VHA HANDBOOK 1200.09 Transmittal Sheet July 15, 2013

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH

- 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**. There are no substantive changes. The Purpose, Goal, and Scope sections were revised for consistency with current Handbook formatting guidelines.
- 3. **RELATED DIRECTIVE**. VHA Directive 1200.
- 4. **RESPONSIBLE OFFICE**. The Office of Research and Development (10P9) is responsible for the contents of this VHA Handbook. Questions may be addressed to 202-443-5600.
- 5. **RESCISSION**. VHA Handbook 1200.09, dated March 10, 2008, is rescinded.
- 6. **RECERTIFICATION**. This VHA Handbook is scheduled for recertification on or before the last working date of July 2018.

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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. The authority for this Handbook is 38 CFR Part 16 and 38 U.S.C. 7303.
- **2. DEFINITION OF RACIAL AND ETHNIC MINORITY:** The VA Office of Research and Development (ORD) adopts the definitions of racial and ethnic minorities established by the Office of Management and Budget (OMB) in the 1997 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity. These categories apply to any subset of the United States (U.S.) population that is distinguished by racial, ethnic, and/or cultural heritage.
 - a. The OMB categories for race are:
 - (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 ethnicity are:
 - (1) Hispanic or Latino, and
 - (2) Not Hispanic or Latino.

NOTE: Individuals should be offered the option of selecting one or more racial designations.

3. BACKGROUND

- a. The primary goal of 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 so long as this inclusion does not compromise the scientific integrity of the research.
- b. The demographic profile of Veterans is unlike the U.S. population as a whole, and is changing as the nature of today's military changes. While women constitute a small portion of all Veterans currently seen in VA, they now make up over 15 percent of the entire military, and over 10 percent of military personnel deployed into combat. Additionally, racial and ethnic

minorities are disproportionately represented among current military personnel, and their demographic is similarly changing (e.g., increased proportion of Hispanics).

- c. Special efforts must be made, when scientifically appropriate, to include women Veterans and Veterans who are members of minority groups in studies of diseases, disorders, and conditions that disproportionately affect these Veteran groups. This policy applies to all VA research activities involving human subjects, human specimens, and/or tissues. When there are insufficient numbers of Veterans to complete a study, every effort must be made to enter non-Veterans subjects who meet the demographic profile of our Veteran Population.
- **4. SCOPE:** The requirement to include women and minorities in VA research studies extends to all VA research, including research that is unfunded, funded by non-VA entities, or research proposals reviewed and funded by the ORD, including Biomedical Laboratory Research & Development Service, Clinical Science Research and Development Service, Rehabilitation Research and Development Service, and Health Services Research and Development Service.
- **5. RESPONSIBILITIES OF VHA ORD:** VHA ORD is responsible for convening scientific peer review groups to evaluate all research proposals submitted for funding involving human subjects, human specimens, and/or tissues for compliance with this Handbook.
- **6. RESPONSIBILITIES OF VETERANS INTEGRATED SERVICE NETWORK (VISN) DIRECTORS: Each** VISN Director is responsible for ensuring that each facility conducting research within the VISN is in compliance with this policy and has procedural guidelines relating to the inclusion of women and minorities in research.
- **7. RESPONSIBILITIES OF THE FACILITY DIRECTOR:** Each facility Director is responsible for the facility's research and development (R&D) program, and they are advised and assisted by an R&D Committee. The facility Director 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. Facility research offices, provide to all applicants for research support information sufficient to familiarize them with the requirements of this Handbook and ensure their compliance. All research proposals involving human subjects, human specimens, and/or tissues must include an acknowledgement of VA policy to include women and minorities in research, as applicable to the stated research goals.
- c. Facility research offices, ensure progress reports for VA-funded research accurately reflect the demographics of the study population.