Research Non-Compliance Reporting and Management

1.0 Research Non-compliance

Research non-compliance is a failure by a research team member to abide by research related requirements, good clinical practice requirements, GRU 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 non-compliance 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 reported within fourteen calendar 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 / monitoring of the informed consent process;
- Any individual or organization may submit a written complaint or allegation to the Regulatory Compliance Manager, the IRB Chair, or a member of Research Administration leadership
Research Non-Compliance Reporting and Management

- Anonymously reporting the non-compliance via the Institutional Compliance Hotline at 800-576-6623
- Information is discovered during the routine audit and compliance process
- Information identified in any other manner

3.0 Review by GRU IRB Office/IRB Committee

The IRB Office Director/Regulatory Compliance Manager 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 IRB Office Director/Regulatory Compliance Manager will communicate directly with the investigator, IRB Chair, other Research Administration leadership, and Legal as appropriate. During the course of the investigation, the IRB Office Director/Regulatory Compliance Manager may request additional information about the allegation from the research team or request a “for cause” audit of the research by an IRB Office Auditor.

If the allegation of non-compliance proves to have merit based on the investigation, the IRB Office Director/Regulatory Compliance Manager will notify the IRB Chair and applicable Research Administration leadership. A summary of the non-compliance issue(s) as well as any additional findings from subsequent audits or inquiries will be presented to the IRB to make a determination if the non-compliance 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 IRB Office Auditor. The Principal Investigator and/or research team member 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 IRB Chair and the IRB Office Director/Regulatory Compliance Manager will prepare a report summarizing the information it has considered and outlining its conclusion and recommended actions.

If the fully convened IRB determines the non-compliance 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 and/or research team member 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.
Research Non-Compliance Reporting and Management

If the fully convened IRB determines the non-compliance is serious and/or continuing, the IRB Chair and the IRB Office Director/Regulatory Compliance Manager will write to the Principal Investigator regarding the findings and actions taken by the IRB and may 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 / 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 GRU;
- 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 GRU Research Administration leadership that further action be taken
- Recommend a mentor

The review process will be considered as completed once the investigator has completed the requirements and/or responded to the IRB. The IRB Chair and the IRB Office Director/Regulatory Compliance Manager 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
Research Non-Compliance Reporting and Management

The Institutional Official (IO) and a member of the applicable Research Administration leadership will review the written appeal from the investigator or research team member and the final report from the IRB Office Director/Regulatory Compliance Manager and IRB Chair. The decision will be presented in writing to the investigator or research team member within 14 days of the decision and shall be final immediately.

The IO will investigate the non-compliance process and, if it is determined that the process was inappropriate, then the IRB will be required reconsider the decision. No other entity within GRU may override a decision by the IRB, or the IO (through the IRB Office Director/Regulatory Compliance Manager and IRB Chair) 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 Office Director/Regulatory Compliance Manager will ensure that proper documentation is provided in the minutes to include the IRB determinations and corrective actions. If not properly documented, the non-compliance issue will be presented at the next IRB meeting to be addressed. If all items are addressed in minutes, the IRB Office Director/Regulatory Compliance Manager will promptly prepare 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 IRB Office 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)
Research Non-Compliance Reporting and Management

- 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 IRB Chair, Institutional Official, applicable Research Administration leadership, and the Office of Legal Affairs will review the letter and modify as needed. The IRB Chair and IRB Office Director will sign the letter. The IRB Office Director or designee will send 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 federal wide 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
- Department Chair 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
Research Non-Compliance Reporting and Management

- 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 IRB Office Director/Regulatory Compliance Manager will ensure that all the required elements have been addressed by the IRB and will report to within 15 business days of the IRB determination. For more serious actions, the IRB Office Director will expedite reporting.