



VANDERBILT®

Human Research Protection Program Compliance Plan

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I. INTRODUCTION

Human Research Protection Program Mission

Protecting the safety, rights, and welfare of human research participants through:

Collaboration

- **Collaborating** with Investigators, key study personnel, other supporting institutional bodies and external entities toward a common goal of protecting human research participants.

Service

- **Guiding and Supporting** the development of research based on sound research design and strong ethical principles that contribute to scientific and scholarly advances in behavioral, social, biomedical, and other sciences.
- **Developing and Implementing** human research protections education programs on the application of IRB policies and procedures, and Federal regulations and guidelines.
- **Continuing** education of Investigators and key study personnel resulting in an up-to-date and knowledgeable research community in human research protections, regulations and institutional policy and procedures.
- **Consulting** with Investigators and key study personnel in the development of research programs to facilitate compliance with regulations, and assuring adherence to FDA and other regulatory guidelines, ethical considerations, and institutional policies related to human research protections.
- **Administer** a Community Outreach Program that serves the Nashville community for education on the rights of research participants.
- **Providing** an Outreach Program for the Vanderbilt Community to educate them on the Federal regulations and human research protections.

Quality

- **Post Approval Monitoring of** human research activities to assure compliance with Federal regulations, VHRPP, and institutional policies and procedures.
- **Supporting** a continuous quality improvement program through continuous assessment, evaluation and action.

II. STANDARDS OF CONDUCT

Vanderbilt University (VU), Vanderbilt University Medical Center (VUMC), Investigators and research staff, the Vanderbilt Human Research Protection Program (VHRPP), and the VUMC IRB equally share the responsibility for the protection of human research participants as required by local, state, and federal laws and as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or what is commonly referred to as *The Belmont Report*. Because of this shared responsibility, standards of conduct, local policies and procedures that define expectations and requirements for the ethical conduct of human research at VU and VUMC have been established.

A. Institutional Standards

VU and VUMC pledge adherence to its federally approved assurance by creating an institutional culture that promotes and upholds the highest ethical standards in the conduct of human research. As such, VU and VUMC will be responsible for the performance of all human research conducted at VU or VUMC including complying with local, state, and federal laws when applicable to such research. VUMC also pledges to provide sufficient resources and support for the research community, the VHRPP and the VUMC IRB.

The Executive Vice President for Research (VUMC) and the Vice Provost for Research and Graduate Education (VU) has designated an HRPP Institutional Official (IO) to assure that the HRPP functions effectively and the Institution is informed of the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the respective institutions named in their Federalwide Assurances. Vanderbilt University Medical Center as well as Vanderbilt University faculty, staff, and students (comprising of its schools, departments, divisions, and facilities) are subject to the respective Assurances and VUMC IRB policies and procedures (IRB Policy I.A “Institutional Oversight of Assurance”).

B. Investigator Standards

The individual Investigator is the ultimate protectors of the rights and welfare of research participants. They are responsible for carrying out sound ethical research consistent with the research plans approved by the IRB; and for the ongoing requirements in the conduct of approved research. This includes:

- Obtaining and documenting informed consent of subjects or their legally authorized representative prior to participation in research, unless these requirements are waived by the IRB. The Investigator must assure that each participant is adequately informed via an IRB-approved informed consent process and freely consents to participate in the research.
- Personally assuring that every reasonable precaution is taken to minimize risks to the participant.
- Assuming responsibility for compliance with all federal, state, local and institutional rules related to research involving human participants and human participant-derived information and materials. For example, the Investigator may not initiate

any research involving human participants without prior IRB approval; further the Investigator must obtain prior IRB approval for modifications of previously approved research, except when necessary to eliminate apparent hazards to the subject; submit progress reports and requests for continuing review; promptly report any unanticipated problems involving risks to subjects or others; and maintain records in accordance with IRB Policies. In addition, the Investigator must comply with any sponsor and funder(s) requirements.

C. Vanderbilt University Medical Center Institutional Review Board Standards

Responsibility for the review of research involving human participants prior to the initiation of any investigation or recruitment of participants lies solely with the VUMC IRB. This responsibility is delegated by the Chancellor (VU) and President and CEO (VUMC) of the respective entities through the Executive Vice President for Research (VUMC) and the Vice Provost for Research and Graduate Education (VU) to the VUMC IRB. The VUMC IRB has been given the authority to approve, require modifications in, disapprove, suspend, terminate, and conduct continuous review of all human subjects research activities that falls within its jurisdiction (IRB Policy I.A).

