



**Department of Veterans Affairs
Jesse Brown VA Medical Center
820 S. Damen Avenue
Chicago, IL. 60612**

R&D 537/151
September 29, 2010
Version 1.0

**SOP: Audits, On-Site Evaluations,
FDA Inspections, General Visitors
to Research and Development**

PURPOSE

The purpose of this SOP is to standardize the procedure for visitors, audits, on-site evaluations and inspections conducted on VA research data at the Jesse Brown VA Medical Center.

POLICY

Investigators must inform the Research & Development Office and Collaborative IRB # 4 prior to scheduling any on-site sponsor monitors inspections, internal audits (such as those recommended by affiliate departments), and external (including other federal agencies such as the FDA) audits conducted on VA human subjects research data at the Jesse Brown VA Medical Center and must follow VHA handbook 1200.05. Investigators must notify the Research and Development Office of any internal or external audits or site visits involving animals, safety, security or any other areas under research purview.

All visitors to Research and Development are required to check in with the R&D office.

PROCEDURE

1. Upon notification by an auditing body to the Investigator or study team that an audit, on-site evaluation or inspection is to occur involving VA research data at the Jesse Brown VAMC, the investigator or study coordinator must:
 - a. Notify the Collaborative IRB #4 for human subjects research.
 - b. Notify the Research and Development Office, Jesse Brown VAMC for all research including human subjects, animal research and safety issues.
2. Auditors, site monitors and inspectors must sign in with the Research and Development office and obtain a visitor badge prior to beginning the audit. The visitor will be escorted by research staff to the audit location. The PI and/or study coordinator/staff must be present during the audit. The visitor must sign out in the Research and Development office before leaving the facility.
3. In accordance with VHA Handbook 1200.05:

- a. The required records, including the investigator's research records, must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10-1).
 - b. All records must be accessible for inspection and copying by authorized representatives of VA, OHRP, FDA and other authorized entities at reasonable times and in a reasonable manner.
 - c. Records are the property and the responsibility of the local research office. The medical center must designate where the records will be maintained and/or stored.
4. All visitors to Research and Development must sign the visitors log in the Research and Development office, 6215, and obtain a visitors pass. The pass must be worn while visiting the R&D area. Visitors must return the pass and sign out when leaving. Visitors must be escorted by R&D staff (administrative, laboratory, etc) while on the premises.

REFERENCES

VHA Handbook 1200.05

REVISION LOG:

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Version (#, date)	Replaces (#, date)	Summary of changes
1.0; September 29, 2010		