

Human Research Protections Program (HRPP)

Institutional Role in Complaints and Allegations of Potential Non-Compliance

The investigation and reporting of complaints and allegations of potential non-compliance at MCG fall under the jurisdiction of the Director of the Office of Human Research Protection (OHRP) who serves as the Human Protections Administrator (HPA). The HPA has immediate responsibility for ensuring day-to-day institutional adherence to federal, state, and local human subject protection policies and laws. The HPA reports to the Vice President for Research, who may refer the matter to the Provost and/or President. The HPA is responsible for handling complaints and allegations of potential non-compliance at all levels of the HRPP (i.e., investigators, IRB, OHRP staff, and institutional officials). For this policy, the HPA will be referred to as the OHRP Director. For the purpose of the non-compliance policy, *respondent* means the person against whom an allegation of non-compliance is directed or the person whose actions are the subject of the inquiry or investigation. To exercise his or her authority under this policy, the HPA shall:

- Review allegations of non-compliance with human research subject protection policies, guidance, or regulations;
- Ensure prompt reporting to the IRB, relevant institutional officials and sponsors, federal department and agency heads of any serious or continuing non-compliance with the requirements of the IRB, other HRPP policies, and state or federal regulations;
- Provide recommendations and guidance to the Vice President for Research or other institutional officials as required to enforce the goals of the HRPP.

Procedure for Investigation and Reporting of Non-Compliance

The OHRP Director receives the complaint, reviews the initial allegation of non-compliance or harm, initiates an inquiry, and determines if there is merit to the complaint or allegation, either handles the allegation of research non-compliance or refers the matter to the Vice President for Research for additional investigation, as appropriate. During the review process, the OHRP Director will communicate directly with the respondent, the IRB, and other institutional or government officials, as is appropriate, may consult legal counsel, and has direct access to the Vice President for Research and the President, when necessary. The OHRP Director shall issue written recommendations to the VP for Research, the IRB, and the respondent, and if appropriate, Legal Counsel. Findings may also be forwarded to the research sponsor and/or federal or state regulatory agencies, if appropriate.

The OHRP Director and Vice President for Research will consult with Legal Counsel, if appropriate. The Vice President for Research and the OHRP Director issues a recommendation as to whether the complaint or allegation should be dismissed, continued for further review, or whether corrective actions at this level are appropriate. The Vice President for Research (VPR) and the OHRP Director issues written findings and recommendations to the Respondent, affected IRB and/or the Institutional Official, and federal or state agencies, as necessary. The summary report includes a review of the information examined, stating the OHRP Director's conclusions and recommendations, as appropriate. The report is forwarded to the IRB Chairperson. The respondent has seven calendar days to appeal in writing to the HPA. If there is no appeal, the determination of the Vice President for Research, the OHRP Director and IRB Chairperson becomes final.

Human Research Protections Program (HRPP)

Ways to Report or Initiate a Written Complaint or Allegation of Non-Compliance

There are four ways to report or initiate a written complaint or allegation of non-compliance and each of these are to be commenced within fourteen days of becoming aware of the non-compliance:

- The investigators may discover and must self-report an instance of non-compliance to the appropriate IRB;
- The IRB may initiate an inquiry based on information available to it gained through the ongoing-review of research and/or monitoring of the informed consent process;
- Any individual or organization may submit a written complaint or allegation to the HPA, the IRB Chairperson (for HAC or CRRRI) or the Office of the Vice President for Research; or
- Information is discovered during the routine A&C process.

Reporting to Regulatory Agencies and Institutional Officials

MCG has a procedure for addressing allegations and findings of non-compliance with Human Research Protection Program requirements. Non-compliance, serious non-compliance and continuing non-compliance as defined below:

- Non-compliance is defined as failure to follow the regulations or the requirements and determinations of the IRBs for MCG and MCGHI
 - For Charlie Norwood VA Medical Center researchers, this also includes non-compliance with VA requirements
- Serious non-compliance is defined as significant failure by an investigator to abide by the University and federal regulations protecting human subjects of research. Examples are beginning research before securing the IRB approval, misuse or non-use of approved consent forms, failure to secure IRB approval before introducing changes in an ongoing protocol, and continuing to gather data from subjects after the IRB approval expires.
- Continuing non-compliance is defined as those instances in which an investigator continues to be non-compliant after being counseled.