III. COMPLIANCE ACTIVITIES

The VHRPP Compliance Team serves as the focal point for all IRB education and compliance activities in conjunction with the VHRPP Regulatory Compliance Manager(s) and Director. Further, the VHRPP Compliance Team is required to directly report all IRB compliance activities to the Regulatory Compliance Manager and the VHRPP Director(s).

As a means of evaluating compliance, the VHRPP and VUMC IRB conducts audits and post approval monitoring of IRB approved research for which it is the IRB of record. They are designed to identify standards of excellence and potential areas for improvement in order to promote a solid foundation for the conduct of human subjects research, while maintaining compliance with the federal regulations.

A. VU and VUMC Institutional Audits and Post-Approval Monitoring Activities (PAM)

VUMC Institutional audits and compliance reviews are performed at VUMC sites and are conducted by the VHRPP Compliance Team or designee in the form of directed audits (for cause audits) and post-approval monitoring (randomly selected not for cause monitoring). These audits and PAMs are designed to assess compliance with local, state, and federal laws; research participant safety; and IRB policies and procedures. Audits or reviews will be performed based on volume and needs.

1. Directed Audits: Directed audits are conducted to assess the Investigator's compliance with federal regulations, state and local laws, and Institutional and IRB policies and procedures. They are designed to help identify areas for improvement and suggest recommendations based on existing policies and procedures. These audits of IRB-approved research studies are in response to allegations of non-compliance, identified concerns or complaints; and can originate from different sources (IRB P&P II.1.I), which may include:
 - An IRB Committee Member;
 - The Full IRB Committee;
 - VHRPP Director(s) or the OC;
 - Any Investigator;
 - Any external body (e.g. OHRP, FDA or Sponsor);
 - A participant, a family member, or other Institutional personnel; and/or
 - The public, media or an anonymous source.

A member of the Compliance team or designee will be available to attend Committee meetings upon request to ask and/or answer questions regarding a directed audit, including its scope and topic.

The request for a directed audit will be communicated to the Principal Investigator via written correspondence and will include the reason for the review as well as an invitation to attend. An exit interview will also be conducted to discuss findings and to inform the PI that information will be shared with appropriate individuals/groups.

Upon completion of the audit, the results will be reported to the Regulatory Compliance Manager(s) and VHRPP Director(s). Results will be provided as a written summary along

with relevant supporting documents (such as letters, email correspondences, PI corrective action plan). Results will also be shared with the IRB Chair, the IRB Committee, and the individual who requested the audit. Audits requested outside of the IRB Committee may also be presented to the IRB Chair of the appropriate Committee, and may be referred to the full board for Committee determination.

The results of audits requested by the IRB Committee will be reviewed at full Committee for a determination (IRB Procedure II.A.1 Procedure for Compliance Activities). The Regulatory Compliance Manager(s), or a member of the Compliance Team or a designee will present the findings at the convened meeting.

Possible IRB actions may include:

- Accept the audit findings with no conditions;
- Request modification of the study protocol; request additional information (e.g. corrective action plan); or impose additional oversight/increased monitoring;
- Request further education for PI and/or staff;
- Provide information about non-compliance to participants;
- Destroy collected data;
- Determine findings of serious and/or continuing non-compliance;
- Suspend or terminate the study;
- Modify the continuing review cycle;
- Request a re-audit or additional compliance monitoring;
- Observe the informed consent process;
- Withdraw or limit the privileges of the Investigator to conduct human research;
- Referral to other organizational entities (OC, Risk Management, Privacy Office, University or Medical Center Compliance Office, Dean of School); and/or
- Other actions deemed appropriate.

IRB determinations and audit findings will be communicated to the Investigator via written correspondence. A timeframe for response will be indicated if action items are required. The VHRPP Compliance Team or designee will assist in the drafting of the official letter, if needed. Required follow-up such as education, re-auditing or additional monitoring will be communicated to the Compliance Team by the RCA Team Leader and/or IRB Chair. The RCA team leader will also communicate findings to other IRB Committees if it impacts their studies.

2. Periodic Post Approval Monitoring (PAM) of IRB approved research: Periodic monitoring is conducted using a systematic method to review IRB-approved research or IRB records/activities based on volume and needs.

