TITLE:	Standard Operating Procedure (SOP) Informed Consent Form Requirements and Documentation	**NUMBER:**	NSHA REB-SOP-7-001
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	Executive Chair, Co-Chairs, NSHA REB members, REB Office Personnel and Researchers.		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) describes the requirements for the informed consent form and the process for waiving or obtaining and documenting initial and ongoing informed consent as required by the Nova Scotia Health Authority Research Ethics Board (NSHA REB).

2. POLICY:

The Principal Investigator (PI) is responsible for providing the REB with a detailed description of the rationale for a consent waiver or the consent documents and a description of the consent process. The PI is also responsible for providing a description of the recruitment methods and recruitment materials (if applicable).

When a written informed consent form is used, the PI, the research sponsor and the REB are equally accountable for ensuring that the consent form contains all of the basic elements of consent and the applicable additional elements of consent so that prospective participants can make an informed decision about choosing to participate or continue participating in a research study. The REB is responsible for verifying that the consent form (if applicable) contains the required elements.

The REB must approve the informed consent form (ICF) and/or other means to document informed consent **before** the PI conducts any study related procedures involving participants.

The REB is responsible for determining whether informed consent exemptions or waivers are applicable and appropriate.

The REB Executive Chair or designee is responsible for reviewing consent forms or changes to consent forms if the changes meet the criteria for delegated review.

3. DEFINITIONS:

1) **Circle of Care:** Regulated health professionals who are part of an individual's healthcare team.

2) **Informed Consent**: The voluntary, knowledgeable agreement of the individual or, if the individual lacks capacity, their SDM with what is being done or proposed in relation to PHI. Consent can be express or implied. Express consent is given either verbally or in writing.

3) **Participant:** A person about whom a researcher obtains (1) data through intervention or interaction with the individual or the individual's cadaver, remains, tissues, biological fluids," embryos or fetuses, or (2) identifiable private information (e.g., health information). The term "subject" may also be used.

4) **Principal investigator (PI) –** The person responsible for the conduct of a study at a study site. If a study is conducted by a team of individuals at a study site, the principal investigator is the responsible leader of the team.

4. PROCEDURES:

4.1. REB Review of Required Elements of Informed Consent

4.1.1. Informed consent documents will be available to all REB members via the Researcher's Portal in the case of a Full Board review, or to the applicable reviewer(s) under the delegated review process;

4.1.2. The REB members will review the proposed consent process for appropriateness, and the proposed consent form(s) for formatting and general readability, for appropriateness of the language and content, and for the inclusion of the applicable basic and additional elements as per NSHA REB consent form template(s) and all applicable regulations;

4.1.3. The REB may request a separate consent form for optional procedures whereby the research purpose is not yet known (e.g. tissue, blood, genetic testing or specimen banking for future research). Optional procedures for sub-studies directly related to the main research study may be included in the main study informed consent form provided the details of the sub-study are clearly outlined;

4.1.4. Following the review, the REB may approve the consent form(s) as submitted or may request changes be made. Changes to the consent form(s) will be reviewed by the assigned Co-Chair through a delegated review process or at a Full Board meeting depending on the decision of the initial study review.

4.2. Translation of Informed Consent Documents

4.2.1. The informed consent form should be in language understandable to the research participant (or substitute decision maker if applicable);

4.2.2. When a research participant is non-English speaking, documentation of informed consent can be by one of two methods:

- **Written consent:** The REB approved English version of the informed consent form may be translated into the research participant's native language. Translated consent forms must be reviewed and approved by the REB prior to use and must be accompanied by an attestation from the translator certifying that the translated ICF accurately reflects the information contained in the REB approved English consent. A translator should be certified and independent. A translated informed consent document does not replace the need for an interpreter to be present during the consent process and throughout the research. The research participant will sign the translated version of the informed consent form document;

