**Protocol Supplement**

**COVID-19 Procedures**

***General instructions: Highlighted wording indicates a section where study-specific text is required. This general wording is meant to assist researchers but must be tailored to the specific study. Some of the example text below may not apply and should be removed. All changes in study procedures should be documented here.***

***Template version date: April8 2020***

***Please delete this instructional text from the version submitted to the REB.***

***Adapted with permission from Sunnybrook Health Sciences Centre***

**Study Title:** [Insert Study Title]

**Principal Investigator:** [Insert Name]

**Qualified Investigator:** [Insert Name or remove for non-Health Canada regulated studies]

**Co-Investigators:** [Insert Name]

1. **Revised Procedures**

***Describe ALL temporary revisions to study procedures. Examples below refer to conducting remote visits instead of in-person visits but all changes to the study must be described. Please delete this instructional text from the version submitted to the REB.***

The following procedures will be done via telephone. Telephone calls will/will not be audio recorded:

[specify all procedures that will be done over the telephone, including the names of questionnaires/standardized instruments as applicable; if audio recording, provide details of how this will be done and how data will be stored/managed]

The following procedures will be done via videoconferencing using [specify service provider]. [specify service provider] sessions will/will not be recorded:

[specify all procedures that will be done via videoconferencing, including the names of questionnaires/standardized instruments as applicable; if audio or video recording, provide details of how this will be done and how data will be stored/managed]

If applicable:

Holland Bloorview-issued digital recording devices approved by IT security will be used (i.e., it is encrypted, password protected and meets all Holland Bloorview related requirements). Personal recording devices (eg. phones) will not be used. The recording device will be securely stored under the control of Holland Bloorview research personnel while it contains the recordings. Recordings will be transferred to and stored on secure Holland Bloorview servers, and will be deleted from the recording device after review and within 30 days. [If recordings will be shared with collaborators, specify including who and for what purpose, and how they will be shared].

If applicable:

Recordings will by transcribed by [specify e.g., Holland Bloorview research personnel or if vendor, specify]. Identifying information will not be included in the transcription. Transcriptions will be stored with other study data, separate from identifying information, in accordance with the provisions set out in the main study protocol.

Compensation

***Describe ALL temporary revisions to compensation. Examples below refer to conducting remote visits but all changes must be described. Please delete this instructional text from the version submitted to the REB.***

Participants will continue to be compensated at the rate outlined in the main protocol. However, for procedures done remotely, participants will instead be provided with the option to receive compensation by [specify new procedures e.g., mail or email at their preference].

Specify whether the compensation method (i.e. electronic gift card, physical gift card) will remain the same or, if changing, specify the change.

Participant email and/or mailing address will be confirmed as part of the revised procedures. As per usual procedures, contact information will be stored separately from study data on secure Holland Bloorview servers and will be accessible to authorized personnel only.

Informed Consent:

***Examples below refer to changes related to conduct remote visits; any change to the consent process and documentation. Please delete this instructional text from the version submitted to the REB.***

Participants will be verbally informed of these changes to the study by telephone by appropriately trained and qualified Holland Bloorview research personnel who do not have an existing clinical relationship with the participant. The study PI will not obtain participant consent. Participant informed consent will be obtained for ongoing participation.

Informed consent will be documented in writing via the “Documentation of Verbal Consent” document, with the original placed in the participant’s research record. The participant will be provided with the completed “Documentation of Verbal Consent” form by mail or email according to their consent. Alternately, if they do not consent to mail or email, they may pick up a copy of their consent at Holland Bloorview in future when the pandemic has been resolved.

1. **Additional Risk and Mitigation Plans**

[Specify any new or additional risks associated with the revised procedures, and outline mitigation plans as applicable.]