

Research Information Incidents Atlanta VAMC

1. OBJECTIVES:

- a) Outline policies and procedures for the initial reporting and documentation research information incidents in VA research.
- b) Promote compliance with federal guidelines and the Atlanta VA policies and procedures regarding compliance with reporting research information incidents.

2. DEFINITIONS:

VA Research - Research conducted by VA investigators serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments while on VA time, utilizing VA resources (equipment, etc.), or on VA property (including space leased to or used by VA). The research may be funded by VA, by other sponsors, or be unfunded.

Reportable Incidents Regarding Research Information – Any unauthorized use, disclosure, transmission, removal, theft, loss, or destruction of VA research-related protected health information (PHI), individually identifiable private information (III), or confidential information, as defined by the HIPAA Privacy Rule, the Common Rule, the Privacy Act, or 38 U.S.C.

Examples include but are not limited to:

- Lost or stolen laptop, external drive, or flash drive containing PHI, III, or confidential information
- Leaving desk top computer accessible to others (logged in and left unattended)
- Leaving disks or paperwork containing PHI, III, or confidential information unsecured
- Destroying data
- Disclosure of PHI, III, or confidential information without a valid HIPAA authorization or waiver
- Lack of ISO/PO review or inadequate ISO/PO review

3. INVESTIGATOR / STAFF RESPONSIBILITIES:

- 1) PIs and staff must complete training requirements related to information security.
- 2) PIs and staff must safeguard and protect all research-related protected health information (PHI), individually identifiable private information (III), or confidential information.
- 3) PIs and/or staff must promptly report all research information incidents.

4. PROCEDURES FOR REPORTING RESEARCH INFORMATION INCIDENTS:

NOTE: Please See Appendix A

- 1) **Within one hour of discovery, PIs and/or staff must report** any incident described above as **Reportable Incidents** to the Privacy Officer (PO), Information Security Officer (ISO) and Associate Chief of Staff-Research (ACOS-R) or designee.
- 2) The ACOS-R or designee **must immediately notify** the facility Director, RCO, the R&D Committee, and any relevant research review committee upon discovery and must ensure that the Atlanta VAMC ISO and PO have also been notified.
- 3) The RCO will conduct an initial inquiry for any alleged or discovered research noncompliance related to research information security or privacy. If research noncompliance is suspected or alleged, the facility Director will submit a preliminary report of the noncompliance through the RCO to the Office of Research Oversight **within 5 business days of notification.** The facility Director will ensure the PO/ISO have been notified.
- 4) The RCO will provide follow-up reports to the Office of Research Oversight as directed.
- 5) For Information Security incidents, the ISO will follow VA procedures for investigating and reporting such incidents. For unauthorized access, use or disclosure of sensitive data including PHI or III or other privacy issues, the PO will follow VA procedures for investigating and reporting such incidents, including entering information into the Privacy Violation Tracking System (PVTs) within specified timelines.
- 6) The PO or ISO will provide a final report to the RCO upon completion of their investigation. The final report will be submitted to the IRB for a determination of research non-compliance. (See MCM 151-7 for further information regarding procedures for non-compliance).

