

COMPLAINTS AND/OR ALLEGATIONS OF NONCOMPLIANCE IN HUMAN RESEARCH STUDIES

1. PURPOSE: To notify all staff of the policy and procedures regarding complaints and/or allegations of noncompliance in human research conducted at the Augusta VA Medical Center.

2. RESPONSIBILITIES: The principal investigator of the research study bears the ultimate responsibility for the conduct of the research project in compliance with all national, local, and institutional policies and procedures. Complaints and/or allegations of noncompliance may be brought to the attention of the Research Administrative Office at VA extension 2510 or to the Office of Human Subjects Protection (OHRP) at the Medical College of Georgia at (706) 721-1480.

3. ACTION: The following point outline recommended procedures to be followed for resolving complaints and/or allegations of noncompliance presented to the VA Research Office or the OHRP. Procedures for dealing with instances of alleged violations of ethical standards in Research can be found in greater detail in MCPM 509-07-24/02.

a. When made aware of a complaint and/or allegation of noncompliance, the R&D Administrative Office or the OHRP will compile initial information about the issue and refer it to the appropriate individual, department, or committee for review and follow up action.

b. Care is taken to maintain confidentiality when corresponding with/leaving messages for all involved parties.

c. Records will be maintained by the Research Administrative Office and/or the OHRP to ensure that each complaint and/or allegation receives a formal written response outlining findings and recommended actions.

d. If the MCG Human Assurance Committee (HAC) also conducts an investigation of the complaint/allegation, the procedures outlined in the Standard Operating Procedures <http://www.mcg.edu/research/ohrp/hac/polsect39.htm> will be followed.

e. Remedial action for and consequences of findings of noncompliance will be established for each incident. These include but are not limited to compliance audits, letters of reprimand, suspension and/or termination of research protocol, and restrictions on serving as an investigator on human subjects protocols.

f. Findings will be reported to the VA Medical Center Director and all other appropriate parties and authorities.

4. REFERENCES:

a. VHA Handbook 1200.5

b. VHA Directive 10-92-014 dated January 27, 1992

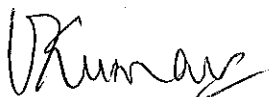
c. DHHS Guidance "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" (69 Federal Register: pages 26393-26397, dated May 12, 2004).

d. PHS Policy on Human Care and Use of Laboratory Animals, 1996.

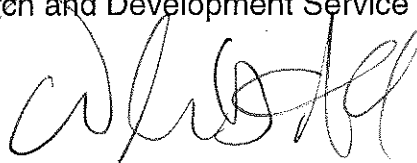
5. RESCISSION: R&A Service Line Bulletin 509-04-24/01 dated December 16, 2004.

6. RECERTIFICATION: This Policy Memorandum will be recertified on or before February 12, 2010.

7. FOLLOW-UP RESPONSIBILITY: Research and Development Service Line (24).



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Research and Development Service Line



William D. Hill, Ph.D.
Chairman
R&D Committee