EMS Research Steering Committee

Nova Scotia EMS Research

Standard Operating Procedure

SOP #: 7	**Title:** Responsibilities of the Principal Investigator	
Approval Date: 2013 07 24	**Review Date:** 2017 12 04	**Revision Date:** 2015 12 04
Signature of SOP Sub-committee Chair: 		

DEFINITIONS

1. ETHICAL ACCEPTABILITY: The acceptability of a research project based on the study's foreseeable risks, potential benefits and ethical implications.
2. RESEACH ETHICS BOARD (REB): An established body consisting of researchers, lawyers, community members and others, whose mandate is to ensure the safety, rights and well-being of research participants, through reviewing the ethical acceptability of all EHS research involving human participants.
3. PRINCPAL INVESTIGATOR: The researcher who holds overall accountability for a research project at a study site. The PI is responsible for the delegation of research tasks and holds final decision making ability in a team research environment.
4. INFORMED CONSENT: A process in which an individual consents to participation in a research study after they have been provided all relevant information pertaining to their participation in the study.
5. INVESTIGATIONAL PRODUCT: A pharmaceutical form of an active ingredient, a genetic, biologic, or natural health product, a medical device, or a placebo being tested or used as a reference in a clinical trial.

6. RESEARCH PARTICIPANT: An individual whose data, responses to interventions, questions or stimuli are relevant to answering the research question posed by a researcher.
7. RESEARCH TEAM: The group of researchers headed by the principal investigator(s) who are responsible for conducting a research project.
8. STUDY PROTOCOL: A document that denotes the objectives, design, and methodology of a research project.
9. SUBINVESTIGATOR: A researcher who is recruited to a research project to assist in tasks as delegated by the principal investigator.
10. SUPERVISING INVESTIGATOR: If the principal investigator is a trainee, student or does not have sufficient credentials (according to the REB), a supervising investigator with these credentials is required to oversee the study.

PROCEDURE

1. All EHS research projects are to be overseen by a principal investigator (PI). A research study shall only have one PI per study and/or research site. For clinical trials, the PI is to be designated as the qualified investigator.
2. The PI has overall accountability of a study. Although specific research tasks may be delegated to members of a research team, overall clinical, ethical, scientific, financial and administrative conduct, as well as the upholding of patients' rights and safety is to be the final responsibility of the PI.
3. A principal investigator must:
    a. Have suitable credentials; including education, training and experience to assume responsibility of a research project.
    b. Determine resource requirements and study feasibility prior to the commencement of a study.
    c. Ensure a study receives initial Research Ethics Board (REB) approval and provide continuing documentation to the REB as per REB mandates.
    d. Ensure that the rights and welfare of research participants are upheld.
    e. Assure the integrity, security and validity of data.
    f. Assure proper administrative and research related documentation is recorded.
    g. Coordinate and delegate research among the research team (if applicable).
    h. Provide, in conjunction with the EHS Provincial Medical Director (PMD), oversight for all trial-related clinical and medical decisions. The ultimate clinical oversight of care in EHS lies with the EHS PMD.
    i. Provide oversight of the research project and manage the research protocol.
    j. Assure the proper use and storage of investigational products, if applicable.

BACKGROUND

1. Credentials
    a. The principal investigator is to:
        i. Ensure that he/she has the education, training and experience requirements to lead a study as per EHS research guidelines.
        ii. Have knowledge of and abide by EHS research standard operating procedures (SOPs), ethical procedures and regulatory mandates.
        iii. Maintain a current Curriculum Vitae.
        iv. Maintain a current license to practice (if applicable).
2. Determination of Feasibility and Resources
    a. Prior to the commencement of a study the Principal Investigator is to:
        i. Design a study protocol and assess study feasibility.
        ii. Consider the ethical acceptability of the study.
        iii. Determine if the time frame and sample size/distribution requirements of the study are attainable and reasonable.
        iv. Determine if the data to be collected will answer the study question.
        v. Determine if additional assistance are required to conduct the study.
        vi. Ensure safeguards are in place as per EMS research SOPs to protect the security and validity of the data as it is collected and stored.
        vii. Determine the study budget and ensure that funding is in place is to support the study.
3. Communication with the appropriate Research Ethics Board
    a. A principal investigator is to:
        i. Provide a research proposal and all requested documents to the EMS Research Steering Committee prior to the commencement of a study.
        ii. Provide a research proposal and all requested documents to the appropriate REB prior to the commencement of a study.
        iii. Provide continued documentation to the REB as per their request.
        iv. Notify the REB in writing if there is a change in the study protocol, or if an unforeseen risk or circumstance arises.
        v. Notify the REB in writing upon the conclusion of the study.
            1. If applicable, indicate any long term risks arising from the study and if the unblinding of results is occurring.
        vi. Yearly renewal via the REB online reporting system (ROMEO).
        vii. Follow all REB mandated actions, recommendations and directives.
4. Assure patient welfare and rights are maintained.
    a. A principal investigator is to:
        i. Ensure that free and informed consent as per EHS policy is obtained prior to participant enrolment in a study or the use of personal health

