**ATLANTA VA HEALTH CARE SYSTEM (AVAHCS) PROTOCOL DEVIATIONS and NONCOMPLIANCE POLICY**

1. **OBJECTIVES:** 
   1. To describe the Principle Investigators (PI) responsibilities for reporting protocol deviations and noncompliance
   2. To describe the procedures for reporting protocol deviations and noncompliance
2. **DEFINITIONS:**
3. **Continuing Noncompliance:** is the persistent failure to the legal and policy requirements governing human research.
4. **Corrective and Preventive Action (CAPA) Plan:**a plan developed by an investigator, with or without the assistance and guidance of the IRB, following an audit into an instance of noncompliance or other problems in the conduct of human subjects research. The CAPA must include measures designed to correct the immediate problem and prevent its recurrence or the recurrence of a similar type of problem. CAPA plans are reviewed and may be modified by the IRB before being approved. Investigators are responsible for implementing CAPAs in a timely manner.
5. **Minor Protocol Deviation:** A deviation from a research protocol that was approved by the IRB and VA R&D Committee that does not (a) adversely affect the rights, welfare or safety of subjects; (b) adversely affect the integrity of research data; (c) adversely affect the subjects’ willingness to continue participation in the research;or (d) was not undertaken to prevent immediate hazard to a human subject or noncompliance
6. **Noncompliance*:*** Failure to comply with any of the regulations and policies of the IRB and/or VA, and failure to follow the determinations of the IRB and R&D Committee. Noncompliance may be minor or sporadic, or it may be serious and/or continuing. Noncompliance can be on the part of Researchers, staff, other employees, and of the IRB.
7. **Protocol Deviation (PD):** A deviation is a departure from the IRB-approved protocol. Deviations may represent minor departures and/or noncompliance.
8. **Reportable Protocol Deviation:**A protocol deviation is reportable if it meets any of the following criteria:
   1. Adversely affects the rights, welfare or safety of subjects or presenting a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information.
   2. Adversely affects the integrity of the researchdata.
   3. Adversely affects the subject’s willingness to continue participation in the research.
   4. Concerns study documentation associated with an FDA-regulated study.
   5. Was a protocol deviation undertaken to prevent immediate hazard to a human subject.
   6. A persistent failure to adhere to the legal and policy requirements governing human research.
   7. Substantively compromising a facility’s Human Research Protection Program (HRPP).
   8. Substantively compromising a facility’s research information security program.
9. **Serious Noncompliance:**Serious noncompliance is any failure to adhere to requirements for conducting human research that may reasonably be regarded as:
   1. Presenting a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or
   2. Substantively compromising a facility’s Human Research Protection Program (HRPP).
10. **Serious Problem:** A serious problem is a problem in human research or research information security that may reasonably be regarded as:
    1. Presenting a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or
    2. Substantively compromising a facility’s Human Research Protection Program (HRPP) or research information security program.
11. **RESPONSIBILITES AND PROCEDURES:** 
    1. **REVIEW:**
       1. The PI shall review any instance of a deviation from a researchprotocol that has not been approved in advance by the IRB to determine if the protocol deviation meets any of the following criteria.
          1. Adversely affects the rights, welfare or safety of subjects or presenting a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information.
          2. Adversely affects the integrity of the researchdata.
          3. Adversely affects the subject’s willingness to continue participation in the research.
          4. Concerns study documentation associated with an FDA-regulated study.
          5. Was a protocol deviation undertaken to prevent immediate hazard to a human subject.
          6. A persistent failure to adhere to the legal and policy requirements governing human research.
          7. Substantively compromising a facility’s Human Research Protection Program (HRPP).
          8. Substantively compromising a facility’s research information security program.
       2. The PI shall **review** any instance of **serious noncompliance** which isany failure to adhere to requirements for conducting human research that may reasonably be regarded as:
