memorandum

To: Nova Scotia Health Research & Innovation Community

From: Dr. Adrian MacKenzie, Director, Research
Dr. Marie Tremblay, Manager, Research Ethics
Michele Chappell, Program Manager, Research Quality

Date: August 11, 2020

Re: Instructions on how to conduct verbal informed consent

This pandemic brought upon many changes to our daily operations that forced us to adopt alternate and sometimes creative procedures and practices. One of these changes included a deviation from our standard of written consent forms signed with an ink ('wet') signature to explore other options such as verbal (oral) consent as well as the eConsent using electronic signatures. Although the pandemic has brought about some flexibility in regulations and guidance documents, it is important to remember that we must still follow the regulations in place. Nova Scotia Health's Research Ethics Board and Research Quality offices are sending this memo as a guide and reminder on how and when to conduct verbal consent.

Ethical Mandate: "Consent Shall Be an Ongoing Process"

Please keep in mind that basic ethical research principles warrant us to treat informed consent as a *continuum* and not simply as a signed form at the study's initiation with periodic updates throughout (TCSP2). As dictated by TCSP2, we as researchers must ensure that the research participant freely provides their *informed* consent throughout the study and beyond until the destruction of their data (7 years after study closure and 25 years for medical device, investigational drugs, and natural health product studies).

Remote/Verbal Consent During a Pandemic

Remote and verbal consent is an acceptable method of obtaining informed consent if obtaining informed consent in a face-to-face manner is not possible or poses an increased risk to the research participant. Face-to-face was either impossible or posed an increased risk at the height of the pandemic, which justified verbal informed consent for a short time. Now that we are starting to re-open province-wide, it is important to remember that *verbal consent is not a substitute for in-person consent* if there is opportunity and ability. Written consent remains the 'gold standard' and be acquired through eConsent or a paper consent.

The following sections of this memo provide our research community with guidance navigating regulations, policies, documentation around remote or verbal informed consent.

Consenting patients with methods other than in-person have risks. It is important to verify that consent was obtained in the event of questions or concerns by a study participant or family member, especially if the study participant's capacity is questioned. Article 10.2 of TCPS2 may be helpful.

What changes in my consent process should I submit to the REB?

Anytime there is a change in process for obtaining informed consent, there must be an amendment submitted to the Research Ethics Board to justify and explain the change. This can be done by:

1) Attaching an updated Standard Operating Procedure (preferred, especially for clinical trials), or
2) Providing the information in the appropriate section of the amendment.

Verifying the capacity of your research participant is one of the basic requirements for informed consent. Please consider how you will verify the capacity of your research participants.

Health Canada Regulated Studies

Health Canada regulated studies must follow the guidance of ICH-GCP E6, section 4.8 and TCSP2.

Verbal consent:

Obtaining informed consent verbally for a regulated study requires that the researcher do each of the following:

- Read the contents of the informed consent form to the trial participant;
- Receive the individual's informed consent before a witness, preferably for the entire process; if not feasible, document why;
- Acquire the attestation by the witness that informed consent was given;
- Document the process, including the informed consent; and
- Obtain, when feasible, the written reconfirmation of the informed consent from the participant on the first site visit.

What constitutes a witness?

A witness should ideally be impartial to the study. According to ICH-GCP E6, the definition of an impartial witness is a person:

- Who is independent of the trial;
- Who cannot be unfairly influenced by people involved with the trial;

- Who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read;
- And who reads the informed consent form and any other written information supplied to the subject.

New: eConsent

Use of eConsent requires each of the following on the part of the researcher:

- Confirmation that the signature belongs to the person who applied it;
- Limited access email address is best (not work or family) or set-up a password in the eConsent (survey login options in REDCap);
- Documentation of informed consent process, including consent discussion;
- Re-written confirmation of e-consent is recommended but not required as eConsent signature is considered equivalent to a wet ink signature.

We are asking groups wishing to use e-consent to gain permission from their Sponsor due to the validation requirement in GUI-0100 "electronic signatures are considered acceptable if the electronic system is fully validated," and Nova Scotia Health's system has not yet been fully validated. We will keep our research community updated on our progress in this regard.

Remote Consent

Verbal and eConsent are both methods of remote consent. When conducting remote consent, it is important to:

- Confirm patient identity and signature (e.g. witness);
- When feasible, written reconfirmation of informed consent from research participants. Study participants can initial the previously signed document or in the case of eConsent, you may add an additional field to include a reconfirmation signature (initial, signature, date);
- Document your process!! This includes your discussions with participants and their reconfirmation. Remember that consent is always ongoing.

Non-Regulated Studies

Non regulated studies remain obligated to follow the Tri-Council Policy Statement 2018, specifically chapter 3: The Consent Process. In addition, TCSP2 chapter 10, section 10.2: Modalities of Expression of Consent is a good reference for groups engaged in qualitative research.

Verbal Consent

According to TCSP2 section D, article 3.12: "Consent Shall Be Documented," it is the responsibility of the Principal Investigator of the study to decide if documentation is needed

beyond "either in a signed consent form or in documentation by the researcher of another appropriate means of consent… Whether or not a consent form is signed, *it may be advisable to leave a written statement of the information conveyed in the consent process with the participant* [for their own reference] unless it compromises their safety and confidentiality."

Our Nova Scotia Health REB SOP on informed consent requirements and documentation states that "when seeking verbal/oral informed consent, the procedure used to seek informed consent must be documented by the person obtaining consent. **Ultimately, whenever possible, the research participant should have written documentation of participation in a research project unless it compromises their safety or confidentiality**."

New: eConsent

When using eConsent, please consider implementing the following, if applicable:

- Some confirmation that the signature belongs to the person who applied it.
- Send the eConsent to a limited access email address (i.e. personal) is best. The REDCap platform also includes a password option.
- Documentation of the informed consent process, including documentation on the consent discussion. This can be as simple as an SOP.
- eConsents signatures are equivalent to wet-ink signatures. That being said, re-written confirmation of eConsent is not required but recommended when obtaining remote eConsent. This can be as simple as re-initialling the eConsent (separate field with date of initial). Remember, informed consent is an ongoing process and always best practice to verify and document this consent.

Remote Consent

Remote/electronic and verbal options for consent and re-consent may be used with approval from the REB. The following are recommended good practices for remote consent:

- Written statement of the informed consent form is provided to the participant (ICF is best)
- Confirmation of participant identity and signature (e.g. witness)
- When feasible, written reconfirmation of the informed consent from participants. Study participants can initial previously signed consent during the in-person visit if applicable.
- **Requirement: Documentation of process, including consent discussion, and – if applicable – reconfirmation process**.