OHRP Policy
Reporting and Management of Non-Compliance

1.0 Research Noncompliance

Noncompliance is a failure by a research team member to abide by research related requirements, good clinical practice requirements, GHSU requirements and applicable regulatory requirements. Some examples of noncompliance include, but are not limited to:

- Failure to obtain approval for research prior to initiating the research activities,
- Continuing research activities beyond the expiration date without obtaining continuing review approval,
- Failure to obtain informed consent when required,
- Implementing changes to the protocol without prior approval,
- Performance of research at an unapproved site,
- Failure to adhere to the approved protocol, or
- Failure to properly oversee the conduct of the research

For Charlie Norwood VA Medical Center researchers, this also includes noncompliance with VA requirements

**Serious Noncompliance**

Significant failure by an investigator to abide by the University and federal regulations protecting human subjects of research that has the potential to increase a physical, psychological, safety, or privacy risk to research participants.

**Continued Noncompliance**

A repeated pattern of actions that suggests a future likelihood of reoccurrence of the noncompliance.

2.0 Reporting Noncompliance

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

- The investigator 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 Human Protections Administrator (HPA), the IRB Chairperson or the Office of the Vice President for Research; or
- Anonymously reporting the non-compliance via the Institutional Compliance Hotline at 800-576-6623
- Information is discovered during the routine audit and compliance process.
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3.0 Review by GHSU

The OHRP Director (Human Protections Administrator) 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. During the review process, the OHRP Director will communicate directly with the investigator or research team member, the IRB, and other institutional or government officials, as is appropriate. The OHRP Director may also consult with legal counsel, and has direct access to the Senior Associate Vice President for Clinical Research Administration and the President, when necessary. During the course of the investigation, the OHRP Director may request additional information about the allegation from the research team or request the review of the research by an OHRP Auditor.

If the allegation of noncompliance has no merit, the OHRP Director will document the allegation and determination. This determination will be shared with the IRB Chair and the Senior Associate Vice President for Clinical Research Administration.

If the allegation of noncompliance has merit, the OHRP Director communicates this information to the IRB Chair and Senior Associate Vice President for Clinical Research Administration. The IRB Chairperson and OHRP Director will present the allegation/complaint as well as any additional findings from subsequent audits or inquiries for the IRB to make a determination if the noncompliance is serious or continuing. If any of the members have conflicting interests, the member will be recused from the review and discussion. In order to make the determination, the fully convened IRB may solicit additional information about the allegation from the study team or requesting the review of the research by an OHRP Auditor. The Principal Investigator under investigation will be given an opportunity to submit written comments and to appear before the fully convened IRB.

4.0 Outcomes of IRB review regarding the noncompliance

At the conclusion of the IRB’s review, the OHRP Director will prepare a report summarizing the information it has considered and outlining its conclusion and recommended actions.

If the fully convened IRB determines the noncompliance is not serious or continuing, the IRB may:

- take no action,
- write to the Principal Investigator describing the concern and, or,
- require the Principal Investigator to give an explanation and outline a corrective action to avoid repeating the noncompliance.

If investigator’s reply is not satisfactory, this is handled as serious or continuing noncompliance.

If the fully convened IRB determines the noncompliance is serious or continuing the OHRP Director and IRB Chair will write to the Principal Investigator regarding the findings and actions.
taken by the IRB and request a response. Based on the IRB’s review and determinations, the following actions may be taken by the IRB:

- Request for more information before a final decision can be made;
- Request that the PI implement changes to the research protocol, procedures and/or informed consent documents;
- Request that the PI provide a corrective action plan to avoid a repeated occurrence in the future;
- Suspend or terminate the IRB approval for the study;
- Place the study on administrative hold;
- Review one, some or all of the investigator’s research studies;
- Revise the frequency of the continuing review process;
- Limit the types or numbers of studies for which an individual may serve as investigator;
- Require additional training for the PI and the research staff;
- Disqualification of the PI or member of the research staff from conducting research at GHSU
- Disallowance of research use of data collected;
- Notification of research participants regarding study problems (required when information may relate to the participants willingness to continue participation) or re-consent of participants;
- Recommendation to GHSU Administration that further action be taken;

If the investigator offers a timely and satisfactory explanation for the concern, and the IRB accepts, the review process will be considered as completed and the IRB Chairperson and OHRP Director will notify the investigator in writing that the research may continue and no further action is required. If the investigator offers an explanation that the IRB rejects, or if the investigator fails to respond within the specified time period, the IRB may make a recommendation for further action that includes the items listed earlier in section 4.0

5.0 Appeals

There is an appeals process that allows the investigator or research team member the opportunity to seek reconsideration of the determination by the IRB 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 Senior Associate Vice President for Clinical Research Administration will review the written appeal from the investigator or research team member and the final report from the OHRP Director and IRB Chairperson. The decision of the Senior Associate Vice President for Clinical Research Administration will be presented in writing to the investigator or research team member within 7 days of the decision and shall be final immediately.
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No other entity within GHSU may override a decision by the IRB, or the Senior Associate Vice President for Research Administration (through the OHRP Director and IRB 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.

6.0 Reporting to Regulatory Authorities

If the fully convened IRB makes a determination of non-compliance that is serious and/or continued, the IRB Chairperson, or designee, along with the OHRP Director promptly prepares a letter to the appropriate regulatory authority (DHHS OHRP, FDA, VHA, etc.) that contains the following information:

- 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)
- Name of the institution conducting the research
- Title of the research project and/or grant proposal in which the problem occurred
- Name of the principal investigator on the protocol
- Research project number assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement)
- A detailed description of the problem, including the findings of the organization and the reasons for the decision of the IRB
- Actions the institution is taking or plan of action 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 IRB 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
  - Increase monitoring of subjects to include observation of the informed consent process
- 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
The Institutional Official and Office of Legal Affairs review the letter and modify the letter as needed. The IRB Chair and OHRP Director sign the letter. The OHRP Director or designee sends a copy of the report to:

- IRB by including the letter in the next agenda packet as an information item
- Institutional Official
- DHHS OHRP, if the study is subject to DHHS regulations or subject to a DHHS federalwide assurance
- FDA, if the study is subject to FDA regulations.
- 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.
- Principal investigator
- Sponsor, if the study is sponsored
- Contract research organization, if the study is overseen by a contract research organization
- Chairman or supervisor of the principal investigator
- 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
- The Information Security Officer of an organization if the event involved violations of information security requirements of that organization
- Office of Risk Management of MCGHI, if applicable
- Office of Legal Affairs
- Others as deemed appropriate by the Institutional Official

For Charlie Norwood VA Medical Center research:

- The Chair of the Charlie Norwood VA Research and Development (R&D) Committee
- The Regional VA Office of Research Oversight

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.