EMS Research Steering Committee

Nova Scotia EMS Research

Standard Operating Procedure

SOP #: 15	**Title:** External Audits of Research Studies	
Approval Date: 2013 11 26	**Review Date:** 2017 12 10	**Revision Date:** 2015 12 10
Signature of Research SOP Sub-committee Chair: 		

DEFINITIONS

1. AUDIT: A systematic and independent examination of study-related activities and documents, to determine whether the evaluated activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol and all applicable standards.
2. EXTERNAL AUDIT: An audit performed by an external party such as the study sponsor (or its agents) or a research ethics board (REB).
3. INFORMED CONSENT FORM: A document confirming the research participant's willingness to participate in a particular research study.
4. PRINCIPAL INVESTIGATOR (PI): 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.

PURPOSE

1. PIs are to notify the approving REB and the EMS RSC regarding all external audits of research studies. Most times the REB will notify the PI of an upcoming audit.
2. Any review of participants' personal health information or research records by external auditors or others is to be performed in accordance with all institutional requirements and applicable legislation.

PROCEDURE

1. The PI or designate notifies the EMS RSC chairperson in writing or via email immediately upon learning of an upcoming external audit.
2. Before external auditors review any personal health information, the PI (or designate) verifies that the research participant (or designate) signed an informed consent form granting access to the auditing body, and ensures that review of the personal health information proceeds in accordance with institutional requirements and applicable legislation.
3. If auditors wish to remove copies of personal health information from the site, the PI ensures that these copies are de-identified prior to their removal.
4. The PI (or designate) notifies the REB and EMS RSC chair of any major findings within 14 days of the closing meeting with the auditors.

ABBREVIATIONS

1. REB: Research Ethics Board
2. EHS: Emergency Health Services
3. RSC: Research Steering Committee

RELATED SOPs

1. SOP 7. Responsibilities of the Principal Investigator
2. SOP 10. Obtaining Informed Consent in Clinical Trials
3. SOP 11. Obtaining Consent in Other Studies
4. SOP 12. Privacy and Confidentiality of Research Data

RELATED DOCUMENTS

1. EHS Research Policy (#3500)
2. EHS Request for EHS System Data Policy (Policy #2203)
3. EHS Confidentiality of Patient Information Policy (Policy #2200)

4. Research Steering Committee Terms of Reference: http://emergency.medicine.dal.ca/divemsdocuments/Prehospital%20Steering%20Committee%20Terms%20of%20Reference%20June%2016-2010.pdf

REFERENCES

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2. Canadian Institute of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2010. Retrieved from: www.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf
3. Health Canada. International Conference on Harmonization (ICH) Guideline for Good Clinical Practice (ICH GCP E6), 1997: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php