- **Oral consent:** A qualified interpreter fluent in both English and the research participant's native language may orally interpret the REB approved English consent form to the research participant. The interpreter should be an impartial person. When the person obtaining consent is assisted by an interpreter/translator, the interpreter/translator must document the language the consent form discussion has taken place in and must sign and date the consent form attesting that the study was accurately explained to, and appeared to be understood by the research participant;

4.2.3. The translated materials must be submitted for REB review and approval prior to use, along with a certificate or statement signed by the translator indicating the materials are a true and accurate translation of the REB approved English materials. Delegated review procedures will be followed for if the English language materials have already been approved by the NSHA REB;

4.2.4. A translator/interpreter should be available to the study participant throughout the study;

4.2.5. If a research participant is unable to read, an impartial witness must be present during the entire informed consent discussion. Verbal consent is obtained from the research participant after the informed consent document and any other written information is read and explained to the research participant. Signatures will be obtained from the research participant (if capable) and the impartial witness on the informed consent document, where applicable. The signature of the impartial witness attests that the information was accurately explained to, and apparently

understood by, the research participant, and that informed consent was freely given by the research participant.

4.3. Revisions to the Informed Consent Form and Re-consenting Participants

4.3.1. The study consent form(s) must be amended whenever important new information becomes available that may be relevant to the research participant's consent and willingness to continue participating in the research study. Any revisions made to the previously approved consent form must be submitted to the REB for review and approval prior to use;

4.3.2. The Principal Investigator must inform research participants of any new information that might affect their willingness to continue their participation in the research or that may affect their long term health even if they have completed their participation in the research;

4.3.3. The Principal Investigator must obtain written documentation of the participant's willingness to continue to participate if there is a significant change to the protocol or risk;

4.3.4. Written documentation of re-consent may be obtained by having the participant sign an updated REB approved version of the informed consent form containing the updated information or an REB approved addendum to the original consent form informing participants of the new information;

4.3.5. If applicable, ongoing consent may be obtained orally by contacting the research participant by phone, providing the updated information, and documenting their agreement to continue;

4.3.6. The nature of the provision of the new information to currently enrolled participants and the documentation required will be determined by the REB.

4.4. Recruitment Methods

4.4.1. *Principal Investigator's (PI) Patients:* If the patient is under the care of the PI, the PI may approach the patient directly in such a manner that the patient does not feel pressured or obligated in any way. During these situations, the patient's consent should be obtained by a member of the research team other than the PI. Any exceptions to this procedure must be appropriately justified and submitted to the REB for review;

4.4.2. *In circumstances where the PI will obtain consent:* The PI must ensure that the consent has been obtained without undue coercion or influence and that there is no likelihood of therapeutic misconception, if applicable;

4.4.3. *Referrals:* The PI may send an REB-approved letter to colleagues asking for referrals of potential patients. The PI may provide colleagues with an approved study information sheet/pamphlet to give to their patients. The patient will then be asked to contact the PI or research team directly, or, with documented permission from the patient, the PI or research team member may initiate the call;

4.4.4. *Registries:* If the REB has previously approved a patient research registry and the patient has provided permission to be contacted for future potential research, the PI and/or members of the research team may contact these patients directly for REB approved research. The person contacting the patient should identify him/herself as associated with the patient's clinical caregiver, and remind the patient that they have agreed to be contacted. The patient must be offered the option of having his/her name removed from the database;

4.4.5. *Advertising:* The REB must review and approve the text and the use of any advertisements, notices or media messages prior to use.

4.5. Recruitment Materials

4.5.1. The REB reviews the recruitment materials (e.g., advertisements, information letters, pamphlets) for evidence of coercion or undue influence and ensures consistency with the REB approved research and informed consent document. All recruitment materials must receive REB approval prior to use;

4.5.2. Advertisements should be limited to one page and should include only the necessary information that the prospective participant needs to determine their potential eligibility and interest. Advertisements must contain the following elements:

- The name of the Principal Investigator,
- The name and contact information of the person or office to contact for additional information,
- The NSHA logo,
- The purpose of the research study (in summary).