Determination of Non-Compliance

The HPA serves as the primary individual for screening each incident of non-compliance. Upon consultation with the HAC Chairperson or CRRRI representative, the HPA will initiate an investigation to determine if the incident of non-compliance is serious or continuing non-compliance. The HPA, in consultation with the HAC Chairperson, Vice President for Research, representative from the Office of Legal Affairs, Provost and President determines if each allegation of non-compliance has a basis in fact.

Appeals

There is an appeals process that allows the respondent the opportunity to seek reconsideration of the determination by the OHRP Director and HAC Chairperson under certain circumstances. The grounds for appeals are limited to the following situations: the respondent has new information that was unavailable at the time of the investigation; the procedures outlined in the policy were not followed; or the sanctions are considered to be excessive. The VPR will review the written appeal from the respondent and the final report from the OHRP Director and HAC Chairperson. The decision of the VPR will be presented in writing to the respondent within 7 days of the

Human Research Protections Program (HRPP)

decision and shall be final immediately. No other entity within MCG may override a decision by the IRB, or the VPR (through the OHRP Director and HAC Chairperson) that limits, imposes conditions or in any way restricts the respondent's privileges, or imposes conditions or restriction upon the respondent's research protocols.

Human Assurance Committee Reporting to Regulatory Authorities

- 1) The OHRP Director will initiate the following process within fourteen days upon receipt of information from the investigator or research team member of the incident of non-compliance.
- 2) The HAC Chairperson, or designee, and OHRP Director will:
 - a) Determine that an event may be considered an unanticipated problem involving risks to participants or others
 - b) Determine that non-compliance was serious or continuing
 - c) Recommend suspension or termination of the HAC approval of research
- 3) The HAC will be notified via email and at the next convened meeting for the review and management of the issue.
- 4) The HAC Chairperson, or designee, with the OHRP Director promptly prepares a letter to the appropriate regulatory authority (DHHS OHRP, FDA, VHA, etc.) that contains the following information:
 - a) The nature of the event (unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of approval of research)
 - b) Name of the institution conducting the research
 - c) Title of the research project and/or grant proposal in which the problem occurred
 - d) Name of the principal investigator on the protocol
 - e) Number of the research project assigned by the HAC and the number of any applicable federal award(s) (grant, contract, or cooperative agreement)
 - f) A detailed description of the problem including the findings of the organization and the reasons for the decision of the HAC
 - g) Actions the institution is taking or plans to take to address the problem:
 - Suspending enrollment on the study
 - Suspending any activity on the study as long as subject on active treatment are adequately cared for
 - Asking the OHRP to audit the study or all of the studies under this investigator
 - Requiring continuing review more often than annually
 - Requiring a change in principal investigator (PI)
 - Requiring the addition of a mentor for the PI
 - Requiring additional education and training for the PI and research team
 - Requiring monthly or quarterly reports on the activity of the study
 - Terminating the HAC approval for the study
 - Requesting confirmation from outside experts or consultants related to the activity of the study
 - Requiring additional information from the PI
 - Revise the informed consent document
 - Inform enrolled subjects

Human Research Protections Program (HRPP)

