EMS Research Steering Committee

Nova Scotia EMS Research

Standard Operating Procedure

SOP #: 13	**Title:** Retention of Research Records	
Approval Date: 2013 11 26	**Review Date:** 2017 12 10	**Revision Date:** 2015 12 10
Signature of SOP Sub-committee Chair: 		

DEFINITIONS

1. PRINCIPAL INVESTIGATOR: The researcher who holds overall accountability for a research project. The PI is responsible for the delegation of research tasks and holds final decision making ability in a team research environment.
2. OPERATIONAL RESEARCH RECORD: documents directly related to the study itself, and fall under this policy. See Appendix A for a list of such documents.
3. RESEARCH RECORDS: Study related information in any format, received or generated during the course of a research study.
4. RECORD RETENTION: the safeguarding of records for a specified time to fulfill administrative, legal, operational and fiscal requirements.
5. RETENTION SCHEDULE: the plan for managing the life of a record, identifying how long it is to be retained and how it is to be destroyed at the end of its life.
6. SUBINVESTIGATOR: A researcher who is recruited to a research project to assist in tasks as delegated by the principal investigator.

PURPOSE

1. Research records are retained to enable subsequent evaluation of the conduct of the study and the quality of the data produced, and to meet regulatory requirements. Storage areas must be secure and should be organized for easy retrieval.
2. The retention of research records shall be the responsibility of the principal investigator (PI) or delegated party.
3. All research records shall be retained in accordance with the retention schedule of the authority REB, outlining the storage method, duration and destruction method.
4. Only the PI or delegates may authorize the retrieval of stored records.
5. Destruction of research records shall follow applicable federal, provincial and organizational policies.

PROCEDURE

1. APPROVAL.
    a. The PI or designate should determine institutional, regulatory and sponsor requirements for retaining study records.
    b. The storage location, retention period and method of destruction for retained material are to be included in the REB submission and approved by the REB.
2. STORAGE.
    a. Documents are to be stored in a manner that is compliant with privacy and confidentiality legislation.
    b. Research data is not to be stored on personal computers of researchers.
    c. The storage method may change depending on the phase of the study:
        i. Records are considered ‘active’ when the study is open (e.g., data collection and analysis), and are usually stored in the study team’s location.
        ii. After the study is closed or has been terminated, study records should be stored in EHS onsite storage. A suggested method is: compile all research records onto a USB Drive and have stored at EHS or Dalhousie University secure research offices.
    d. The PI or delegate shall ensure at the conclusion of the study that all duplicates/copies or drafts of research information held by the PI or sub-investigators are destroyed in the manner approved by the REB.
3. DESTRUCTION.
    a. Regulations dictate the amount of time in which research records must be stored following study closure (e.g., 25 or 7 years).

b. After this time has elapsed, the PI is responsible to confirm the records are no longer required. The PI may need to also confirm this with the sponsor.
c. Records are to be destroyed according to the method approved by the REB (e.g., shredding paper records or smashing/shredding CDs/ USBs).

ABBREVIATIONS

1. PI: Principal Investigator
2. REB: Research Ethics Board

RELATED SOPs

1. SOP 7. Responsibilities of the Principal Investigator
2. SOP 9. Delegation of Study Duties

REFERENCES

1. Nova Scotia Health Authority, *Research Manual- Retention of Research Records*, March, 2012. Retrieved from: http://policy.nshealth.ca/Site_Published/DHA9/PolicyManualView.aspx
2. Department of Health and Wellness. (2013).*Toolkit For Custodians: A Guide to the Personal Heath Information Act.* Retrieved from: https://www.gov.ns.ca/dhw/phia/custodians.asp.
3. Nova Scotia Health Authority, *Records Management Guide for Research Records*, September, 2013. Retrieved from: http://www.cdha.nshealth.ca/discovery-innovation/documents

APPENDIX A. Examples of Operational Study Records (3)

- Investigator's Brochures and / or product monographs and updates signed protocol and amendments, if any
- Sample case report form (CRF) and subject diaries, with any revisions
- Copies of signed, dated, completed CRFs and documentation of CRF corrections
- Signed informed consent forms and any revisions
- Any other written information provided to subjects
- Advertisements for subject recruitment
- Signed agreements between involved parties
- Research Ethics Board (REB) membership lists

- All correspondence with the REB, interim and final reports, and dated, documented REB approvals
- Health Canada authorization of the protocol and any amendments
- Curriculum vitae and/or other documents evidencing qualifications of PI and sub-investigators
- Normal values / ranges, certifications / accreditations, quality control assessments / validations for all medical / laboratory / technical procedures / tests included in the protocol
- Sample of labels attached to investigational product containers
- Instructions for handling investigational products and study-related materials (if not included in protocol or Investigator's Brochures)
- Shipping records for investigational products and study-related materials
- Decoding procedures for blinded trials
- Investigational product accountability at the site
- Documentation of investigational product destruction, if product destroyed at the site
- Sponsor's trial initiation monitoring report
- Relevant communication with the sponsor's representatives (e.g. letters, notes of meetings and telephone calls)
- Source documents (to include original documents related to the study, to medical treatment, and history of subject)
- Notification by originating investigator to sponsor of serious adverse events and related reports
- Notification by investigator to REB (and, where applicable, to regulatory authority) of unexpected serious adverse drug reactions and other safety information
- Notification by sponsor to investigators of safety information
- Subject screening log
- Subject identification code list
- Subject enrollment log
- Delegation logs and signature sheets
- Records of retained body fluids / tissue samples, if any
- Final report to the regulatory authority, if applicable
- Clinical study report, if applicable
- Pharmacy logs