not Hispanic or Latino.

NOTE: These categories are intended to be inclusive, rather than exclusive.

3. GOAL

The primary goal VA's research program is to conduct research that addresses the high-priority health care needs of veterans. VA believes it is critical to extend the benefits of research to all individuals, regardless of gender, race, or ethnicity, and strongly encourages its investigators to include all relevant demographic groups. For this reason, the subject population of VA research needs to reflect the demographics of the veteran population.

4. SCOPE

a. The demographic profile of veterans is unlike the U.S. population as a whole, but is changing as the nature of today's military changes. While women constitute a small portion of all veterans currently seen in VA, women now make up over 15 percent of the military and over 10 percent of soldiers deployed into combat. Additionally, racial and ethnic minorities are disproportionately represented among current military personnel, and their make-up is similarly changing (e.g., increased proportion of Hispanics).

b. Considering the constraint that non-veterans may only be entered into VA studies when there are an insufficient number of veterans and the demographic profile of our veteran population, applicants for VHA research support are expected to include women and minorities in their study populations. Special efforts must be made to include women and members of minority groups in studies of diseases, disorders, and conditions that disproportionately affect these veteran groups. This policy applies to all research activities involving human subjects or human specimens and/or tissues conducted completely or partially in VA, or in approved off-site locations.

5. RESPONSIBILITIES OF VHA CENTRAL OFFICE

VHA Central Office, ORD, is responsible for convening scientific peer review groups to evaluate all research proposals involving human subjects or human specimens and/or tissues for compliance with this Handbook.

6. RESPONSIBILITIES OF THE VETERANS INTEGRATED SERVICE NETWORK (VISN) DIRECTOR

The VISN Director is responsible for ensuring that each VISN medical center is in compliance with policy and procedural guidelines relating to the inclusion of women and minorities in research.

7. RESPONSIBILITIES OF THE FACILITY DIRECTOR

Each facility Director, or Chief Executive Officer (CEO), is responsible for the research and development (R&D) program of that institution, advised and assisted by an R&D Committee. The facility Director or CEO is responsible for ensuring:

a. The local R&D committee and human studies subcommittee (i.e., Institutional Review Board) review all research proposals for compliance with this Handbook.

b. Through their research offices, that all applicants and potential applicants for research support are familiar with and comply with the requirements of this Handbook. All research proposals involving human subjects or human specimens and/or tissues must include an acknowledgement of VA policy to include women and minorities in research.

c. Through their research offices, that progress reports of VA-funded research reflects the demographics of the actual study population.