Research Audit Manual

Nova Scotia Health Authority (NSHA)

1. INTRODUCTION

Health research is subject to a wide array of local, national, and international policies, standards, and regulatory requirements. As societal expectations regarding accountability increase, there is a heightened onus on institutions to assure the quality and compliance of the research performed within their jurisdictions.

The audit program described in this manual is an important component of NSHA's quality management system for research. Internal audits assess whether research is being conducted according to applicable requirements and identify opportunities for improvement. The audits assist the NSHA Research Ethics Board (REB) to fulfill its requirement for continuing review, and findings are used to guide quality improvement efforts and system enhancements throughout NSHA.

2. PURPOSE

The audit program provides assurance that:

- Research is conducted according to the highest scientific and ethical standards;
- Research complies with local, national, and international requirements;
- Internal quality systems are comprehensive, appropriate, and effective.

3. GUIDING PRINCIPLES

NSHA's internal research audit program has been designed in accordance with essential guiding principles. The program strives to be:

- Structured and transparent;
- Fair and consistent;
- Respectful and supportive;
- Positive, with an emphasis on capacity building and quality improvement;
- Comprehensive, encompassing all aspects of research quality at NSHA;
- Formative, with a focus on timely assessment and feedback;
- Outcome-focussed (looking beyond 'process' to ensure that the purpose of the process is being achieved);
- Flexible and responsive to changing needs;
- Relevant, practical, and useful to researchers, the institution, and the REB.

4. SCOPE

All research conducted at NSHA is subject to internal audit, and any aspect of the research may be examined. Audits typically include review of:

- Study documents including: the investigator's study file; the REB's study file; informed consent forms;
- Study responsibilities including: degree of investigator involvement; delegation of study procedures; qualifications, training, and licensure of study personnel;
- Procedures for participant recruitment, informed consent, enrolment, and discontinuation;
- Research participants' experience of the study, assessed through telephone interviews;
- Source documentation including: health records; study records; participant diaries and questionnaires; test results;
- Case report forms;
- Protocol adherence;
- Confidentiality;
- Safety reporting;
- Investigational products and associated records;
- Research equipment and associated calibration and maintenance records;
- Biological samples and supplies;
- Research facilities including: clinic rooms; drug storage area(s); areas for the collection, processing, storage, and shipping of biological samples; document storage areas; other work areas;
- Provisions for record retention.

The scope of a particular audit will depend on factors such as the reason for the audit, the type and complexity of the research, and the number of participants enrolled.

5. AUTHORITY

The auditor has authority to examine all documents, records, equipment, and locations specified in the audit plan, and to interview investigators, NSHA personnel, and research participants as appropriate.

6. RESPONSIBILITY

The audit program is overseen by the Research Ethics Board's Executive Committee.

The auditor is responsible for conducting the audit in accordance with the audit plan and the Research Audit Manual.

The principal investigator is responsible for ensuring that:

- The audit is scheduled in a timely way;
- He/she attends the opening and closing meetings;
- All information requested by the auditor is present during the audit;
- Study personnel are available as required during the audit;
- Follow-up actions are completed and reported as required.

7. HUMAN RESOURCES

NSHA's Program Manager – Research Quality manages the audit program and performs the audits. Other individuals may be assigned permanent or temporary roles as required. To ensure that audits are independent and unbiased, auditors will not be directly involved with the area, department, or study being audited.

8. AUDIT SELECTION

The Executive Committee of the Research Ethics Board determines which studies will be audited. Audits may be routine or directed ("for-cause").

The following criteria are used to select studies for routine audit:

- Affiliation of the study sponsor:
  (1) Multicentre study where the sponsor is affiliated with NSHA;
  (2) Single centre study where the sponsor is affiliated with NSHA;
  (3) Study where the sponsor is, or is affiliated with, another academic centre;
  (4) Study with an industry / commercial sponsor.

- Date of the study's initial submission to the REB (studies are more likely to be selected if they were submitted to the REB within the previous 18 months).

- The REB's risk assessment (studies rated as high or moderate risk are more likely to be selected than studies with lower risk assessments).

In most cases:

- A principal investigator will not be selected for routine audit more than once per year;
- Closed studies will not be subject to routine audit if the REB has received written notification of study closure before the study is slated for audit.

The Executive Committee may require a directed audit at any time in response to concerns, complaints, or other special circumstances. Directed audits take priority over other research activities and must be scheduled and proceed as quickly as possible.