          1. Presenting a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or
          2. Substantively compromising a facility’s Human Research Protection Program (HRPP).
    2. **REPORT:** If the protocol deviation/noncompliance meets any of the criteria described above in section 3.a.i or ii:
       1. The PI **must** report the protocol deviation/noncompliance **within 5 business days** after becoming aware to the:
          1. IRB of Record (i.e. Emory University, VA Central IRB, All of Us IRB, National Cancer Institute IRB, or other)
          2. The AVAHCS Research Office at [VAReportableEvents@faver.foundation](mailto:VAReportableEvents@faver.foundation)
             1. Include PI’s name, IRB number, IRB name, protocol title, and summary of event
       2. If the protocol deviation/noncompliance is related to **Privacy and HIPAA** **issues** the PI must also report the protocol deviation and/or noncompliance **within 1 hour** to the Associate Chief of Staff for Research (ACOS),AVAHCS Privacy Office (PO) and Information Systems Security Office (ISSO) by:
          1. Completing Issue Brief: [ISSUE BRIEF](file:///\\V07.med.va.gov\ATG\Atlanta_Research\SIO\HRPP\Protocol%20Deviations\Issue%20Brief%20(Privacy).doc)
          2. Emailing it to: [VHAATGResSecurityInc@va.gov](mailto:VHAATGResSecurityInc@va.gov)
          3. Following the Research Information Security Incidents Policy located on the AVAHCS research website: <https://www.atlanta.va.gov/Docs/Research_Information_Incident_Reporting.pdf>
       3. For a list of some examples of apparent serious and/or continuing noncompliance that would require reporting to the IRB please see the[Office of Research Oversight Examples and Brief Guide for Reporting Apparently Serious or Apparently Continuing Noncompliance in Human Research](https://www.va.gov/ORO/Docs/Guidance/1058_01_Examples_App_Serious_Cont_NonCom_HumanRsch_09_14_2015.pdf)document on the AVAHCS Research website.
       4. For a list of some examples of information security problems that require reporting, please see the [Office of Research Oversight Examples and Brief Guide for Reporting Apparently Serious Research Information Security Problems](https://www.va.gov/ORO/Docs/Guidance/1058_01_Examples_Research_Info_Security_Problems_09_14_2015.pdf) document on the AVAHCS Research website.
    3. **TRACK:** If the PI determines that none of the above criteria are met, then the PI may consider the protocol deviation/noncompliance to be Minor Protocol Deviation/ Noncompliance and reporting of the matter to the IRB is not required, unless mandated by Sponsor, protocol or contract. The PI and study team should correct the issue as allowable and document the issue and any corrections in the regulatory binder’s [Protocol Deviation/Protocol Noncompliance log sheet](file:///\\V07.med.va.gov\ATG\Atlanta_Research\SIO\HRPP\Protocol%20Deviations\PROTOCOL_DEVIATION%20Noncompliance%20Log%207-17-17.docx). The log sheet will also capture the PI’s review of the protocol deviation/noncompliance and reasons for the determination of a Minor Protocol Deviation/Noncompliance.
    4. **EMORY IRB:**
       1. In addition, the following deviations are always reportable to the IRB per Emory guidelines and may also be reportable per other CIRB’s guidelines:
12. Deviations involving errors during eligibility process that caused the enrollment of an ineligible subject
13. Missed protocol-required labs or procedures indicated before study intervention, including pregnancy tests (even if harm did not occur)
14. Risk Evaluation and Mitigation Strategies (REMS) requirements deviations
15. Drug dosing errors involving safety concerns (for example, if a subject was dosed incorrectly at a lower or higher dose, or if the drug was not stored per manufacturer indications)
16. Consent process errors (when subjects did not receive an adequate explanation of study, or there is no correct documentation of consent)
    * 1. For detailed instructions on how to report to eIRB please see [Steps to Filling out eIRB Protocol Deviations.](file:///\\v07.med.va.gov\atg\atlanta_research\administration\policies%20and%20procedures\Web%20Outline\VA%20clinical%20studies%20-%20Human\Protocol%20Deviation%20and%20Noncompliance\Steps%20to%20Filling%20out%20eIRB%20Protocol%20Deviations.docx) located on the AVAHCS research website.
    1. **OTHER IRBs:** For VA Central IRB, NCI Central IRB, All of Us Central IRB, or other IRBs, the PI should report per that CIRB’s policies and procedures, in addition to the procedures outlined above. VA reporting requirements supersede the IRB of records listed above unless the IRB of records requirements are more restrictive.