Holland Bloorview
Kids Rehabilitation Hospital

All There is to Know About Consenting

An important mechanism for respecting participants' autonomy in research is the requirement to seek their free, informed and ongoing consent. This document provides a brief overview of the Informed Consent/Assent process for researchers at Holland Bloorview. For more detailed guidance on institutional requirements concerning informed consent/assent see REB SOP701 *Informed Consent Form Requirements and Documentation*, REB SOP706 *Informed Consent/Assent Process*, N2 SOP006 *Informed Consent Forms* and N2 SOP008 *Informed Consent Process*.

Below is a recap of all the steps to be followed and where to find information.

Prior to REB Submission

- ✓ Develop a capacity assessment process tailored to the nature, degree of risk, and complexity of the research protocol.
  - For details review REB SOP706 Informed Consent/Assent Process
  - Available template: Capacity Assessment Worksheet Template
- ✓ Develop the Informed Consent Form using the appropriate HB Informed Consent Form Template
  - Available templates: HB REB Informed Consent Form templates
  - For details review REB SOP701 Informed Consent Form Requirements + Addendum and Documentation and N2 SOP006 Informed Consent Forms + Addendum
- ✓ Develop the Assent form using the HB Assent Form Template, if applicable.
  - Available template: HB REB Assent Form template
- ✓ If the consent process is to be performed remotely, review Ethical Considerations for Remote Consent and Assent and include applicable appendix(ces) in the main ICF.
- ✓ If research teams are using consent template provided by their external sponsor instead of the HB templates, review the Informed Consent Form (ICF) Elements Checklist and if applicable, the Optional Biobank/Database ICF Elements Checklist**,** to ensure that all essential elements are included in the consent material. Please note that to facilitate the REB review process we encourage using the HB Informed Consent/Assent Templates instead of sponsor's templates.
- ✓ Review the ICF(s) to ensure it is written at a level appropriate for the target population.
- ✓ Ensure the ICF was sent back to the Sponsor (when applicable) for approval prior to submitting to the REB.

REB Submission

Depending on the study design, the following documents may be included in your submission:

- ✓ Capacity assessment document
  - Available template: Capacity Assessment Worksheet
- ✓ Assent Form
  - Available template: HB REB Assent Form template
- ✓ Informed Consent Form
  - Available templates: HB REB Informed Consent Form templates
- ✓ Description of the capacity assessment process, including a description of the following:
  - Who will assess capacity?
  - If participants do not have the capacity to consent, will they be asked to provide assent?
  - For studies where the lack of capacity is expected to be temporary, what is the plan to ensure that capacity is assessed on an ongoing basis, and that they are consented once capacity is acquired/regained during the course of research?
  - For details review N2 SOP706 Informed Consent/Assent Process
- ✓ Description of the assent process including a description of the following:
  - Who will conduct the assent discussion?

- Who will obtain assent?
- How will assent be documented?
- What verbal or non-verbal indicators of dissent will be used?
- For details review N2 SOP706 Informed Consent/Assent Process

✓ Description of the consent process, including a description of the following:
- How will potential participants receive a copy of the ICF prior to the consent discussion?
- How much time will the potential participants be given to review the ICF?
- Who will conduct the consent discussion?
- If the participant has questions, who will they contact?
- Will the consent documentation be in paper or electronic or another format?
- Where will the consent discussion take place, if remotely – what measures will be taken to ensure privacy and confidentiality?
- For participants who do not have access to the software/hardware/expertise for remote consent, how will these participants be consented to ensure they are not excluded from the study?
- For details review N2 SOP706 Informed Consent/Assent Process

✓ Justification for alteration to consent requirements (TCPS2 Article 3.7)

✓ Information Letter/Debriefing material if an alteration of consent is requested.

Prior to Participant Recruitment

✓ Study recruitment and consent process will be implemented as approved by the REB

✓ Study personnel involved in consenting/assenting participants must be delegated on the task delegation log (TDL). Delegated personnel must be appropriately trained, and training must be documented (per institutional and study requirements).
- For details review N2 SOP002 Research Team Roles and Responsibilities, N2 SOP003 Research Team Training

✓ All study activation procedures are completed, as per the Sponsor and/or site SOPs.
- For details review N2 SOP005 Study Initiation and Activation
- Procedures for documenting the capacity/assent/consent process must be in place. Available Templates: Informed Consent Process Worksheet and Capacity Assessment Worksheet.

✓ Consider implementing a process to ensure that the most recently approved capacity/assent/consent documents are used in order to avoid using expired versions.
- Available Template: Protocol and Consent Tracker

Prior to Consenting the Participant

Before scheduling a participant for a consent discussion, ensure the following are completed:

✓ The study team member conducting the capacity assessment/assent/consent discussion is trained/qualified and delegated to do so (see above for details).

✓ The potential participant has received a copy of the consent/assent form and had the opportunity to review the consent documents prior to the discussion.

✓ A quiet and private space available for the consent discussion to occur within.

✓ It should be noted that the expectation is for the research team to be conducting participant facing activities from on-site. In exceptional circumstances approved by the institution in which the study team member is working remotely, the study team member will inform prospective participants of this, and steps taken to protect the privacy and confidentiality of the conversation, as outlined in Ethical Considerations for Remote Consent and Assent for further guidance. Participants should also be given the opportunity to request that the conversation takes place when the research team member is on-site at Holland Bloorview.

- See also HB REB Telephone Script for an example on how to communicate this with the participant.

✓ Ensure the recently approved documents are ready for the discussion (capacity assessment/consent form/assent form).
- For details review REB SOP706 Informed Consent/Assent Process

✓ If assent is required, the SDM must be available and able to sign the consent on behalf of the participant.

After Consenting the Participant

After the consent discussion, ensure the following are completed:

✓ Ensure the consent form is signed and dated properly by the participant and the person obtaining consent. Ensure the participant has received a copy of the signed consent/assent form.

✓ Ensure the consent process-related documents (capacity assessment worksheet, consent/assent form, consent process worksheet) are filed securely and separate from de-identified research data.

✓ Ensure any changes to the documents in the future are submitted to REB and approved prior to use.

✓ Ensure that capacity assessment and the consent process is ongoing.

General guidelines for involving individuals with varying capacity to consent:

Note: Capacity assessment is always required with exceptions* (e.g., healthy adults, HB staff).
*The research team must justify in the REB application why capacity assessment does not apply.

Capacity Level	What documentations are required
Participant has the capacity to consent on their own	Capacity Assessment Form *From Child*: Informed Consent Form *From Parent/SDM*: NA
Participant does not have the full decision-making capabilities however is able to comprehend the nature of the study	Capacity Assessment Form *From Child*: Assent form *From Parent/SDM*: Informed Consent Form
Participant does not have the capacity for meaningful participation in decision making	Capacity Assessment Form *From Child*: NA *From Parent/SDM*: Informed Consent Form

As a reminder, consent and capacity assessment is an ongoing process and must be continuously assessed after initial consent by the participant.

If you have any questions, please contact:

The Holland Bloorview Research Ethics Board
Tel: (416) 425-6220 ext. 3161
researchethicsboard@hollandbloorview.ca

REVISION HISTORY

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