**Verbal Consent Script Template**

**This script is to be used in combination with a letter of information that outlines all required elements.** If you do not provide a letter of information, your verbal consent script will need to include all applicable elements as outlined in the HSREB LOI/CF Checklist posted on [HSREB’s website](https://www.queensu.ca/vpr/ethics/hsreb) unless an alteration or waiver to the consent process have been reviewed and cleared by the HSREB.

**Study Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**Participant Study Number/ID:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

I confirm the following:

[ ]  The identification of the participant.

[ ]  All aspects of this were explained to the study to the participant, they were given an opportunity to ask questions and the participant had sufficient time to consider their participation in the study.

[ ]  The participant was informed that they may choose to stop their participation at any time for any reason without penalty/impact on academic standing/impact on employment/without affecting future care.

[ ]  The participant was informed that their legal rights would not be affected by consenting to participate in this study.

[ ]  The participant consented to the use of Audio Recording/Video Recording/Use of Quotes.

[ ]  The participant stated they were voluntarily accepting participation in the trial.

[ ]  The participant was provided with/offered a copy of the Letter of Information for their records.

**In addition, for Health Canada/FDA Regulated Studies:**

[ ]  An impartial witness was present (i.e. no connection to study) and must sign an attestation the above consent criteria were met. Informed consent procedures must clearly state that the witness to verbal consent must be impartial.

☐ A scanned copy of the attestation must be forwarded to the investigator by email or a picture of the signed attestation can be sent by email or text.

☐ The consent conversation with the participant may be recorded if it is not possible to have a witness (this recording becomes part of the trial records). When using a recording in lieu of using a witness, documentation in the study records includes the recording of the conference call.

[ ]  Additionally, a note in the trial records should be made explaining the circumstances of why informed consent was obtained through an alternative method.

[ ]  The case history (i.e. documentation of consent process) must document that informed consent was obtained prior to participation in the study.

[ ]  At the first in-person visit, participants should bring the original signed LOI/CF that was previously discussed remotely and the attestation by the witness. At this time, person who conducted the remote discussion should sign and date the original LOI/CF that was signed by the participant during first virtual (alternative) visit.

[ ]  A copy of the signed LOI/CF should then be given to the participant and the original should be filed as per record retention requirements.

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Signature of the person conducting Printed name Date

the verbal consent discussion