Follow-up audits may also be requested to verify that serious deficiencies have been addressed.

9. AUDIT PREPARATION

Principal investigators will be notified in writing that their study has been selected for audit and will be asked to schedule the audit at a time that is convenient to his/her research team. If audit dates are not selected within a reasonable period (generally within three weeks of notification), the auditor may schedule the audit unilaterally.

The scope of the audit and the time required will depend on the complexity, extent, and stage of the study (e.g. how many participants have been enrolled, which personnel, facilities and equipment are involved, how much documentation has been generated). In general, the on-site part of an audit takes between half a day (for studies where no participants are enrolled) to five days (for complex studies with many participants).

After the audit has been scheduled, the auditor will provide the principal investigator with an audit plan confirming:

- Date(s) and location of the audit;
- Objectives and scope of the audit;
- Audit criteria (the applicable standards, regulations, guidelines, and SOPs);
- Expectations regarding the opening and closing meetings;
- Preparation and circulation of the audit report;
- Expectations regarding follow-up activities.

10. CONDUCT OF THE AUDIT

Each audit begins with an opening meeting attended by the auditor, the principal investigator, and other study personnel as applicable. The purpose of this meeting is to:

- Introduce the auditor to the principal investigator;
- Briefly describe the audit program;
- Review the audit plan;
- Confirm that the resources, documents, and facilities needed by the auditor are available;
- Provide an opportunity for the principal investigator to summarize study progress and describe his/her degree of personal involvement and oversight;

- Confirm the date and time for the closing meeting and any interim meetings.

Audits often begin with a tour of the facilities and equipment utilized by the study. The auditor will interview study personnel, review study documents and data, and perform other activities in accordance with the audit plan. The auditor records his/her activity and observations on worksheets that will form the basis of the audit report.

To ensure transparency, research personnel are encouraged to ask questions of the auditor and to request feedback on an ongoing basis. Audits should be a learning opportunity for all involved, and are intended to facilitate sharing of knowledge, tools, and best practices.

At the end of the audit, the auditor will hold a closing meeting with the principal investigator and other study personnel as applicable. The purpose of this meeting is to review and discuss audit observations, and to clarify expectations regarding the reporting and follow-up phases of the audit.

11. AUDIT REPORTING

In general, audit reports are prepared within two weeks of the closing meeting. These reports use a standard format to present the auditor's activities and observations. In some cases (e.g., follow-up audits and some directed audits), a letter or abbreviated report may be used.

Audit observations may be categorized as nonconformities (non-fulfillment of written requirements) or as opportunities for improvement.

Nonconformities are recorded in table format with a reference to the unfulfilled requirement and a description of the action needed to rectify the problem or prevent its recurrence.

Opportunities for improvement are recorded in list format and do not require follow-up.

Audit reports may also include commendations when exceptional practices are noted.

Draft audit reports are submitted to the REB Executive Committee for review and approval. All copies of the draft report are to be returned to the auditor for destruction. A copy of the approved report is issued to the principal investigator, copied to his/her supervisor. The auditor retains the original.

In some cases, audit observations pertain to parties other than the principal investigator. The auditor will forward such observations to the relevant parties for their review and follow-up.

12. FOLLOW-UP

All nonconformities require prompt corrective and/or preventive action. Audit responses must be submitted to the auditor within one month of receiving a documented nonconformity. The auditor may consider extensions upon request.

Customized audit response templates will be provided by the auditor. The audit response should specify follow-up actions completed, actions planned (with timelines), and any changes or corrections to the audit report itself.

If the audit findings are sufficiently serious, the REB Executive Committee may implement appropriate actions and/or sanctions. This may include halting recruitment, suspending or terminating study approval, requiring mandatory training, requesting retraction of related publications, and notifying other parties as required. The rationale and practical implications for any such action will be clearly documented and explained to the investigator. Reinstatement of full study approval may depend upon the satisfactory completion of a follow-up audit to verify that all major problems have been rectified.

13. PROGRAM REPORTING

Annual review provides an opportunity for reflection and revitalization of the audit program which, like all aspects of the research enterprise, can always be improved.

The auditor will submit an annual program report to the REB. This report will typically include:

- Summary and recommendations
- Profile of the audited studies
- Activity summary (including late or missing audit responses)
- Common nonconformities

Aggregate information, common findings, and trends will be shared with the research community on an ongoing basis.

Copyright © 2011 Nova Scotia Health Authority, Nova Scotia, Canada. All rights reserved.