The above-described periodic monitoring activities may include but are not limited to the following:

- Requesting progress reports from Investigators;
- Examining the entire or part of the research project;
- Verifying the accuracy of contact information provided to participants; Assigning observers to the sites where research involving human research participants and/or the informed consent process is being conducted;

- Auditing advertisements and other recruiting materials as deemed appropriate by the IRB;
- Reviewing all regulatory documents, including correspondence with the IRB;
- Verifying that protocol deviations, adverse events and unanticipated problems involving risks to participants have been appropriately reported;
- Ensuring that Drugs, Devices, and Biologics are properly and securely stored and dispensed;
- Reviewing projects to verify from sources other than the Investigator that no unapproved changes have occurred since previous review;
- Monitoring conflict of interest concerns to assure the consent documents include the appropriate information and disclosures;
- Monitoring the appropriate use and disclosure of PHI in accordance with the HIPAA regulations; and/or
- Other monitoring or auditing activities deemed appropriate by the VUMC IRB or designee.

The request for an on-site monitoring will be communicated to the Principal Investigator via written correspondence and will include the reason for the review as well as an invitation to attend. An exit interview with the PI will occur to discuss findings and to inform them that information will be shared with appropriate individuals/groups.

Results of all periodic monitoring activities are available to the Regulatory Compliance Manager(s), VHRPP Director(s) and the Chair of the IRB Committee associated with the study. Results will be provided as a written summary, along with relevant supporting documents (such as letters, email correspondences, PI corrective action plan). The Regulatory Compliance Manager(s) and VHRPP Director(s) will determine if the compliance findings need to be shared with the IRB Chair(s). Monitoring activities that do not identify issues or findings and are determined to not require IRB discussion, are reviewed by the Regulatory Compliance Manager(s) and reported to the IRB Committee on a scheduled agenda as a notification.

The IRB Chair may refer compliance findings to the convened IRB Committee for review as needed or request additional information prior to Committee review. The Chair or IRB Committee may request a directed audit specific to the findings from the monitoring.

The result of the monitoring will be communicated to the Principal Investigator via written correspondence or via an exit interview and will include the reason for the review, the findings and any required actions.

B. Non VUMC Institutional Audits and PAMs

External audits and PAMs are conducted by the VHRPP Compliance Team or designee in the form of directed audits and monitoring visits at Non-VUMC sites where the VUMC IRB serves as the IRB of Record, for example VU. These audits and PAMs are designed to assess compliance with local, state, and federal laws, research participant safety, and IRB policies and procedures.

1. Directed Audits: Directed audits are conducted in response to identified concerns that require a convened Committee determination. Upon completion, the final results of all directed audits are reported to the Regulatory Compliance Manager and VHRPP Director(s) and the appropriate IRB Committee Chair. These reviews may include items listed in section A1 above; and
 - A review of documentation required when applying for a Memorandum of Understanding or other Authorization Agreement;
 - A certificate of insurance for general comprehensive liability and professional liability for Investigators and staff involved in research;
 - correct titles and degrees for all research staff;
 - verification of whether the Investigator(s) or key personnel have Vanderbilt faculty status;
 - CVs for all Investigators and key personnel, if applicable;
 - Investigators and key personnel must have taken the VUMC Human Subjects Training program verified with certificates;
 - Name(s) of the local contacts for each non-VUMC site; and/or
 - Name(s) of the institutional signatory official(s), if applicable.

2. Post Approval Monitoring (PAM): Periodic monitoring is conducted using a systematic method to review IRB-approved research conducted at non-VUMC sites or IRB records/activities based on volume and needs. Results of all PAMs are reported to the Regulatory Compliance Manager(s), VHRPP Director(s) and the IRB Committee Chair. These reviews may include items listed in section A2 above.

The IRB outcomes and communication of findings of directed audits and PAMs are outlined in sections A.1 and A.2 above.

If any of the above auditing activities (VUMC and non-VUMC sites) find that participants in a research project have been exposed to unexpected serious harm, the VHRPP Compliance Team will promptly report such findings to the Regulatory Compliance Manager(s), VHRPP Director(s) and the IRB Committee Chair assigned to the study. Once the directed audit has been completed and final review and determination have been made by the full IRB Committee, they may:

1. agree the study is in compliance and continue as currently approved; or
2. accept the audit, however they may impose additional safety monitoring, the creation of an independent data safety monitor, additional educational requirements, or increase the frequency of the IRB required review intervals; or
3. suspend the study to recruitment/screening, enrollment, intervention/interaction, and/or follow-up until corrective actions are taken as described by the IRB Committee; or terminate the study.

