Department of Veterans Affairs **VHA DIRECTIVE 2003-065**
Veterans Health Administration
Washington, DC 20420 **October 30, 2003**

ACCREDITATION OF HUMAN RESEARCH PROTECTION PROGRAMS

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy requiring all VHA facilities conducting human subjects research to obtain accreditation of their Human Research Protection Program (HRPP) by an organization approved by VHA to perform this function. ***NOTE:*** *It describes the accreditation process for a VHA facility using an Institutional Review Board (IRB) that is administered by an affiliated academic institution.*

2. BACKGROUND

a. As a public agency and as a health care delivery system, VHA has an obligation to preserve the public trust in its research program. Appropriate mechanisms must be in place to ensure the ethical conduct of research and that persons participating in VHA research receive the highest level of protection possible.

b. In 1999, the Under Secretary for Health announced before the House Subcommittee on Oversight and Investigations and the House Subcommittee on Health of the Committee on Veterans' Affairs the establishment of an external accreditation program as one means of ensuring that all VHA facilities and investigators engaged in human subjects research in the VHA abide by stringent ethical principles, and rigorous regulatory requirements to ensure the protection of human subjects. ***NOTE:*** *This accreditation effort serves to maintain the public trust and places VA at the forefront of protecting human subjects.*

c. In 2000, VHA contracted with the National Committee for Quality Assurance (NCQA) to develop and provide an accreditation program for VHA HRPPs.

d. **Definitions.** The following definitions apply throughout this Directive:

(1) **Human Research Protection Program (HRPP).** An HRPP is a comprehensive system which ensures the protection of human subjects participating in research. The HRPP consists of a variety of individuals and committees such as: the medical center Director, Associate Chief of Staff (ACOS) for Research and Development (R&D), the Administrative Officer (AO) for R&D, compliance officers, etc., the R&D Committee, the IRB, other committees or subcommittees addressing human subjects protection (e.g., Biosafety, Radiation Safety, Radioactive Drug Research, Conflict of Interest), investigators, IRB staff, research staff, health and safety staff (e.g., Biosafety Officer, Radiation Safety Officer), and research pharmacy staff. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research.

(2) **HRPP Accreditation.** HRPP accreditation is the process of obtaining independent recognition that a HRPP affords protection to human subjects by meeting and exceeding the regulatory requirements and that the HRPP Program engages in continuous quality improvement.

(3) **Accrediting Organization.** The Accrediting Organization is an independent body that has developed standards of performance to assess compliance with the prevailing ethical, professional, and regulatory guidelines for the conduct of human subjects research.

3. POLICY: It is VHA policy that any VHA facility with a human subjects research program must obtain accreditation of its HRPP by an accrediting organization under contract with VHA. ***NOTE:*** *The contract holder as of the date of this Directive is NCQA.*

4. ACTION

a. **Under Secretary for Health.** The Under Secretary for Health requires accreditation of all HRPP at VHA facilities conducting research involving human subjects; and is responsible for ensuring that VHA schedules such facilities for accreditation.

c. **Veterans Integrated Service Network (VISN) Director.** Each VISN Director is responsible for oversight of the HRPPs within the VISN, assisting the medical center Directors where appropriate, and for ensuring that:

(1) Each medical facility conducting research and development within the VISN is in compliance with current policy and procedural guidelines, and

(2) Each HRPP within the VISN obtains accreditation.

b. **Chief Research and Development Officer (CRADO).** The CRADO is responsible for assisting each VHA HRPP in preparing for accreditation.

c. **Medical Center Director.** Each medical center Director whose facility includes a human subjects research program is responsible for oversight of the facility's HRPP. Each medical center Director is responsible for ensuring the:

(1) HRPP obtains accreditation, including coordination of the accreditation process with another VA facility if the VHA HRPP uses another VA facility's IRB as its IRB of record. If the VHA HRPP has designated the IRB of an academic affiliate as its IRB of record, that IRB must be evaluated through one of the following methods:

(a) Inclusion of the IRB of Record in the Accreditation of the VHA HRPP. The accrediting organization under contract with VHA must include a review of the IRB of record in its accreditation of the VHA HRPP. The VHA HRPP must coordinate access by the accrediting organization to all the necessary personnel, documents, and records of the IRB(s) that reside at the affiliate location.

(b) Independent Accreditation of the HRPP Where the IRB of Record Resides. The VHA designated accrediting organization must consolidate the accreditation outcomes of the VHA HRPP and the academic affiliate HRPP, if the affiliate has obtained accreditation from either the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) or the Partnership for Human Research Protection Accreditation Program (PHRP).

(2) Allocation of adequate resources to enable the HRPP to function in compliance with all VA and other Federal regulations and policies related to the protection of human subjects in research. ***NOTE:*** *This support should continue for so long as research administration funds are included in the medical care program.*

5. REFERENCES. Title 38 United States Code (U.S.C.) § 7303.

6. FOLLOW-UP RESPONSIBILITY: The Office of Research and Development (12) is responsible for the content of this Directive. Questions may be referred to (202) 254-0183.

7. RESCISSIONS: None. This VHA Directive expires October 31, 2008.

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