5. ADDITIONAL REPORTING REQUIREMENTS:

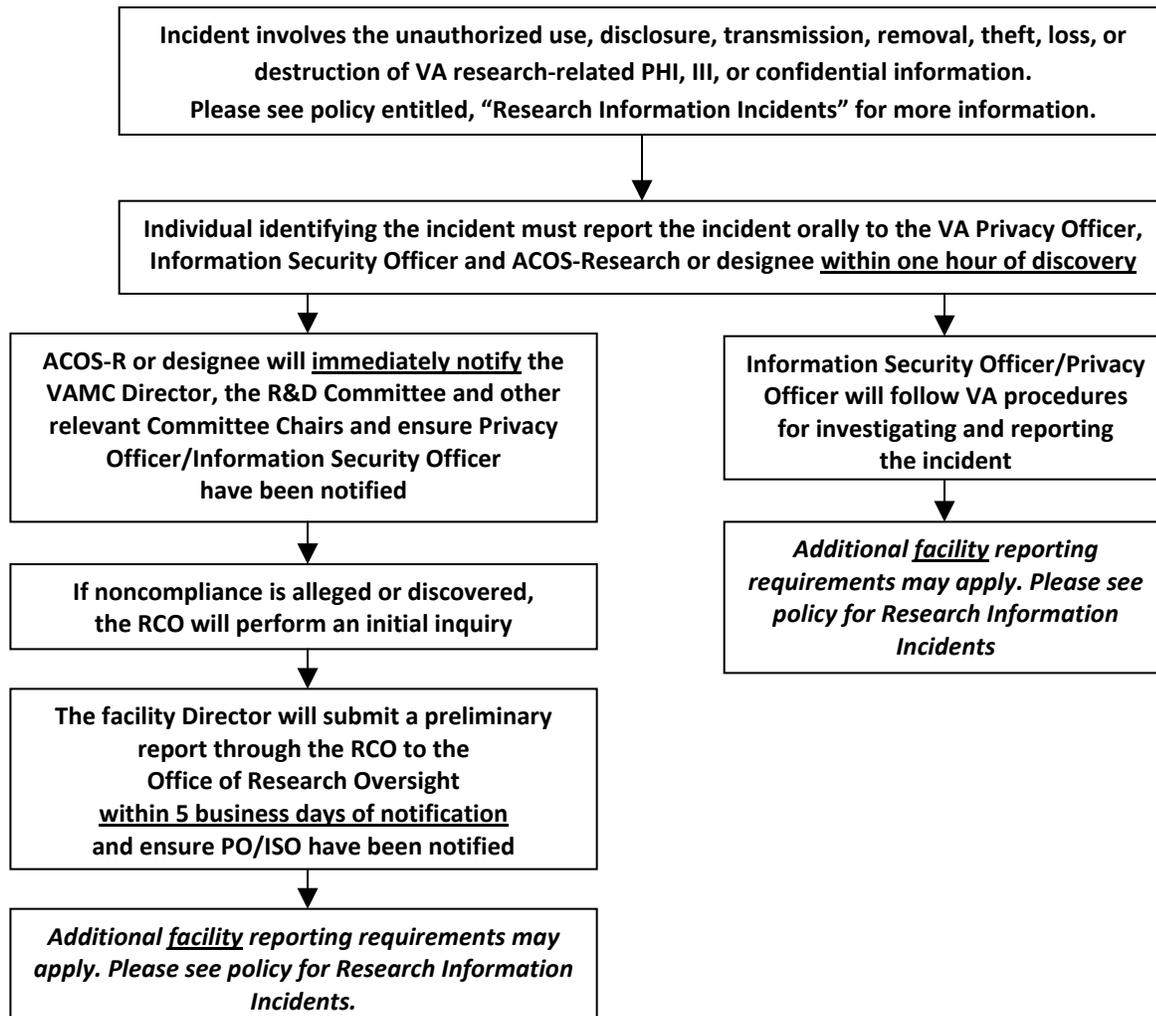
Reports to ORO Regional Office:

- Uses and disclosures of PHI, III, or confidential information without a valid HIPAA authorization or waiver of authorization must be reported by the Atlanta VAMC Director (through the RCO) **within 5 business days of notification.**
- If deemed by any party that an approved project has received a deficient review (ie., all information was not disclosed or forms were completed incorrectly or actual process jeopardized data), the incident must be reviewed and reported to the Atlanta VAMC Director (through the RCO) **within 5 business days of notification.**

Reports to Office of Research Oversight-Central Office:

- All other research information incidents (for example, unauthorized transmission, removal, theft, loss, or destruction of VA PHI related to research) must be reported by the Atlanta VAMC Director (through the RCO) **within 5 business days of notification.**

Appendix A
Reporting Research Information Incidents



****Contact Information:**

Privacy Officer, PJ Marti-notify by email: paula.marti@va.gov AND ext. 2749 or (404) 216-1169

OR Email: VHAATG Privacy@va.gov

Information Security Office- notify ISO group by email: VHAATG ISO@va.gov

AND telephone:

Autry Curry, ISO ext. 6735 or (404) 406-0894

Curtis Allen, ISO ext. 4048 or (404) 984-9415

DeShawn Fox, ISO ext. 6735 or 4048 or (770) 807-4906

Mike Hart, Associate Chief of Staff-Research (ACOS-R) ext. 7278 or (404) 538-2016

Tony Laracuate, Administrative Officer-Research (AO-R) ext. 7740 or (678) 699-7444

Elizabeth Lively, Research Compliance Officer (RCO) ext. 6964 or (770) 265-6722