C. IRB Departmental Quality Assurance Reviews and Continuous Quality Improvement

Other aspects of internal compliance monitoring will be conducted by performing Quality Assurance reviews and Continuous Quality Improvement activities. The Quality Assurance reviews verify that the electronic database is accurate. These projects are initiated to improve new and existing processes by identifying the root cause of a problem, developing and initiating an action plan, and evaluating the outcome to assure problem resolution. The PDSA cycle incorporates the following process: Plan, Do, Study, Act. It is the goal of the VHRPP to educate the staff on this process and promote its use to achieve and document standards of excellence in VHRPP practices.

D. Expert Consultation

At the direction of the VHRPP Director(s), an expert consultant may be engaged to perform or assist with any of the above-described auditing and reviewing activities. If any of these audits or reviews identifies instances of serious or continuing non-compliance with regulatory guidance and IRB policies; injuries to participants, or other unanticipated problems involving risks to participants or others, the Regulatory Compliance Manager, VHRPP Director(s) and the appropriate IRB Committee Chair will be notified. IRB Procedure II.C.1, "Investigating and Managing Issues of Potential Noncompliance," will be followed.

E. Education

As part of its responsibility for the protection of human research participants the VHRPP is committed to providing high quality, comprehensive education and training for HRPP staff, IRB Committee members, and VUMC Investigators and their staff regarding human research protections, current events, federal regulations and IRB policies and procedures. The VHRPP Compliance Team and designees are responsible for providing both initial and continuing education to the research community, the IRB and VHRPP staff. In addition, they provide individualized education to the research Investigators and/or their staff in response to Investigator deficiencies identified by the IRB Committee, the VHRPP or the IRB OC, through compliance reviews and reviews of complaints. The VHRPP Compliance Team also provides human research protections training at the Department or Investigator's request (see Human Research Protection Program Education Plan & IRB Procedure VIII.A.1 "Procedure for Investigator and Key Study Personnel").

F. Office of Research, Research Support Services

The Research Support Services (RSS) office provides a quality improvement program called IMPACTT (Individualized Measured Performance and Collaborative Training Techniques), which is designed to assist investigators in human subject's research by providing program consultation. The goals of IMPACTT are to assist the research team in identifying strengths and weaknesses, to provide education, and to make recommendations for improvement in their research program. Study teams have requested IMPACTT assessments for:

- Review of study documents prior to FDA audit;
- Comprehensive review of study conduct and documentation after staff turn-over;
- Consultation regarding problematic protocols and/or persistent protocol deviations;
- Assistance in developing standard operating procedures; and/or
- Assessment to identify potential problems and/or data issues during early phase of enrollment.

The IRB may recommend Investigators participate in this initiative e.g. as a result of an audit. The IMPACTT Consultation Team will perform a short-preliminary interview to explain the goals and conduct an on-site assessment examining the necessary elements involved in managing a research study. At the conclusion of the on-site assessment, an exit interview will be scheduled to discuss the assessment with the Investigator and key study personnel.

V. COMPLAINT REPORTING AND INVESTIGATING

The VUMC IRB and VHRPP staff maintains an open line of communication between research participants and any other individuals associated with the conduct of human subjects research. All individuals who have questions or who are interested in voicing a concern or complaint are encouraged to contact the VHRPP directly at 615-322-2918 or toll free at (866) 224-8273. Complaints may come from any source, including individuals involved or not involved in the research process. Investigators are responsible for notifying the VHRPP of complaints received from participants and/or other individual's regarding the research.

Upon receipt, all complaints are taken seriously and promptly investigated by the Research Subject Advocate, the Regulatory Compliance Manager(s) and/or the VHRPP Director(s) in accordance with IRB Policy II.C (Investigating Any Non-Compliance, Serious or Continuing Non-Compliance) and II.D (Reporting to the Appropriate Institutional Officials, and the Department or Agency Head(s)). Complaints that are substantiated may be further investigated by the HRPP Compliance Team or designee, reviewed by the IRB Chair, and if warranted by the IRB Committee (IRB Policy II.E "Complaints Regarding Human Subjects Research"). Strict confidentiality is maintained regarding the content of a complaint and the name of any individual associated with the report.

