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RESEARCH INSTITUTE

Guidance Document	Ethical considerations for remote consent and assent
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Please note that this version of the document has had specific institutional details added for Holland Bloorview Kids Rehabilitation Hospital. Details may be different depending on the institution. However, this document represents an overall consensus on the approach to remote consent.

Background and Scope:

Research teams may require flexible informed consent processes when the researcher and participant cannot meet in person. This document provides a broad framework for different remote consent options and informed consent documentation. **The REB will determine on a case-by-case basis whether the requested adaptations are appropriate for any given study.** Depending on the study, the REB may require for an in-person consent option (i.e. if the potential participant does not have the software/hardware/expertise to access remote consent options, if the potential participant prefers in person interaction, etc.) in addition to the REB approved mechanism for remote consent.

Consent procedures must adhere to ethical principles and privacy protections. Research teams must be aware of and comply with any additional requirements of their sponsors, funders, and institutions.

For the purpose of this document, "remote consent" refers to the process of conducting the consent discussion and obtaining informed consent when the research team and the prospective participant/ Substitute Decision Maker (SDM) are not physically in the same room, and it is unlikely that the participant/SDM will be seen in-person. While there may be instances where in-person study activities will appropriately follow remote consent, the expectation remains that if participants/SDM are seen in- person, informed consent will be completed and documented in-person

Ethical Considerations

Informed consent is a cornerstone of ethical principles including the Tri-Council Policy Statement (TCPS 2 (2018)[1]. While logistics may sometimes challenge the ability to obtain informed consent in person, the ethical principles for obtaining and documenting informed consent have not changed.

The Informed Consent Form (ICF) is a tool for enhancing communication and discussion between prospective participants/substitute decision makers (SDM)*; the ICF is not the sole component of obtaining informed consent. ICFs can be lengthy and complex, and correspondingly require clear and open communication with prospective participants to ensure informed consent is obtained. This may be particularly challenging when consent is not obtained in person.

For some minimal risk research projects (e.g., anonymous online surveys), the REB may waive the requirement for a discussion between the prospective participant and the research team prior to informed consent being obtained; this is outside the scope of this document.

The standard REB requirements outlined in REB SOP(s) regarding informed consent, also apply to remote consent. Regardless of the mechanism by which informed consent is obtained, researchers must be certain that voluntary informed consent (or assent as appropriate) has been provided by all research participants (or their SDM, where appropriate) prior to participation in the research project.

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[1] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2018.

* *Please note, for the purposes of this document, all subsequent references to 'participant' should be understood to refer to the participant as well as their substitute decision maker, in cases where such a decision-maker is required*

Research teams must be cognizant of the challenges that exist when consent is obtained remotely. Additional care must be taken to ensure the prospective participant is engaged in the consent process and understands the information that they are being provided with as part of the consent discussion, particularly when consent is obtained remotely. Researchers should consider that some options may be challenging to some participants – for example, that some participants may struggle with accessing or using online documentation platforms or other methods of technology. Research teams should ensure that the consent procedures are equitable and do not exclude prospective participants who lack access to technology that may be required.

When consent is not obtained in-person, prospective participants should be provided with information on what to expect in terms of the consent discussion in advance. Clear and open communication is critical to ensure that prospective participants understand that different options are available, and the research team will work with them to resolve any challenges that might occur. Research teams should consider incorporating the following into the consent discussion (these are generally applicable to all consent discussions but are particularly important for remote consent discussions):

- Ensuring that both the research team member, and as much as possible, the potential participant, have access to a location where the discussion can be conducted in a secure/private manner. Prospective participants should be given the opportunity to request that the conversation take place when the research team member is on-site at Holland Bloorview;
- Confirming at the beginning of the discussion that the individual has the ICF with them and can follow along with the document during the discussion. If the consent discussion is conducted using videoconferencing software, consider sharing the ICF on the screen;
- Pausing during the consent discussion to ask for questions or ask if the prospective participant wants to further discuss or re-review any information;
- Asking questions throughout the consent discussion to gauge engagement and comprehension;
- Support participants in their use of any technological platforms, as applicable. Explain in lay terms how participants can complete the documentation process.

The REB application must clearly describe all aspects of how informed consent will be obtained and documented for a research project. This includes the context or location of consent, timeline between a participant receiving the ICF and being asked to document consent, how a participant will receive a fully executed copy of the ICF how subsequent assent (as applicable) will be obtained, and how the informed consent discussion and/or identity verification will occur. When possible or applicable, more than one process may be used. The consent process (and any changes) must be approved by the REB prior to implementation.

