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 #: 10	**Title:** Obtaining Informed Consent in Clinical Trials	
Approval Date: 2012 10 30	**Review Date:** 2017 12 10	**Revision Date:** 2015 12 10
Signature of Research SOP Sub-committee Chair: 		

DEFINITIONS

1. CLINICAL TRIAL: Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to: drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.
2. INFORMED CONSENT: A process by which a participant voluntarily confirms his/her willingness to participate in a particular trial, after having been informed of all aspects of the trial 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).
3. SPONSOR: An individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial.
4. PARTICIPANT: An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

PURPOSE

1. This standard operating procedure describes the procedure for obtaining free, written informed consent from each participant (or his/her representative) prior to their participation in an EMS clinical study.
2. Obtaining consent is a process involving dialogue between the research investigators, research staff, clinicians and research participants. Effective communication is the key to enabling participants to make informed decisions about participation in a research study.
3. Written informed consent will always be obtained before any study-related procedures are undertaken, unless permission is given by an REB for an alternate form of consent.

PROCEDURE

1. RESPONSIBLE PERSONNEL
    a. Consent must only be obtained by persons who possess the knowledge necessary to adequately present the pertinent risks, benefits, and alternative treatments, and who have been assigned this task on the delegation and signature list/log.
    b. Any research team member obtaining consent must be fully informed and familiar with the entire contents of the consent form.
    c. The Principal Investigator, Co-Investigators, and study coordinators are usually involved in obtaining informed consent. The study coordinators must be well trained and under the supervision of the investigator. In some studies, the clinicians (e.g., EHS paramedics) may be delegated to obtain informed consent.
2. INFORMED CONSENT TRAINING
    a. EHS staff who will be required to obtain informed consent from EHS patients who may become study participants must receive specific training on this. Successful completion of the training will be documented and only those who have completed the training will obtain informed consent.
3. DRAFT THE INFORMED CONSENT FORM AND OBTAIN SPONSOR AND REB APPROVAL
    a. In some circumstances, the REB may approve the use of a short-form ICF (with later follow-up with standard ICF), verbal assent for consent or waiver for the need for consent.
4. OBTAINING CONSENT IN SPECIAL CIRCUMSTANCES
    a. The research protocol should describe how arrangements for any special requirements such as translation services or large print consent forms will be made available.
    b. In certain acute circumstances, an abbreviated consent will first be obtained.
    c. The researcher should consult with the REB for further guidance if he/she is unsure about any specific circumstances related to obtaining informed consent.

5. CONSENT IN EMERGENCY SITUATIONS
    a. As per section 4.8.15 of ICH GCP guidelines, in emergency situations when prior consent of the participant is not possible, the consent of the participant's legally acceptable representative, if present, should be requested prior to enrollment.
    b. When neither prior consent from the participant nor consent from the participant's legal representative is not possible, enrollment of the participant should require measures described in the protocol and/or elsewhere, with documented approval of the REB. This may be in the form of verbal assent or waiver for the need for informed consent.
    c. The REB may approve an exception to the requirement for informed consent, if all stipulations of Article 3.8 of the TCPS are fulfilled (Chapter 3B) (2).
    d. The participant or the participant's legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent obtained as appropriate.
6. DOCUMENTATION OF THE INFORMED CONSENT PROCESS
    a. The PI and the study research coordinator are responsible for the documentation of the Informed consent process.
    b. The Informed consent form will be stored with the study documents. The research protocol should explicitly state how this documentation will be transferred from the EHS staff to the research staff.
7. RESPONSIBLE PERSONNEL
    a. Document who is responsible for obtaining informed consent on the study delegation log. In the case where the paramedics are obtaining consent, the EHS site investigator should be named on the delegation log, and a list kept of all of the trained paramedics who are conducting the consent process.
8. INFORMED CONSENT TRAINING
    a. Training for EHS staff should include a review the ICH GCP guidelines for informed consent, and specific training on obtaining consent for the particular study, in accordance to the REB-approved study protocol.
    b. The research coordinator will record documentation of training in a training binder on a yearly basis.
9. DRAFT THE INFORMED CONSENT FORM AND OBTAIN SPONSOR AND REB APPROVAL
    a. Draft the informed consent form (ICF) as per the relevant REB's policies, procedures, and templates. Ensure that the ICF accurately reflects the protocol and contains all required elements, and that it is written in language that is understandable to research participants.
    b. Submit the draft ICF to the sponsor for approval, if applicable.
    c. Prior to submitting the ICF and associated information to the REB, the Principal Investigator reviews the information and signs the appropriate forms.
    d. Submit the sponsor-approved ICF to the REB for review. If revisions are required, ensure that the changes are acceptable to the sponsor before submitting the revised ICF to the REB.

e. Send a copy of the approved ICF and documentation of REB approval to the sponsor, if applicable.
f. Maintain the approved ICF and associated REB documentation in the study files.

