



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

R&D 537/151
November 25, 2009
Version 3.5

**SOP: Jesse Brown VAMC
Research Audit Subcommittee**

Purpose:

The Audit Subcommittee is a subcommittee of the Research and Development Committee. The Audit Subcommittee was formed to comply with VHA Directive 2008-064. The Audit Subcommittee review process is a means to assess and track the adherence to research regulations rendered by individual Research Principal Investigators. A program to review and quantify quality with the intent of promoting ongoing improvement is a basic tenet of monitoring overall Research Service system quality. The Audit Subcommittee purview includes open Human Subjects protocols, and documentation related to aforementioned protocols.

POLICY:

- a. The Audit Subcommittee is comprised of VA clinicians, with membership based on recommendation from the clinical service chiefs. The program shall include a quality review of research record documentation as a peer-to-peer review. The Research Compliance Officer (RCO) shall be an Ex-Officio nonvoting member of the committee. Audits conducted by the Subcommittee are independent of the RCO, and independent of the RCO's audits.
- b. Research Principal Investigators shall have a minimum of twelve (12) research records reviewed on an annual basis.
- c. A copy of all research record reviews shall be provided to the PI and a copy maintained in the research office protocol file.
- d. The research record review shall be documented using the **Jesse Brown**

VA Medical Center Research Review Form (Attachment 1).

- i. A minimum of three (3) records shall be reviewed on a quarterly basis (and/or if indicated) if available, ideally, one from each month in the quarter.
- ii. Additional record reviews shall be conducted if the findings suggest a possible need for improvement.
- iii. The number of additional reviews shall be determined by the Subcommittee Chair, in consultation with the committee.

Ongoing Peer-to-Peer Professional Performance Evaluation Reporting:

IRB:

In the event that the peer-to-peer audit results in a finding of potential professional performance non-compliance, the IRB will be notified in writing through the ACOS for R&D within 5 days of the audit. The IRB is ultimately responsible for any determinations of non-compliance. Determining whether a report of serious or continuing non-compliance must be made to oversight bodies is the responsibility of the IRB, which will notify the Facility Director, who in turn will make the formal report.

Principal Investigator (PI): A copy of all research record reviews shall be provided to the PI and a copy maintained in the research office protocol file.

The Audit Subcommittee may request further information and/or follow-up from the PI. Typically a PI's written response to this request is expected within 30 days, although a more timely response may be required in some circumstances.

Research and Development Committee (R&DC): Peer –to-peer professional evaluation is separate from the IRB review and its findings are reported to the R&DC on a monthly basis. If significant concerns are documented that are thought to compromise the safety or scientific integrity of the protocol, the Associate Chief of Staff for Research (ACOS/R) or a member of the Audit Subcommittee can request that the R&DC evaluate the audit and determine if 1) the protocol should be suspended until the issues are adequately addressed by the PI, 2) the study must be closed, or 3) if the study can continue. Per VHA Handbook 1058.01 **Serious or Continuing Noncompliance**. Within 5 business days of becoming aware of possible serious or continuing noncompliance with VA or other Federal requirements related to human research (e.g., VHA Handbook 1200.5; the Common Rule at 36 CFR 16; Food and Drug Administration (FDA) regulations at 21 CFR 50 and 56) or with IRB requirements or determinations, members of the VA research community must report the possible noncompliance to the ACOS

for R and the IRB. **NOTE:** For purposes of this Handbook, “possible serious or continuing noncompliance” includes all findings of noncompliance related to human research by any VA office, any other Federal department or agency (e.g., FDA), or any other entity.

Committee Membership and Length of Terms:

The Medical Center Director appoints the Chair and members to the committee for a three year term, which can be renewed. The Audit Subcommittee consists of at least three members. Membership on the committee is based on recommendations by clinical service chiefs, to provide to provide the appropriate expertise needed for peer-to-peer review.

Meetings and Records:

The Audit Subcommittee routinely meets on a monthly basis to review audited protocols. Minutes from the meeting are retained by the Research Office. Minutes are submitted for Research and Development Committee review on a monthly basis.

Audit Procedures:

The Auditor’s role:

1. Uses a protocol-specific audit report form in performing the audit, conducts the audit and completes the audit report.
2. Discusses the audit findings and any deviations in protocol with the Audit Subcommittee Chair prior to the monthly meeting.
3. Answers any questions the committee may have regarding the audit report as needed.

Protocol-Specific Audit Report Form:

Attachment A

Audit Documentation:

All audit documentation is maintained in the JBVAMC Research and Development Office.

References:

VHA Directive 2008-064, “Research Compliance Officers and the Auditing of VHA Human Subjects Research to Determine Compliance with Applicable Laws, Regulations, and Policies”, dated October 16, 2008.

VHA Handbook 1200.05, “Requirements for the Protection of Human Subjects in Research”, dated July 31, 2008

VHA Handbook 1605.1, "Privacy and Release of Information",
dated May 17, 2006

VHA Handbook 1058.01, "REQUIREMENTS FOR REPORTING RESEARCH
EVENTS TO FACILITY OVERSIGHT COMMITTEES AND THE OFFICE OF
RESEARCH OVERSIGHT", February 27, 2009

REVISION LOG:

SOP: Jesse Brown VAMC Research Audit Subcommittee

Version (#, date)	Replaces (#, date)	Summary of changes
3.5; November 25, 2009		