

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

DEPARTMENT OF VETERANS AFFAIRS
MARYLAND HEALTH CARE SYSTEM
(VAHMCS)

VAMHCS POLICY MEMORANDUM 512-151/RD-003
VAMHCS RESEARCH SERVICE SOP HRP 01.06
November 2007

ESTABLISHMENT OF HUMAN RESEARCH PROTECTION OVERSIGHT AND COMPLIANCE SUBCOMMITTEE

1. PURPOSE: The purpose of this bulletin is to define the functions, responsibilities, reporting structures and membership of the Human Research Protection Oversight and Compliance (HRPOC) Subcommittee.

2. POLICY: To review, have oversight and make recommendations for improvement of the Human Research Protection Program at the VA Maryland Health Care System.

3. MEMBERSHIP:

- a. Associate Chief of Staff, Research & Development
- b. Physician Investigator
- c. Research Compliance Officer
- d. Research Compliance Monitoring Specialist
- e. Quality Management Specialist
- f. Research Investigational Pharmacist
- g. Performance Improvement Specialist

4. ACTIONS:

a. The HRPOC will act as a sub-committee of the Research & Development Committee with reports and minutes going to the Medical Center Director.

b. The committee makes an assessment of Research Service programs' strengths and weaknesses.

c. Activities include reviewing Research Service operating procedures and other VAMHCS procedures that impact human research participants.

d. The HRPOC initiates actions to improve the protection of human subjects in VA research programs. This will include the development of needed policies and procedures for all staff involved in human subjects research as well as providing ongoing education and consultation to improve ongoing research programs.

e. HRPOC members must complete annual mandatory trainings as listed on the Research Service website (www.maryland.research.edu)

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5. REFERENCES: Association for the Accreditation of Human Research Protection Programs,
6/1/07
VHA Handbook 1200.5

6. RESPONSIBLE OFFICE: The Associate Chief of Staff for Research and Development
(151/RD) is responsible for this policy.

7. RECISSION: NONE

DENNIS H. SMITH
Director
VA Maryland Health Care System