- Increase monitoring of subjects to include observation of the informed consent process
- h) Plans, if any, to send a follow-up or formal report by the earlier of:
 1. A specific date
 2. When an investigation is completed or a corrective action plan is implemented
- 5) The Institutional Official and Office of Legal Affairs review the letter and modify the letter as needed.
- 6) The Institutional Official signs the letter and returns it to the OHRP Director or designee.
- 7) The OHRP Director or designee sends a copy of the report to:
 - a) HAC by including the letter in the next agenda packet as an information item
 - b) Institutional Official
 - c) DHHS OHRP, if the study is subject to DHHS regulations or subject to a DHHS federalwide assurance
 - d) FDA, if the study is subject to FDA regulations.
 - e) For Charlie Norwood VA Medical Center research:
 - i) The Chair of the Charlie Norwood VA Research and Development (R&D) Committee
 - ii) The Regional VA Office of Research Oversight
 - f) If the study is conducted or funded by any Federal Agency other than DHHS that is subject to "The Common Rule", the report is sent to OHRP or the head of the agency as required by the agency Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of the organization, and the agency has been notified of the event by the investigator, sponsor, another organization, or other mechanisms.
 - g) Principal investigator
 - h) Sponsor, if the study is sponsored
 - i) Contract research organization, if the study is overseen by a contract research organization
 - j) Chairman or supervisor of the principal investigator
 - k) The Privacy Officer of a covered entity, if the event involved unauthorized use, loss, or disclosure of individually-identifiable patient information from that covered entity
 - l) The Information Security Officer of an organization if the event involved violations of information security requirements of that organization
 - m) Office of Risk Management of MCGHI, if applicable
 - n) Office of Legal Affairs
 - o) Others as deemed appropriate by the Institutional Official

The OHRP Director ensures that all steps of this policy are initiated within 15 days of the action. For more serious actions, the OHRP Director will expedite reporting. Final reports will be forwarded within 15 days of the completed investigation if the matter is determined to be serious or continuing non-compliance.

CRR I Reporting to Regulatory Authorities

- 1) The OHRP Director will initiate the following procedures within fourteen days upon receipt of information from CRR I to notify the institution of actions taken:

Human Research Protections Program (HRPP)

- a) Determines that an event may be considered an unanticipated problem involving risks to participants or others
- b) Determines that non-compliance was serious or continuing
- c) Suspends or terminates approval of research
- 2) The OHRP Director or designee prepares a letter that contains the following information:
 - a) The nature of the event (Unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of approval of research)
 - b) Name of the institution conducting the research
 - c) Title of the research project and/or grant proposal in which the problem occurred
 - d) Name of the principal investigator on the protocol
 - e) Number of the research project assigned by the CRRI and the number of any applicable federal award(s) (grant, contract, or cooperative agreement)
 - f) A detailed description of the problem including the findings of the organization and the reasons for the decision of the CRRI
 - g) Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.)
 - h) Plans, if any, to send a follow-up or formal report by the earlier of
 - (1) A specific date
 - (2) When an investigation is completed or a corrective action plan was implemented
- 3) The OHRP Director, the Institutional Official and a representative of the Office of Legal Affairs review the letter and modify the letter as needed.
- 4) The Institutional Official signs the letter and returns it to the OHRP Director or designee.
- 5) The OHRP Director or designee sends a copy of the report to:
 - a) CRRI by including the letter in the next agenda packet as an information item
 - b) Institutional Official
 - c) DHHS OHRP, if the study is subject to DHHS regulations or subject to a DHHS federalwide assurance
 - d) FDA, if the study is subject to FDA regulations.
 - e) If the study is conducted or funded by any Federal Agency other than DHHS that is subject to "The Common Rule", the report is sent to OHRP or the head of the agency as required by the agency (NOTE: Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of the organization, and the agency has been notified of the event by the investigator, sponsor, another organization, or other mechanisms.)
 - f) Principal investigator
 - g) Sponsor, if the study is sponsored
 - h) Contract research organization, if the study is overseen by a contract research organization
 - i) Chairman or supervisor of the principal investigator
 - j) The Privacy Officer of a covered entity, if the event involved unauthorized use, loss, or disclosure of individually-identifiable patient information from that covered entity

Human Research Protections Program (HRPP)

- k) The Information Security Officer of an organization if the event involved violations of information security requirements of that organization
- l) Office of Risk Management at MCGHI, if applicable
- m) Office of Legal Affairs
- n) Others as deemed appropriate by the Institutional Official

The OHRP Director ensures that all steps of this policy are initiated within 15 days of the action. For more serious actions, the OHRP Director will expedite reporting. Final reports will be forwarded within 15 days of the completed investigation if the matter is determined to be serious or continuing non-compliance.