After a complaint has been properly and promptly investigated, it is the responsibility of the VUMC IRB to determine what actions are necessary, if any. These actions may include any form of Investigation, suspension, or termination of an approved study, a directed audit, or any other action as deemed appropriate by the VHRPP Director(s). When possible, communication with the complainant is maintained and he/she is fully informed of all actions taken and the final outcome of any investigation, as appropriate. The responsibility for the implementation and coordination of these activities lies with the VHRPP Director(s), the Regulatory Compliance Manager, the Research Subject Advocate and/or a Regulatory Compliance Analyst .

The findings of a complaint investigation are also communicated to the Investigator, and/or others (e.g. Institutional Official, Department Head of School, Risk Management, Funding Body) as deemed appropriate, in accordance with IRB Policy & Procedure II.D and II.D.1, "Reporting to the Appropriate Institutional Officials, and the Department or Agency Head(s)".

VI. RESPONSE AND PREVENTION

The decision to suspend or terminate the approval of an existing human research study or the determination that the conduct of an Investigator constitutes serious or continuous noncompliance is the responsibility of a convened IRB Committee. The same procedure is followed when an Investigator is in direct violation of requirements or determinations made by the VUMC IRB. However, recommendations regarding corrective action are shared with the VHRPP Director(s) in conjunction with all or a sub-group of the members of the IRB Optimization Committee. The Director(s) will notify the IRB Medical Director, the Executive Vice President for Research (VUMC), the Vice Provost for Research and Graduate Education (VU), the Investigator's Department Head, the Dean of the Investigator's School, and the Chair of the IRB Committee responsible for the review. When applicable, notification will also be forwarded to the Investigational Drug Service, the Office of Contracts Management, the Office of Sponsored Research, the Faculty Advisor, and the appropriate institutional officials at the external sites where VUMC serves as the IRB of record. Regulatory authorities will be notified by the appropriate institutional officials listed on the VUMC Federal Wide Assurance (FWA). It is the Investigator's responsibility to report the decision to the appropriate sponsor.

A. VUMC IRB Committees

Continuing oversight and review of research findings for approved human subjects research is an important function of the VUMC IRB Committees. Whether it is during continuing review or the review of audit findings, the VUMC IRB Committee responsible for the review of a specific study may choose to suspend or terminate the approval for cause. Further, it may be necessary for the VUMC IRB to consider whether specific noncompliance with local, state, or federal regulations by an Investigator is serious in nature or appears to be a continuing occurrence or is in direct violation of the policy or determinations of the VUMC IRB. The IRB Committee may also make recommendations regarding the development of a corrective action plan for the Investigator. No final determination will be made without a thorough investigation of the issues and providing the Investigator with the opportunity to respond to concerns in writing or in person to the VUMC IRB. Any of the above-described actions must be reported immediately to the VHRPP Director(s) and the Regulatory Compliance Manager(s).

B. VUMC IRB Optimization Committee

The VUMC IRB OC consists of senior leadership within the Committees and the department. The VUMC IRB OC will review any potential issues of serious and continuing noncompliance to assure compliance with the federal regulations and VHRPP policies and procedures. The VUMC IRB OC will assure investigations are thorough and complete and all avenues of improvement have been discussed. The VUMC IRB OC will provide time for reflection and additional collection of thoughts before a determination is made to allow for an unemotional and objective decision. Additionally, they are charged with bringing resolution to inconsistencies across IRB Committees and providing guidance on the ethical conduct of research to ultimately protect human research participants.

It is the responsibility of the VUMC IRB Optimization Committee to provide guidance in creating and constructing an appropriate corrective action plan, designed to resolve any program weaknesses or deficiencies found during the audit. The plan should include a rationale or explanation for the determination, address identified deficiencies and provide detailed descriptions of the development and implementation of educational processes and procedural changes needed, which should include a time-line for implementation. It is the responsibility of the VUMC IRB Committee to review, modify, and approve a corrective action plan for the Investigator.

VII. ENFORCEMENT AND DISCIPLINE

A. VU and VUMC Enforcement and Discipline

VU and VUMC are committed to the accurate and complete documentation of research and health care services and the conduct of research with scientific and scholarly integrity. Vanderbilt has adopted, and published in the Faculty Manual, policies and procedures designed to deal with misconduct in research, and it is essential that the conduct of research activities and the delivery of health care services be documented as required by applicable laws, rules and regulations.

Federal regulations relating to accurate reporting and appropriate expenditure of grant funds must also be followed. Additionally, members of the Medical Center community, including physicians, billing representatives, and independent contractors must follow laws and regulations governing financial and billing transactions. All Medical Center physicians must follow the documentation rules in the Medicare Teaching Physician guidelines.

