COMPLIANCE AUDITING FOR HRPP

1. POLICY

The Birmingham VA Medical Center (BVAMC) Human Research Protection Program (HRPP) is committed to protecting the safety and welfare of veterans participating in VA research. This Standard Operating Procedure (SOP) establishes policy requiring the Research Compliance Officer (RCO) to audit BVAMC IRB approved research involving human subjects to assess compliance with all applicable laws, regulations, and policies including those related to privacy, confidentiality, and information security requirements.

2. BACKGROUND

VA must exercise prudent stewardship of public resources, including public funds that support research programs. Appropriate mechanisms must be in place to evaluate the functioning of the Human Research Protection Program (HRPP) and the safeguards in place to protect human research subjects in VA research. Auditing is a mechanism to evaluate VA’s human subject research program and, when appropriate, identify areas for corrective action. An active auditing program should provide reasonable assurance of the integrity of the research program and that adequate protections for research subjects are in place. To provide this reasonable assurance the staff conducting the audits must be independent of the research program and the research study. VHA Handbook 1200.05 currently requires that the Institutional Review Board (IRB) develop written procedures for conducting audits of protocols and other IRB activities. This SOP requires that specific policies are in place for periodic and random audits of human subject research protocols and HRPP processes, and require appropriate and timely corrective actions when deficiencies are identified.

3. RESPONSIBILITIES

The BVAMC Director has ultimate responsibility for the HRPP. Specifically the facility Director is responsible for appointing and supervising the RCO for the HRPP, ensuring that each VA-approved human research study is completely audited by the RCO following VA auditing requirements. VA requires audits of each study involving humans at a minimum of every 3 years for compliance with the regulations and policies and annual audits of signed informed consents after the recruiting process begins for each active study. Audits may be conducted more frequently as deemed appropriate. The Director is responsible for ensuring that the compliance audits assess compliance with all applicable laws, statutes, regulations, and policies including those related to privacy, confidentiality, and information security. Annually, the Director will
evaluate the effectiveness of the auditing program assuring that adequate resources and personnel are made available to achieve the objectives of this policy.

**Research Compliance Officer (RCO)** is responsible for the development and implementation of the facility's research Compliance Program. This includes developing and updating policies and SOP's for the HRPP that include the auditing program. The policies and SOP's must address the VA requirement for conducting regulatory audits and informed consent audits. Regulatory audits must include review of all regulatory compliance with federal, FDA and VA regulations. The frequency of audits to be conducted (in addition to the required protocol regulatory audits), is based on such criteria as risk to human subjects, importance of the issue to HRPP operations, and local HRPP concerns.

**Associate Chief of Staff, Research and Development (ACOS/R&D)** is responsible for the oversight of the HRPP policies and procedures including those for the auditing program.

**BVAMC Research and Development (R&D) Committee** reviews reports of all audits conducted and makes recommendations for appropriate corrective action related to research findings and votes on any recommendations for actions proposed by the IRB as a result of an audit.

**BVAMC Institutional Review Board (IRB)** is responsible for reviewing audit reports and making recommendations when/if needed. The IRB reviews all audit reports pertaining to human research, makes appropriate recommendations for quality improvement actions/measures to improve performance and votes on all recommendations for action forwarded to the R&D Committee.

**Principal Investigators** are responsible for cooperating in the auditing process, ensuring study related documents are available for review and following recommendations made by the RCO, IRB, ACOS, and R&D Committee regarding findings.

**Anyone involved in VA research** must comply with the state and federal statutes, VA and BVAMC HRPP SOPs, including cooperating with audits and procedures.

4. **PROCEDURES**

All VA IRB research involving human subjects is audited by the RCO at a minimum of triennially and all signed informed consent forms are audited yearly. If a study is open less than three years it must be audited at least once during its life cycle. Audits may be conducted more often then required at the request of the Director, ACOS, R&D, IRB, R&D Committee, Office of Research Oversight (ORO), Office of Research and Development (ORD), Veterans Health Administration (VHA), or Office of Human Research Protections (OHRP). Each of these agencies or individuals can also require focused audits of 1 or more aspects of the study, increased frequency of audits or to audit specific aspects of the study based on such considerations as:

1. Involvement of vulnerable populations;
2. Level of risk;
3. Phase I or Phase II studies;
4. Involvement of FDA approved drugs for which there has been a safety warning, or change in the labeling that indicates increased risks;
5. Issues of noncompliance; or
6. Data breach.

