

HAC Policies and Procedures

Research Non-Compliance

Allegations of research noncompliance with federal and state laws including VHA Handbook 1200.5, rules and regulations and institutional policies and procedures are referred to the MCG Office of Human Research Protection (OHRP).

Who Refers Studies For Audit?

The Chairperson of the Human Assurance Committee (HAC) at the request of the HAC may refer a study to the MCG OHRP for audit. The MCG OHRP also conducts an audit program as defined on their web site.

What Happens If MCG OHRP Finds Significant Issues Or Problems?

Should MCG OHRP determine that the alleged practices appear to: (1) cause injury or any other anticipated problems involving risks including but not limited to, physical, social, psychological, confidentiality, financial or emotional, to subjects or others or (2) constitute serious or continuing noncompliance with HAC Policies or Procedures, then the MCG OHRP may recommend further action to the HAC Chairperson.

What Will Be The Decision of the HAC Chairperson If The MCG OHRP Finds These Types Of Problems?

The HAC Chairperson may suspend the study pending a timely investigation and review. The Chairperson may recommend to the full HAC that the study should be terminated. The HAC has the authority to suspend or terminate protocols that are found to be non-compliant with federal and state laws, rules and regulations and institutional policies and procedures. Other sanctions imposed by the HAC and/or MCG OHRP may include, but are not limited to, routine compliance audits, letters of reprimand and restrictions on serving as an investigator on human subjects protocols.

Some actions may require referral by the HAC to the Research Misconduct Policy.

How Are HAC Suspensions Or Terminations Reported?

Suspensions or terminations are reported to the appropriate institutional officials responsible for the federalwide assurance (FWA) and the human research protections program (HRPP). Serious or continuing noncompliance will require reporting to both sponsor and/or federal agencies.

Are There Special Notifications for the Augusta VAMC?

Notifications of serious or continuing non-compliance are sent to:

- Office of Research and Development.
- Regional VA Office of Research Oversight.

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- VA Privacy Officer, when the report involves the unauthorized use, loss, or disclosure of individually identifiable patient information.
- VHA Information Security Officer when the report involves violation of VA information security requirements.

Is There Additional Information On The Auditing Program?

Yes. Please refer to the OHRP web site for additional information such as the current audit plan, worksheets and standard operating procedures (SOPs).