All Medical Center faculty, staff and representatives, as well as those who hold professional staff privileges, must carry out their duties for the Medical Center as stated in the Standards of Conduct policies, and, as required by law, report violations of local, state or federal laws, rules or regulations to a supervisor or the Medical Center Compliance Officer. If any faculty, staff or representative does not report violations, knowing that such a failure violates a clear legal obligation, the individual may be subject to disciplinary action and may be terminated from employment. Such disciplinary conduct must abide by all substantive and procedural protections applicable to discipline in the Faculty Manual or, for staff, in the Human Resource Services' Staff Guidelines. Disciplinary action may apply to a supervisor who knowingly directs or approves a person's improper actions, or is aware of those improper actions but does not act appropriately and within the supervisor's scope of authority to correct them, or who, by knowingly violating a clear legal or professional duty, otherwise fails to exercise appropriate supervision. See the [Compliance Office's Standards of Conduct](#) for further details.

B. VUMC IRB Enforcement and Discipline

The VUMC HRPP is charged with the implementation and enforcement of its policies and procedures. It is the responsibility of the VHRPP and the IRB to assess all complaints of non-compliance in human subjects research under its jurisdiction to determine if the event is credible. Reports of alleged noncompliance can come from any source including IRB Committee members, Investigators, participants, institutional personnel, other institutional committees, the media, anonymous sources, or the public. All reports of alleged noncompliance that are determined credible must be managed by the VHRPP and IRB to assure that the safety of human research participants is maintained during the investigation, appropriate action plans are developed to minimize reoccurrence and appropriate regulatory bodies are notified, if applicable. It is the responsibility of the Investigator to respond to all requests, concerns and fully cooperate with the IRB Committee, the VHRPP Director(s), the Regulatory Compliance Manager(s) the VHRPP

Compliance Team, and/or regulatory bodies addressing any potential issues of noncompliance.

1. Assuring the safety of participants during review of alleged noncompliance

The following determinations and actions may be considered at any time during an investigation to assure the safety of participants:

- a. The Compliance Team may recommend the Investigator place activities on hold if more information needs to be gathered provided participants are not placed at imminent risk;
- b. The IRB Committee may determine upon initial review of the alleged allegation that participants are not at imminent risk and the particular study can continue during the investigation; and/or
- c. The IRB Committee may suspend the study or related studies for which the same Investigator is responsible on based on preliminary information, the seriousness of the situation, potential risk to participants or allegations toward the Investigator.

2. Audits

The IRB may find it necessary to request further investigation if the breadth of noncompliance is not known. The IRB Committee may request an audit of an ongoing study or suspend the study pending investigation. It is the responsibility of the Regulatory Compliance Manager(s), VHRPP Compliance Team or designee conducting the audit to report new areas of concern to the assigned IRB Committee for consideration in determining additional actions.

3. Outcomes (also see section IV.A.1)

- a. Compliance: The IRB may determine that the research study under review is in compliance with federal and state regulations and IRB policy, and that no further action is required.
- b. Compliance with enhancement: The IRB may determine that the research study under review is substantially in compliance with federal, state regulations and IRB policy, but may make specific recommendations to improve or enhance the study's human subjects protections, require additional education, or impose additional oversight of the research.
- c. Noncompliance of a non-serious or non-continuing nature: The IRB may determine that the research study under review is not in compliance with federal, state regulations and/or IRB policy, and/or the Investigator's response is not adequate to satisfy the Committee's concern. However, the incident appears to be isolated, and in essence, is a miscommunication, misunderstanding, or lack of education. The Committee may impose restrictions and/or require additional subjects protections, additional education, or impose additional oversight of the research.
- d. Noncompliance of a potential serious or continuing nature: The IRB may determine that the Investigator's failures to comply with federal, state regulations and/or IRB policy pose such significant risk to participants in the research that the Committee may suspend or terminate its approval of the study. A written notice of suspension and the criteria for suspension must be sent to the Investigator for each study suspended. Issues of serious

and/or continuing noncompliance must be reported in writing to the VHRPP Director(s). Issues of serious and/or continuing noncompliance should be presented to the Optimization Committee for recommendations according to IRB Policy II.C. All investigations and audits for noncompliance are to be reviewed by the assigned IRB Committee Chair and the VHRPP Director(s).