EMS Research Steering Committee

Nova Scotia EMS Research

Standard Operating Procedure

SOP #: 9	**Title:** Delegation of Study Duties	
Approval Date: 2013 12 18	**Review Date:** 2017 12 04	**Revision Date:** 2015 12 04
Signature of SOP Sub-committee Chair: 		

DEFINITIONS

1. DELEGATION LOG: A record of the research tasks delegated to investigators or others during the course of a research project.
2. PRINCIPAL INVESTIGATOR: The person responsible for the conduct of an EMS research study.
3. RESEARCH ETHICS BOARD: An established body consisting of researchers, clinicians, lawyers, community members and others, whose mandate is to ensure the safety, rights and well-being of research participants, by determining the ethical acceptability of all EHS research involving human participants.
4. RESEARCH SITE: The location(s) where study-related activities are conducted.
5. SPONSOR: An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a research project.
6. SUB-INVESTIGATOR: A researcher who is recruited to a research project to assist in tasks as delegated by the principal investigator.

PURPOSE

All team members should understand their role in the study.

PROCEDURE

1. A principal investigator (PI) may delegate study duties to sub-investigators or other study personnel as deemed necessary. When establishing and conducting a study involving sub-investigator(s) and the delegation of study duties, a PI must:
    a. Ensure that a sub-investigator has the appropriate qualifications, including education, training and experience to assume responsibility of delegated tasks within a research project.
    b. Document the delegation of study tasks before beginning a study through the completion of a delegation log in clinical trials. If it is determined a delegation log is not required, it is best practice to list responsibilities in the study protocol and REB submission.
    c. Provide ongoing documentation updated throughout the course of the research project and properly archive documentation at the conclusion of the study.
    d. Remain cognizant that regardless of the delegation of tasks, the overall research project accountability remains the responsibility of the PI.
2. After initial REB approval and the determination that assistance will be required to complete the research project, the PI is to:
    a. Develop a delegation log to keep track of responsibilities. The delegation log can take any format but shall at minimum include the following:
        i. The principal investigator's name, location and organization.
        ii. The research centre, site number or EHS bases from which a study is to be conducted, if applicable.
        iii. The study name/ number.
        iv. The sponsor's name, if applicable.
        v. The names of all sub-investigators involved in the study.
        vi. The responsibilities of all investigators in the project, including all procedures outlined in the REB approved protocol.
        vii. It is good practice in all studies, and may be required in some studies, to document the following:
            a. Start dates of the delegation (the date of full REB study approval or the date the person became involved with the study, unless otherwise specified).
            b. A signature provided by all investigators recognizing that they have read the REB approved protocols, and understand their delegated tasks and responsibilities within the research project.
            c. A signature or initials provided by the PI to authorize each entry.
            d. Record stop dates of the delegation of tasks for persons who cease to be involved with the study.

e. Ensure the delegation log remains complete, accurate, and up to date.

3. It is also good practice in all studies, and may be required in some studies, to document the following at the conclusion of the study:
    a. Ensure that stop dates of the delegation are recorded for each person listed.
    b. Verify, sign, and date the log.
    c. Archive the original log with other study documents as per REB requirements.

ABBREVIATIONS

1. EHS: Emergency Health Services
2. PI: Principal Investigator
3. REB: Research Ethics Board

RELATED SOPs

1. SOP 3. Research Ethics Board Approval
2. SOP 7. Responsibilities of the Principal Investigator

REFERENCES

1. NSHA, *Research Manual-Delegation of Study Duties*, May 2007. Retrieved from: http://policy.nshealth.ca/Site_Published/DHA9/PolicyManualView.aspx
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