If required and when appropriately worded, the following items may also be included:

- The basic eligibility (inclusion) criteria that will be used,
- The commitment(s) required of the participants,
- The location of the research,
- Information about reimbursement/compensation and/or cost for study participants;

4.5.3. Advertisements may indicate that participants will be reimbursed for out-of-pocket expenses (e.g., parking, meals) or that some form of compensation may be provided for their time but the specific dollar amount or item should not be specified;

4.5.4. Advertisements should not list the name(s) of the study drugs or contain any therapeutic claims.

4.6. Documentation of Informed Consent

4.6.1. The REB requires documentation of informed consent by the use of a written informed consent form approved by REB which is signed and dated by the research participant or the participant's substitute decision maker (SDM), and by the person obtaining consent. The Principal Investigator's signature must be obtained within two weeks of the research participant's signature. An exception to the above requirements may be granted to studies eligible for a waiver or alteration of Informed Consent;

4.6.2. A signed copy of the informed consent form shall be provided to the research participant;

4.6.3. The Principal Investigator is to inform the research participant's primary physician about the research participant's involvement in the research;

4.6.4. The REB may approve a short form written consent document in cases where the research participant may lack the capacity to consent. The short form consent form contains all required elements of informed consent. A written summary of the information in presented orally to the research participant or their substitute decision maker (SDM). The short form consent document is signed by the research participant or the SDM. The person obtaining consent must sign a copy of the written summary of the information that is presented orally;

4.6.5. The REB may approve a process that allows the informed consent document to be delivered by regular mail, email or facsimile to the potential participant, and to conduct the consent discussion by telephone when the participant can read the consent form as it is discussed. All other applicable conditions for documentation of informed consent must be met when using this procedure;

4.6.6. In some types of research, and for some groups or individuals where written signed consent may be felt by the participants as mistrust on the part of the Principal Investigator, the REB may approve the process of oral consent, a verbal agreement or a handshake;

4.6.7. Where consent is not documented in a signed consent form, a range of consent procedures may be used by the research team (e.g., oral

consent, field notes, implied consent through the return of a completed questionnaire);

4.6.8. The procedures used to seek consent must be documented by the person obtaining consent and approved by the REB;

4.6.9. Whenever possible, the research participant should have written documentation of participation in a research project unless it may compromise their safety or confidentiality.

4.7. The Consent Form Process

4.7.1. The REB requires that the standard operating procedure (SOP) for obtaining informed consent be reviewed and approved by the REB prior to consenting patients. The SOP can be a document on its own or it can be detailed in the ethics application form (EAF) at the time of the initial submission;

4.7.2. The informed consent discussion must take place with a qualified and knowledgeable Investigator or other member of the research team who is not in a position of authority with prospective participants;

4.7.3. The consent discussion must inform the prospective participant and/or their substitute decision maker of all the essential elements described within the approved informed consent form;

4.7.4. The prospective participant and/or their substitute decision maker should be given the opportunity to ask questions, and to have their study related questions answered by the Principal Investigator or member of the research team;

4.7.5. The original, signed consent form is to be stored with study-related research files and should be kept confidential and secure as per applicable regulatory requirements.

4.8. Consent Monitoring

4.8.1. In considering the adequacy of informed consent procedures, the REB may require monitoring of the consent process by an impartial observer;

4.8.2. Such monitoring may be particularly warranted where the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information to be provided;

4.8.3. Monitoring may also be appropriate as a corrective action where the REB has identified problems associated with a particular investigator or a research project.