10. OBTAIN INFORMED CONSENT FROM RESEARCH PARTICIPANTS
    a. Identify potential study participants and assess inclusion and exclusion criteria. Please refer to the REB-approved research protocol for complete description of this procedure.
    b. Ensure that the person obtaining informed consent has been assigned this task on the delegation log. If a large group of clinicians are obtaining consent or the initial consent, it is acceptable to list the person responsible (investigator) on the delegation log. Document the training each clinician received with date, EHS registration number and signature on the training log.
    c. Ensure that informed consent is obtained before initiating any study-related procedures.
    d. Verify that the most recent REB-approved version of the ICF is used to obtain consent.
    e. When possible, ensure that there is ample time to conduct the informed consent process and that the informed consent is obtained in an appropriate setting.
    f. A verbal explanation and overview of the study using non-technical language is usually first provided by the study coordinator, the investigator or their delegate. At the end of the explanation and prior to the actual reading of the consent form, the participant's initial reaction is evaluated.
    g. Ensure that prospective participants are aware that their involvement in the study is completely voluntary and they are free to withdraw at any time without repercussions.
    h. Inform the prospective study participant about all aspects of the study. Review the entire informed consent document with the participant.
    i. Provide the participant with ample time to ask any question relevant to make his/her decision to participate in the study. Answer all relevant questions and concerns. Provide the participant with a copy of the ICF for further review.

    j. Verify the participant understands the study by using open-ended questions. For example: What is the purpose of the research? What are the risks? What are the benefits? Provide additional clarification until you and the participant are satisfied with their level of understanding. If this cannot be achieved, then discontinue the consent process.
    k. If the participant agrees to participate in the study, ask the participant to sign and date the consent form.
    l. The consent form is signed and dated by the medically qualified person who provided the information, by the participant and by a witness.
    m. The Research Coordinator verifies that all signature and date lines are complete.
    n. Provide the participant with a photocopy of the signed informed consent form prior to their participation in the study. The original copy is filed with the

participant's other study related information (Note: If necessary, the ICF can be copied prior to the investigator's signature). Distribute any other copies as required.

11. OBTAINING CONSENT IN SPECIAL CIRCUMSTANCES
    a. If a potential study participant or their substitute decision maker is unable to read, an impartial witness must be present during the entire informed consent discussion. Refer to ICH GCP article 4.8.9.
    b. If a potential study participant is not capable of providing informed consent then consent must be obtained from their substitute decision maker.
    c. The investigator should notify the REB if there are any exceptions, inconsistencies or irregularities discovered with the consent process.
12. DOCUMENTATION OF THE INFORMED CONSENT PROCESS
    a. EHS staff who obtain informed consent should document the following in the narrative section of their patient care report:
        i. Who participated in the consent discussion;
        ii. If capacity to provide informed consent is in question, document the circumstances and the involvement of any third parties;
        iii. Whether the participant (and/or their representative) demonstrated understanding of the study;
        iv. All questions / concerns expressed by the participant (and/or their representative) and whether they were addressed to their satisfaction;
        v. Whether consent was obtained prior to initiating any study procedures, and whether the participant (and/or their representative) was given a copy of the signed ICF.
        **Note: It is good practice to record the dates and times that the participant signed the ICF; received a copy of the signed ICF; and began the first study procedure.
        vi. Any exceptions, inconsistencies, or irregularities with the consent process.

ABBREVIATIONS

1. ICF: Informed Consent Form
2. REB: Research Ethics Board
3. EHS: Emergency Health Services
4. NSHA: Nova Scotia Health Authority
5. ICH-GCP: International Conference on Harmonization – Good Clinical Practice

RELATED SOPs

1. SOP 3. Research Ethics Board Approval
2. SOP 7. Responsibilities of the Principal Investigator
3. SOP 9. Delegation of Study Duties

RELATED DOCUMENTS

4. NSHA REB Guidelines for Consent Form Preparation and Use.
5. EMC Policy 2004.1. Completion of Patient Care Report Record
6. EHS Policy 6180.01 Medical Responsibilities of Paramedics
7. NSHA Research Policy. Delegation of Study Duties. RS-03-002.
8. NSHA. Definitions Used in Research Policies. July 29, 2012.

REFERENCES

1. World Health Organization
2. International Conference on Harmonization (2008) E6: Guideline for Good Clinical Practice
3. International Conference on Harmonization (2008) E8: General Considerations for Clinical Trials
4. Tri-council Policy Statement 2. Chapter 3, Article 3.8 (2010)
5. Health Canada. Division 5. Drugs for Clinical Trials Involving Human Subjects (2001).