information occurs.
   ii. Ensure ongoing consent is obtained (if applicable).
   iii. Ensure that a participant's rights, safety and well-being are paramount to research objectives.
   iv. Ensure that participant confidentiality is maintained through the use of appropriate security measures as per REB guidelines and EMS research SOPs.
   v. Report all study related adverse events to the REB as per REB guidelines.
   vi. Report all unusual clinical or operational occurrences to the EMS Research Steering Committee.

5. Assure Data integrity, security and validity
   a. A principal investigator is to:
      i. Ensure that collected data is stored in a secure manner as per EMS SOPs and provincially legislated guidelines.
      ii. Ensure that research equipment is correctly functioning and calibrated and/or that surveys and other means of data measurement are accurate, timely and free of potential bias.
      iii. Conduct data checks (or delegate checks to a sub-investigator) to ensure that collected data is complete, accurate, timely and free of potential bias.
6. Documentation
   a. A principal investigator is to:
      i. Ensure that research related documents are properly collected and stored.
      ii. Ensure that administrative documents showing the allocation of funds and budgeting are developed and retained.
      iii. Ensure that all documentation is stored at the conclusion of a research project as per EHS guidelines.
      iv. Ensure that the research roles and responsibilities of principal and sub-investigators (if applicable) are documented and retained.
7. Coordinate Research (if applicable)
   a. A principal investigator is to:
      i. Determine if the credentials of potential sub-investigators are suitable to conduct research as per REB guidelines.
      ii. Allocate research tasks and objectives to sub-investigators that are within their scope.
      iii. Share data or information with sub-investigators that is relevant to the research study.

iv. Assume overall responsibility for the actions of sub-investigators when they are correctly following study protocol and following EHS research policy and procedures.

8. Provide, in conjunction with the EHS PMD, oversight for all trial-related clinical and medical decisions. The ultimate clinical oversight of care in EHS lies with the EHS PMD.
    a. A principal investigator is to:
        i. Ensure that all study related clinical/medical interventions and decisions are performed by qualified clinicians.
        ii. Ensure that appropriate clinical care is provided to individuals who experience adverse events.
        iii. Ensure that follow-up of enrolled participants occurs (if applicable).
        iv. Ensure that EHS front-line staff make receiving hospital staff aware of the individual's participation in the research study, to ensure that appropriate care is provided (if applicable).
            1. The PI should ensure hospitals that will receive patients enrolled in an EMS study are aware of the details of the study.
9. Provide oversight and ensure compliance with study protocol.
    a. A principal investigator is to:
        i. Maintain an understanding of the study protocol and ensure that he/she adheres to the protocol at all times.
        ii. Ensure that sub-investigators are aware of the study protocol and adhere to the protocol at all times (if applicable).
        iii. Advise the REB and any sub-investigators if there is a change to the study protocol.
10. Assure the proper use and storage of investigational products (if applicable).
    a. The Principal investigator is to:
        i. Be knowledgeable in the proper use of the investigational product.
        ii. Ensure that clinicians handling the investigational products are aware of how to properly store, handle and administer (if applicable) the product.

ABBREVIATIONS

1. EHS: Emergency Health Services
2. PI: Principal Investigator
3. REB: Research Ethics Board
4. SOPs: Standard Operating Procedures
5. PMD: EHS Provincial Medical Director

RELATED SOPs

1. SOP 2. Research Steering Committee Composition and Review Process
2. SOP 3. Research Ethics Board Approval
3. SOP 10. Obtaining Informed Consent in Clinical Trials
4. SOP 11. Obtaining Informed Consent in Other Studies

REFERENCES

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. www.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf
2. NSHA, *Research Manual- Responsibilities of the Principal Investigator*, May 2007. Retrieved from: http://policy.nshealth.ca/Site_Published/dha9/document_render.aspx?documentRender.IdType=6&documentRender.GenericField=&documentRender.Id=43007.
3. Health Canada. *ICH Guidance E6: Guideline for Good Clinical Practice. (2004).* Retrieved from*:* http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php.