Regulatory audits that are conducted routinely and without cause (at a minimum of triennially) will be conducted by the CQI team which consists of the Research Compliance Officer, Information Security Officer and the Privacy Officer, using the regulatory audit form provided by ORO.

The areas of a research study to be audited during a regulatory audit include, but are not limited to:
   (a) Regulatory compliance (including federal, FDA and VA);
   (b) Adverse event reporting;
   (c) Inclusion and exclusion criteria;
   (d) Documentation of informed consent;
   (e) Waiver of informed consent;
   (f) Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliant authorization; (reviewed with/by Privacy Officer)
   (g) Waiver of HIPAA compliant authorization and the required documentation by the IRB (reviewed with/by Privacy Officer)
   (h) Compliance with all data security and data use requirements; and
   (i) Compliance with all privacy and confidentiality requirements (reviewed with/by Privacy Officer and the Information Security Officer)

Regulatory audits will be conducted monthly and written reports will be submitted quarterly to the IRB, ACOS, R&D, Director and the R&D Committee. These reports will include the name of the Investigator, name of each study and any corrective action needed in addition to the items listed above a-i. Any major violations or deviations that could result in patient safety or harm will be verbally reported within 24 hours to the IRB Chair, ACOS, R&D and the Director for specific corrective actions/plans to protect subjects and/or their data (See SOP #18).

Informed consent audits will be performed monthly on all active studies involving human subjects who have signed an informed consent. Each month specific studies with active participation will be audited for informed consent compliance, assuring that all informed consent forms are appropriately executed. A waiver to this requirement has been approved for the Million Veteran Program (MVP) study. MVP informed consents will be audited in the following manner: 100% of the consents will be audited for the timeframe of June, 2011 thru September, 2011; starting October, 2011, 10% of consents obtained will be audited on a monthly basis. The RCO will provide the MVP PI/Coordinator with a list of subjects (10% of total consented) from the previous month. The subjects’ files will be pulled for the RCO to review. MVP audit results will be reported to ORO according to ORO’s schedule. These reports will be submitted with the quarterly regulatory audit reports and annually as part of the Director’s Oversight Checklist to ORO.
All corrective actions that may be necessary for compliance will be included in the quarterly report, with follow up audits as needed. All serious issues of non-compliance (especially those involving the safety or security of subjects and their data) will be referred to the IRB, ACOS, R&D or Director for suspension of some or all of the research and/or disciplinary action and will be reported as necessary to all oversight agencies (see SOP #18).

Additionally the RCO will review the adequacy of HRPP processes, such as the effectiveness of communication with all applicable committees, persons, and officials; ensuring documentation and reporting requirements of the auditing program. This includes the annual review and oversight of the IRB in its ability to perform its duties (including the timeliness of initial IRB approval), compliance with HRPP training, and compliance with federal regulations regarding exempt and expedited reviews, compliance with data and privacy policies and compliance with investigational drug policies. It includes review of the adequacy of the R&D Committee to fulfill its role and obligation to the HRPP, as outlined in VA Handbook 1200.01 Research and Development Committee.

Non-compliance issues or continuing non-compliance issues that occur as defined and directed in VHA Handbook 1058.01 Compliance Reporting Requirements in Research and VHA Directive 2008-064 will be reported as required. Copies of audits that require reporting and/or remediation action plans will be submitted to ORD and ORO as required to monitor remediation action plans.

**Findings of Noncompliance**

See the BVAMC HRPP SOP#18 Allegations of Non-Compliance for details on how findings of noncompliance is addressed by the BVAMC HRPP.

5. REFERENCES
   VHA Directive 2008-064 Research Compliance

6. ATTACHMENTS
   Regulatory Audit form
   Informed Consent audit form

7. RESCISSIONS

8. REVIEW DATE
   January 1, 2021
   [Signature]
   Louis Dell'Italia, MD
   ACOS, Research and Development