Please note that if videoconferencing platforms will be used, the research team must use the BRI Zoom/Teams accounts using an institutionally approved device.

Study-specific Considerations

For each research project where remote consent is proposed, the research team must consider the logistical aspects that may interfere with feasibility. This is particularly of note if both research teams and prospective participant are working off-site. 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, when both research teams and participants are working off-site the

following should be considered:

- Requirements of the applicable regulations/guidelines for the research project
- How participants will be provided with a copy of the ICF prior to the consent discussion
- How informed consent and the consent process will be documented
- How capacity to consent will be assessed and documented (when applicable)
- When and how the consent process will be explained to the prospective participant so that they are aware of what will happen and what the expectations are
- Do the proposed procedures require prospective participants to have computers/tablets/printers/scanners/internet or other technical components? How likely is it
- that they will have these components? Are these otherwise required for study participation? Is an alternative option available for those who lack these components or who are technologically inexperienced to support equitable recruitment?
- How the research team will provide a copy of the signed ICF to the research participant
- Contact with the research participants should only be made through the use of institutionally approved devices (e.g. Personal cell phones should not be used to contact participants…)
- Institutional requirements with respect to collecting and saving PII/PHI. As a reminder no PII/PHI should be stored or moved outside of the institution without proper agreements/consents in place
- Institutional requirements regarding the use of email, videoconferencing/teleconferencing technology, electronic signatures, and electronic consent platforms
- Have the institution and the REB been made aware that the research teams will be off-site while consenting participant?
- If the research team is working remotely and will be speaking to research participants, does the research team member have a private room/space where they can conduct the research activities? Does the REB-approved script include the disclosure of this information to the participant?
- Is the prospective participant located in a place where they feel comfortable that the discussion can take place?

Prior to the Consent Discussion

Research teams must provide the prospective participant with the REB-approved ICF prior to the consent discussion, to assist in the consent discussion. This allows the prospective participant to review the material in advance and to follow along during the consent discussion.

If there are instances for low risk studies where researchers propose that the ICF not be provided in advance, this must be appropriately justified and the expectation is that the full ICF would be read verbatim to the participant prior to seeking consent.
Based on the prospective participant's preference and prior agreement (where applicable) and as permitted by local policy, this could be achieved via secure file transfer (SFT), email*, mail, courier, texting a link, or posting a publicly available consent form, for example.

**At Holland Bloorview Email may only be used in research studies that are not related to a diagnosis and do not reference any potential Personal Health Information PHI within the ICF. Additionally, the use of email must be approved by the REB on a study-by-study basis and participants consent must be obtained prior to the use of the email.*

Conducting the Consent Discussion

Remote consent does not remove the expectation for a consent discussion to occur with the prospective participant. Whether conducted in person or remotely, (video, telephone, etc.), informed consent requires a discussion to ensure prospective participants:

- understand the procedures, risks and benefits of the study,
- can easily ask and get answers to questions, and
- understand that participation is voluntary.

The consent discussion also addresses other requirements of informed consent, such as assessing/ demonstrating capacity.

A discussion of the research project with the prospective participant occurs via telephone or teleconferencing/videoconferencing service where permitted. Videoconferencing is preferred when possible as it most closely mirrors the in-person process, but may not be feasible for all participants. Individuals should not be excluded from participation because they do not have access or otherwise do not agree to use of email and/or teleconferencing/videoconferencing, unless use of these technologies is specifically required as part of the research project (e.g., required to implement the study procedures).

As always, prospective participants should be provided with sufficient time to review the consent form, prior to providing informed consent. Research teams should address any questions raised by prospective participants prior to documenting informed consent. If the consent discussion does not include the necessary individuals to answer questions, a separate session should be arranged.

Research teams should inform prospective participants if the research team member is working remotely and inform the prospective participant of the steps taken to protect the privacy and confidentiality of the conversation (i.e. that the individual is in a private room setting with no other individuals in the house and/or the room, all smart devices have been turned off, etc.). Prospective participants should be given the opportunity to request that the conversation take place when the research team member is on-site at Holland Bloorview.

Documenting Remote Consent

The options for documenting remote consent differ based on the type of research project and can include considerations including whether it is Health Canada regulated, US federally funded or FDA regulated (i.e., Investigational New Drug (IND), Investigational Device Exemption (IDE), or Pre-Market Approval (PMA) application).

Researchers must be aware of and are expected to comply with additional requirements from funders, sponsors, and their institution and obtain any additional approvals as applicable. This should occur prior to REB submission.

