



Nova Scotia EMS Research Steering Committee

Inter-Agency Committee Chaired by the Division of EMS,
Dalhousie University, Department of Emergency Medicine

Standard Operating Procedure

SOP #: 3	Title: Research Ethics Board Approval	
Approval Date: 2013 07 24	Review Date: 2017 11 06	Revision Date: 2015 11 06
Signature of Research SOP Sub-committee Chair:		
		

PURPOSE

1. Every study conducted in the Nova Scotia EMS system must be approved by or granted a waiver from an appropriate REB prior to commencing.
 - a. Nova Scotia EMS studies will use the NSHA REB.
 - b. Studies approved at REBs outside of Nova Scotia require review by a Nova Scotian REB.
2. The role of the REB is to assess all research involving EMS patients, employees, resources and data. The REB shall:
 - a. Review a study prior to commencement, deciding to approve or reject a study, based on its ethical acceptability.
 - b. Review ongoing research for ethical acceptability.
 - c. Terminate or impose modifications to ongoing or proposed research based on its ethical acceptability.
3. Activities such as quality improvement studies, program evaluation activities, and performance reviews or testing when used exclusively for assessment, management

These research SOPs are adopted with permission from the NSHA Research Manual. Researchers are responsible to follow the policies and procedures of their research ethics board and research financial services departments. The most recent version of these SOPs may be found at: <http://emergency.medicine.dal.ca/DivEMS.cfm>



or improvement purposes does not constitute research, and therefore shall be excluded from the REB review process. However, if those leading the project are interested to present their findings outside of EMS or publish their findings, or if they are unsure if their project is a study or not, they are to seek the advice of the REB. Obtain an answer in writing.

DEFINITIONS

1. **ETHICAL ACCEPTABILITY:** The acceptability of a research project based on the foreseeable risks, potential benefits and ethical implications associated with the research.
2. **RESEARCH ETHICS BOARD (REB):** An established body consisting of researchers, lawyers, community members and others, whose mandate under the Tri-Council Policy Statement is to ensure the safety, rights and well-being of research participants, by determining the ethical acceptability of all research involving human participants.
3. **RESEARCH PARTICIPANT:** An individual whose data, responses to interventions, questions or stimuli are relevant to answering a research question.

PROCEDURE

1. Determine if a proposed activity constitutes research that involves EHS participants (see Policy point 3, above).
2. Confirm if the lead investigator meets the qualifications of an investigator, as per the REB. If not, a supervising investigator must oversee the conduct of the study and REB submission.
3. Submit a research proposal to the appropriate REB for review.
4. The REB shall accept the submission, impose modifications or reject the study, based on the study's ethical acceptability. The REB shall also make a determination as to the frequency and nature of continuing ethics reviews throughout the project.
5. A study may proceed only after the REB has granted approval. A researcher must abide by all REB mandated guidelines.
6. If at any time during a study the research protocols change or unforeseen risks or circumstances arise, the principal investigator is responsible for contacting the REB and communicating the change in writing.
 - a. The principal investigator is responsible for closely monitoring the ongoing safe conduct of the study.
 - b. The REB may mandate the study to have an independent data safety monitoring board, to ensure ongoing safety of the study.
7. The REB must be notified in writing upon the conclusion of the study.

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ABBREVIATIONS

1. REB: Research Ethics Board
2. EHS: Emergency Health Services
3. EMS: Emergency Medical Services
4. NSHA: Nova Scotia Health Authority

RELATED SOPs

1. SOP 2. Research Steering Committee Composition and Review Process
2. SOP 7. Responsibilities of the Principal Investigator

RELATED DOCUMENTS

1. 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
2. NSHA *Research Manual-Research Ethics and Board Jurisdiction*, July 2015
Retrieved from:
http://policy.nshealth.ca/Site_Published/DHA9/PolicyManualView.aspx.

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