4.9. Waiver of Informed Consent

4.9.1. The legislation of Nova Scotia's Personal Health Information Act (PHIA), requires the express consent (written or oral) of the patient for use of personal information for research unless the REB agrees to waive the requirements for consent or agrees that access is within the circle of care;

4.9.2. Under the Personal Health Information Act (PHIA),waiver of consent for research may be granted by the REB if all of the following conditions are met:

- The research cannot be conducted without the use of the PHI,
- PHI is strictly limited to that necessary to accomplish the research,
- PHI is in the most de-identified form possible for the conduct of the research,
- PHI must be used in a manner that ensures its confidentiality,
- It is impracticable to obtain consent;

4.9.3. Principal Investigators who request a waiver of consent to access personal information must support their request with an explanation as to why the research could not be done if consent was required;

4.9.4. It is at the REB's determination whether informed consent waivers or alterations will be granted. The NSHA REB may also consider:

- The manner in which the confidentiality of the research data/information will be maintained,
- Whether the public interest in conducting the research outweighs the public interest in protecting the privacy of the individuals,
- The vulnerability of participants who lack the capacity to provide consent.

4.9.5. Whenever appropriate, the research participants will be provided with additional pertinent information after participation;

4.9.6. These findings and their justifications shall be documented by the REB when the REB exercises this waiver or alteration provision;

4.9.7. Copies of REB approved waivers of consent will be sent electronically to the Privacy Officer at NSHA (privacy@nshealth.ca) and in turn, forwarded to the Department of Health and Wellness (DHW).

4.10. Consent for Research in Health Emergencies

4.10.1. The REB establishes the criteria for the conduct of research involving medical emergencies prior to approval of the research. The Researcher

must justify to the REB the reasons why an exception to obtaining informed consent from participants is required;

4.10.2. The REB allows research that involves health emergencies to be carried out without the free and informed consent of the participant or of his/her authorized third party if ALL of the following apply:

- A serious threat to the prospective participant requires immediate intervention,
- Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant in comparison with standard care,
- Either the risk of harm is not greater than that involved in standard therapeutic care, or it is clearly justified by the potential for direct benefit to the participant,
- The prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research project,
- Third-party authorization cannot be secured in sufficient time, despite diligent, and documented efforts to do so, and
- No relevant prior directive by the participant is known to exist;

4.10.3. When a previously incapacitated research participant regains capacity, or when an authorized third party is found, free and informed consent must be sought for continuation in the research study and for subsequent research-related procedures.

4.11. Consent and Secondary Use of Identifiable Information

4.11.1. The REB allows the secondary use of identifiable information for research purposes without obtaining consent from research participants if the Principal Investigator is able to satisfy the following conditions:

- Identifiable information/materials is essential to the research,
- The use of identifiable information/materials without the participant's consent is unlikely to adversely affect the welfare of individuals to whom the information relates,
- The Principal Investigator will take appropriate measure to protect the privacy of individuals, and to safeguard the identifiable information/materials,
- The Principal Investigator will comply with any known preferences previously expressed by individuals about any use of their information/materials,
- It is impossible or impracticable to seek consent from individuals to whom the information relates/materials were collected, and

- The Principal Investigator is has obtained any other necessary permission for secondary use of information/materials for research purposes;

4.11.2. In cases where the secondary use of identifiable information/materials without the requirement to seek consent has been approved by the REB, if the Principal Investigator proposes to contact individuals for additional information and/or materials, REB approval must be obtained prior to contact.

4.12. Incidental Findings

4.12.1. Investigators have an obligation to disclose to the participant any material incidental findings discovered in the course of research. The Investigator's plan to identify and to disclose incidental findings must be submitted to the REB and approved prior to implementation.

5 REFERENCES

I. Personal Health Information Act, Article 57 (Bill 89);
II. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014), Chapter 3;
III. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), Section 4.8;
IV. Health Canada, Division 5 of the Food and Drug Act;
V. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 21 Part 50.20, 50.23, 50.24, 50.25, 50.27;
VI. US Department of Health Services (HHS) 45 Code of Federal Regulations (CFR) Title 45 Part 46.116, 46.117.

6 RELATED DOCUMENTS:

- Consent Form Preparation and Use
- ICF templates (clinical trials and non-interventional studies)
- NSHA REB-SOP-4-004- Ongoing Review and Reporting

Version History

Effective Date	Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)
June 3, 2016		Reflect the change from nine DHA's to one
September 29, 2017		Harmonize with CAREB/N2 SOP's