EMS Research Steering Committee

Nova Scotia EMS Research

Standard Operating Procedure

SOP #: 11	**Title:** Obtaining Consent in Other Studies	
Approval Date: 2015 11 26	**Review Date**: 2017 12 10	**Revision Date:** 2015 12 10
Signature of SOP Sub-committee Chair: 		

DEFINITIONS

1. INFORMED CONSENT: A process by which a participant voluntarily confirms his/her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the participant's decision to participate. Informed consent is documented by means of a written, signed and dated Informed Consent Form (ICF).
2. WAIVER OF INFORMED CONSENT: A research ethics board may waive the requirement for researchers to obtain informed consent, following the requirements set out in the Tri-Council Policy Statement 2.
3. PARTICIPANT: An individual who participates in a study, such as a patient or staff member. Those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question.
4. HUMAN RESEARCH: an undertaking (i.e., study) intended to extend knowledge

through a disciplined inquiry or systematic investigation that involves living human participants or their biological materials.

5. IMPRACTICABILTY: Defined by the Personal Health Information Act (PHIA) as a situation in which obtaining informed consent for a study is a "degree of difficulty higher than inconvenience or impracticality but lower than impossibility."

PURPOSE

1. In all EMS research studies, research ethics board review (REB) and approval must be obtained prior to enrolling participants, collecting data or screening participants for study inclusion.
2. For consent to be informed, the following three principles must be adhered to:
    a. *Consent must be given voluntarily.* Care must be taken to ensure the participant is not under undue influence to participate in the study.
    b. *Consent must be informed.* Full information must be provided to the participant for them to make an informed decision about whether to participate.
    c. *Consent shall be an ongoing process.* Researchers have a duty to inform participants with all information relevant to their ongoing consent and participation.
3. Informed consent should be obtained from participants prior to enrolment in a study or the utilization personal health information for recruitment purposes.
4. In certain studies the need to obtain informed consent for screening or enrolment may be waived.
    a. Waiving of informed consent must be approved by a relevant REB who shall determine that obtaining consent is either not necessary due to the nature of the study or is impracticable based on the design of the study and /or population being examined.
    b. The REB may designate informed consent impracticable when:
        i. The size of the study population makes obtaining informed consent from every individual impracticable.
        ii. A large proportion of the study population may have died or relocated since the data were collected.
        iii. There is a potential for introducing bias by obtaining informed consent, or the process of obtaining informed consent will create hardship or burden on the researcher or organization to the point that the research could not be performed.
    c. Under all circumstances obtaining informed consent shall only be waived after the REB review and approval. For a study to proceed without informed consent, the REB must determine that the benefits of the study outweigh the risk of personal harm or infringement of the individual's right to privacy and confidentiality.

d. All data collection shall be in accordance with the REB approved protocols and abide by all provincial and federal privacy and confidentially guidelines.

PROCEDURE

1. The research protocol and/or ethics submission documents will be reviewed by the EMS RSC (as per SOP 3).

2. If informed consent is required for the study, the PI or designate must conduct a discussion with the participant about the study and obtain informed consent prior to enrolling the participant or collecting data.
3. If the need for informed consent is waived, the REB should provide the PI a letter confirming this.

ABBREVIATIONS

1. SOPs: Standard Operating Procedures
2. EHS: Emergency Health Services
3. REB: Research Ethics Board
4. RSC: Research Steering Committee

RELATED SOPs

1. SOP 3: Research Ethics Board Approval
2. SOP 10: Obtaining Informed Consent in Clinical Trials

RELATED DOCUMENTS

1. EHS Request for EHS System Data Policy (Policy 2203.00)
2. EHS Confidentiality of Patient Information Policy (Policy 1010)
3. SOP Research Steering Committee
4. Research Steering Committee TOR

REFERENCES

1. TCPS 2, Chapter 2. Scope and Approach. Retrieved from: http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf
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3. NSHA. Consent Preparation and Use. 2006 Retrieved from: http://www.cdha.nshealth.ca/discovery-innovation/research-ethics

4. Toolkit for Custodians: A Guide to the Personal Health Information Act. 2012. Retrieved from www.**novascotia**.ca/dhw/phia/documents/PHIA-complete-**toolkit**.pdf