**Department of Veterans Affairs** **VHA DIRECTIVE 2003-031**
**Veterans Health Administration**
**Washington, DC 20420** **June 13, 2003**

# ESTABLISHMENT OF A FACILITY HUMAN PROTECTIONS PROGRAM

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive establishes a new policy for the establishment of a Facility Human Protections Program (FHPP) to help Department of Veterans Affairs (VA) medical centers fully cover costs associated with human subjects protection. This policy applies to all newly funded and VA approved industry-funded studies conducted at VA facilities. ***NOTE:*** *This policy is not retroactive and thus does not apply to previously negotiated agreements.*

## 2. BACKGROUND

a. Clinical research involving human subjects requires intensive oversight in order to ensure the protection of study participants; as a result, human subjects research incurs substantial costs. Top professional staff must perform necessary, labor-intensive activities associated with research involving human subjects, including education and training of clinician investigators and research staff, ensuring compliance with applicable regulations, credentialing of research staff, and operation of Institutional Review Board (IRB) committees. In addition, VA medical center staff must perform heavy regulatory administrative duties.

b. Forty percent of all VA research involving human subjects is funded by industry, with funds (hereafter referred to collectively as "grants") accepted by VA in accordance with the gift acceptance authority in Title 38 United States Code (U.S.C.) § 8301. When simple chart reviews are excluded, 80 percent of all human subjects research conducted at VA facilities is industry-funded. Compliance costs associated with these trials have been estimated to be approximately 10 percent of the funds spent in direct support of these studies, excluding IRB-related costs.

c. University affiliates and VA non-profit corporations (NPCs) administer industry-funded grants that are conducted at VA medical centers. The university affiliates typically charge an indirect rate of approximately 26 percent for industry-funded trials, while NPCs charge variable indirect rates ranging from 5 to 25 percent.

d. A review has revealed the existence of systemic weaknesses in the human research protections program, especially in studies funded by industry. There is a clear need for ongoing quality assurance at every VA research site. To address these weaknesses the Office of Research and Development (ORD) has identified four broad compliance-related activities that need to be carried out at every research site:

(1) Training and education of lead investigators and research staff,

(2) Credentialing of research staff,

(3) Ensuring compliance with applicable human research protection standards, and

(4) Accrediting of the facility Human Subjects Protection Program by the National Committee for Quality Assurance (NCQA)

e. Existing methods used by the entity administering study funds for the collection of fees to cover IRB-related costs need to continue. ***NOTE****: IRB-related costs, including initial and continued review, are not to be included with the compliance-related activity costs identified in the preceding.*

**3. POLICY:** As of July 1, 2003, it is VHA policy that VA medical centers can not accept industry grants (including grants funded through NPCs) that are not sufficiently funded to support the Facility Human Protections Program (FHPP).

**4. ACTION**

a. **Facility Associate Chief of Staff for Research (ACOS/R).** The facility ACOS/R is responsible for:

(1) Notifying, in writing, the entity administering the study funds about the implementation of the new FHPP policy.

(2) Ensuring that any grant accepted by VA includes an amount equal to 10 percent of the direct cost of the study, or a flat fee of $1200, whichever is greater, to be applied towards FHPP-related costs incurred by the VA medical center.

(3) Obtaining from the entity administering the study funds an annual accounting of the total amount of direct costs of industry-funded studies conducted at VA medical center(s) as well as the amount of funds that were made available for support of FHPP costs. This accounting will be compared to records maintained by the local R&D Office.

b. **Facility R&D Office.** The facility R&D Office annually reports to the Director of Finance, ORD:

(1) The information received from the entity administering the study funds, and

(2) An accounting of all expenditures in support of the compliance-related activities.

***NOTE:*** *ORD annually verifies that sites have complied with this directive and assesses the appropriateness of FHHP rate.*

**5. REFERENCES:** None.

**6. FOLLOW-UP RESPONSIBILITY:** The Office of Research and Development (12) is responsible for the contents of this Directive. Questions may be addressed to (202) 254-0201.

**7. RECISSIONS:** None. This VHA Directive expires June 30, 2008.

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Under Secretary for Health

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