Bloorview RESEARCH INSTITUTE

Holland Bloorview Kids Rehabilitation Hospital

Research Ethics Board Standard Operating Procedure Addendum

The Holland Bloorview Research Ethics Board (HB REB) has adopted the N2/CAREB REB SOPs. Some internal practice requirements differ from those in the N2/CAREB SOPs. This SOP addendum describes the specific HB REB requirements related to the N2/CAREB SOP noted below.

SOP #	Title
701.004	Informed Consent Form Requirements and Documentation

N2/CAREB REB SOP Section #	HB REB SOP Addendum
3.0 Responsibilities The Researcher 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.	Additionally: For all research involving children and youth, the Researcher must Submit for REB approval a study-specific process to assess whether a prospective participant has the capacity to consent to participate in the study. Capacity refers to the person's ability to understand and appreciate relevant information and appreciate the potential consequences of the decision on whether or not to participate in a research study. Capacity to consent is study specific, is assumed to be present unless it can be shown otherwise, and should be considered during the consent discussion.
5.2 *Translation of Informed Consent Documents* 5.2.2 When a research participant is non-English or French speaking, documentation of informed consent can be by one of two methods: • **Written consent**: The REB approved English/ French version of the informed consent document is translated into the research participant's native language. The REB may require that translated informed consents be accompanied by an attestation from a translator certifying that the translated informed consent accurately reflects the REB approved English informed consent. This method is preferred if it is anticipated that a significant percentage of a prospective research population is non-English speaking. A	Replaced by: 5.2.2 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 document is translated into the research participant's native language. The REB may require that translated informed consents be accompanied by an attestation from a translator certifying that the translated informed consent accurately reflects the REB approved English informed consent. This method is preferred if it is anticipated that a significant percentage of a prospective research population is non-English speaking. A translated informed consent document does not replace the need for an interpreter to be

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**: If applicable/acceptable, a qualified interpreter fluent in both English/French and the research participant's native language orally interprets the REB approved English /French consent form to the research participant. The interpreter should be an impartial person. When the person obtaining consent is assisted by an interpreter, the interpreter must sign and date the consent form;	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**: If applicable/acceptable, a qualified interpreter fluent in both English and the research participant's native language orally interprets 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, the interpreter must sign and date the consent form;
5.2.4 The REB requires that the translated informed consent materials be submitted for review and approval prior to use in enrolling non-English/French-speaking participants. The REB may require that the Researcher include a certificate or statement signed by the translator indicating that the translated materials are a true and accurate translation of the REB approved English materials;	Replaced by: The REB requires that the translated informed consent materials be submitted for review and approval prior to use in enrolling non-English-speaking participants. The REB may require that the Researcher include a certificate or statement signed by the translator indicating that the translated materials are a true and accurate translation of the REB approved English materials;
5.5 Recruitment Materials	In addition: Please refer to the REB website for available recruitment material templates.
5.4 Recruitment Methods 5.4.4 **Health Records Department:** The Researcher may ask the Health Records Department to identify patients who appear to meet the research's eligibility criteria. The Researcher should supply Health Records with a standard letter describing the research to give the patient's physician, and asking whether the physician would be willing to approach his/her patients about participation. It is NOT acceptable for the Researcher or his/her staff to contact patients identified through hospital records, clinic charts or other databases independently by	In addition: Researchers should attempt to recruit using the BRI connect2research program prior to contacting the Health Records Department to assist with recruitment.

phone, unless the patient has previously agreed, or is already under the medical care of the Researcher;	
5.6 Documentation of Informed Consent 5.6.4 The Researcher or designee should document details of the consent process in the research participant's medical record, according to the organization's guidelines; 5.6.6 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. The short form consent document is signed by the research participant or the substitute decision maker. An impartial witness must be present during the oral presentation. The witness must sign both the short form consent document and a copy of the written summary. The person obtaining consent must sign a copy of the written summary of the information that is presented orally;	Replaced by: 5.6.4 The Researcher should not document details of the consent process in the research participant's medical record unless it is required in order to minimize risk of harm to participants or has implications for their current or future medical care. Replaced by: 5.6.6 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. The short form consent document is signed by the research participant or the substitute decision maker. An impartial witness might be present during the oral presentation. The witness must sign both the short form consent document and a copy of the written summary. The person obtaining consent must sign a copy of the written summary of the information that is presented orally; In addition: When appropriate, the REB may approve the criteria listed in 5.6.6. However, the REB will generally expect Researchers to follow the Informed Consent/Assent Process SOP REB-706.
5.9 Consent for Research Involving Individuals who Lack Capacity	In addition: The REB will generally expect Researchers to follow the Informed Consent/Assent Process SOP REB-706.
5.11 Consent for Research in Health Emergencies	This section is not applicable as the BRI is housed within a rehabilitation hospital and does not conduct research in health emergencies.

Revision History	
Version Date	Summary of Changes
October 23, 2020	Original Version
June 26, 2023	Clarification of requirements for recruiting non English-speaking participants
September 18, 2024	Updated in alignment with revisions to the BRI and REB Consent SOPs.
This N2/CAREB REB SOP Addendum has been reviewed and approved for use by the HB REB	