INFORMATION SYSTEM SECURITY OFFICER (ISSO) & RESEARCH PRIVACY OFFICER (RPO) REVIEW OF HUMAN SUBJECTS RESEARCH

1. **PURPOSE:** To ensure appropriate review of research practices that maintain confidentiality and security of personally identifiable information (PII) and protected health information (PHI) obtained from human research subjects or from other sources, such as administrative or clinical databases, in compliance with federal regulations and VHA Directives 1200.01, 1200.05, 1605.01, and 1605.03.

2. **POLICY:** The ISSO and RPO are involved in the review of human subjects research to address and mitigate any potential concerns regarding privacy, confidentiality, and information security.

3. **RESPONSIBILITIES:**

   a. Investigators: Investigators are encouraged to seek guidance from the ISSO and RPO early in the submission/review process, but ISSO/RPO review must occur before final approval is given by the Research & Development Committee (RDC). As part of each initial review submission, investigators are required to provide information regarding the use, disclosure, transmission, and storage of PHI and sensitive information.

   b. HRPP/IRB Staff: Human Research Protection Program (HRPP)/Institutional Review Board (IRB) staff assign new submissions to IRB member(s), the RPO and the ISSO for their review.

   c. Information Systems Security Officer (ISSO) and Research Privacy Officer (RPO):

      i. Review all proposed human subjects research protocols (including IRB-exempt protocol submissions) prior to initial review by the appropriate oversight committee (i.e., IRB of record or RDC). Ensuring congruence among the protocol, informed consent form, and HIPAA Authorization form is a conjoint responsibility of the IRB reviewer(s), ISSO and RPO.

      ii. Conduct a final review of all initial protocol submissions following IRB/RDC approval to confirm that the privacy of study participants, the confidentiality of identifiable data, and the security of sensitive information.

      iii. Review proposed protocol amendments that impact privacy or information security.

      iv. Are available to researchers, the IRB, and the RDC for guidance regarding privacy, confidentiality, and information security.

      v. Report any privacy, confidentiality, and information security non-compliance per VA policy.

      vi. Regularly attend Research & Development Committee (RDC) meetings as non-voting members and report significant research-related privacy/confidentiality/information security issues to the committee. RPO attends Minneapolis VA IRB meetings as a consultant.

      vii. Participate in the facility's Research Information Privacy & Security Workgroup (RIPS).

4. **PROCEDURES:**

   a. Investigators provide information (via electronic protocol management system) regarding the use, disclosure, transmission, and storage of PHI and sensitive information at initial review and when amendments to the study affect confidentiality, privacy and/or information security.

   b. The HRPP/IRB/RDC staff notifies the ISSO and RPO when a new (or amended) project requires review.

c. The ISSO and RPO complete a *preliminary review* of study documents prior to Minneapolis VA IRB/RDC review to ensure that all privacy, confidentiality, and information security elements have been addressed.

d. If deficiencies are identified in their respective reviews of the proposed research, the RPO/ISSO will make recommendations to the investigator of options available to correct the deficiencies.

e. Any requested changes that might impact the privacy and security requirements of the study must be reviewed and approved by the RPO/ISSO prior to final study approval.

f. Following IRB/RDC approval, the RPO will conduct a *final review* of all initial protocol submissions to ensure that the research complies with local, VA, and other federal requirements before the investigator initiates the study.

g. The RPO and/or ISSO will review proposed protocol amendments that impact privacy or information security to confirm compliance with privacy and security requirements prior to the IRB/RDC approval determination.

h. Documentation of completed RPO/ISSO reviews remain with the research protocol.

i. The RPO/ISSO will work with HRPP/IRB/RDC staff and the Research Compliance Officer (RCO) to address and report any non-compliance with privacy, confidentiality, and information security policies.

j. The ISSO and RPO will conduct additional reviews when appropriate.

5. **REFERENCES:**

- VHA Directive 1200.01 - RESEARCH AND DEVELOPMENT COMMITTEE (1/24/2019)
- VHA Directive 1200.05 - REQUIREMENTS FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH (01/07/2019)
- VHA Directive 1605.01 - PRIVACY AND RELEASE OF INFORMATION (8/31/2016)
- VHA Directive 1605.03 - PRIVACY COMPLIANCE ASSURANCE PROGRAM AND PRIVACY/FREEDOM OF INFORMATION ACT (FOIA) CONTINUOUS READINESS REVIEW AND REMEDIATION (9/19/2019)
- VA Handbook 6500 – RISK MANAGEMENT FRAMEWORK FOR VA INFORMATION SYSTEMS – TIER 3: VA INFORMATION SECURITY PROGRAM (3/10/2015)

This document supersedes HRPP Policy #10-001: INFORMATION SECURITY OFFICER (ISO) AND PRIVACY OFFICER (PO) REVIEW OF HUMAN STUDIES PROTOCOLS (March 2020).