Documentation methods and potential uses

The following table outlines potential methods for documenting remote consent based on different study requirements. Of note, different institutions and sponsors may have additional restrictions in place, particularly as it concerns Health Canada or US regulated research or sending personal health information (PHI) to participants. Additional requirements such as validation of electronic systems or tools may also

apply (for Health Canada or US regulated research, for example).

Observational Research (Not subject to Health Canada regulations, not US regulated)	• Written Signature on Paper Copy by Mail, Email* or Secure File Transfer • Electronic Signatures using approved Electronic Signature Software/e-Consent platforms (REDCap e-consent Framework) • Verbal Consent following corresponding process for observational research
Interventional Research (Not subject to Health Canada regulations, not US regulated)	• Written Signature on Paper Copy by Mail, Email* or Secure File Transfer • Electronic Signatures using approved Electronic Signature Software/e-Consent platforms (REDCap e-consent Framework) • Verbal Consent following corresponding process for interventional research
Health Canada Regulated Research	• Written Signature on Paper Copy by Mail, Email* or Secure File Transfer • Electronic Signatures using approved Electronic Signature Software/e-Consent platforms
US Federally Funded or FDA Regulated Research	• Written Signature on Paper Copy by Mail, Email* or Secure File Transfer • Electronic Signatures using approved Electronic Signature Software/e-Consent platforms • Verbal consent can only be used if the requirements for an REB waiver of written consent as outlined in 21 CFR 56.109(c) (for FDA regulated research) or in 45 CFR 46.117(c)(1) (for US federally funded research) are met.

Written Signature on Paper Copy by Mail, Email*, or Secure File Transfer (SFT)

When possible, the ICF should be signed by the prospective participant and the person conducting the consent discussion, along with any others as applicable to the consent process. To this end, the study team may establish a process, in alignment with research regulations, whereby the paper ICF is mailed to the prospective participant and, following the consent discussion, the participant signs the paper ICF and mails it back to the institution. The person conducting the consent discussion (and any others as applicable) can then sign the ICF.

Alternately, the study team may send the ICF by SFT or email* and, following the consent discussion, the participant signs the consent and mails, faxes, scans, or sends a photograph back to the study team. Email* should generally be considered the last resort for the consent process due to lack of security.

The use of a wet-ink signature is generally considered the most compliant option, and may be the only option in some circumstances, but it may come with ethical challenges particularly with respect to equity, privacy, complexity and potential burden to participants. Postage should always be paid for by the study team.

Because the study team and participant will not necessarily be signing the ICF on the same date, the person obtaining informed consent should otherwise document (e.g. note to file) the consent discussion on the day it occurs. Then, the person obtaining informed consent should write a note on the ICF when they sign the document that explains the date discrepancy.

**At Holland Bloorview Email may only be used in research studies that are not related to a diagnosis and do not reference any potential Personal Health Information PHI within the ICF. Additionally, the use of Email must be approved by the REB on a study by study basis and participants consent must be obtained prior to the use of the email.*

Electronic Signatures using approved Electronic signature software/electronic consent (eConsent) platforms

Another method of obtaining signatures on the ICF is via electronic signature software/electronic consent platforms such as the REDCap e-consent framework. The advantage of these systems is that they may provide a user-friendly option for individuals to personally sign the ICF. However, in the research setting, additional institutional approval and validation processes may apply and there may be costs to study teams.

These processes may reduce the burden on participants (by avoiding printing/scanning/photographing for example), but they may also require additional resources (email, devices [smartphone/tablet/computer]) and be complex for less tech-savvy individuals.

Researchers and institutions must consider privacy implications (for example, if personal health information is stored on an electronic system) and regulatory considerations regarding the use of electronic signature software/electronic consent platforms. For example, for US federally funded studies, Health Canada regulated studies, and US Food and Drug Administration (FDA) regulated studies, the system must be validated (other considerations apply).

*Currently, Holland Bloorview supports the use of **REDCap e-consent Framework for research that is not Health Canada or FDA regulated**. Please consult BRIs REDCap Guidance Document and associated templates.*

Health Canada and FDA Regulated research must use Written Signature on Paper Copy by Mail or Secure File Transfer.

As with the paper process, all required signatures (including participant, PCCD, and any others as required by the e-consent) must be obtained through the consent process before any research participants may be enrolled or data collection from or about the participant can begin for research purposes.

The Holland Bloorview REB consent form templates must be used when building your study-specific consent in an online platform.

Reminder: e-Consent refers to the *documentation* of informed consent, **not** the process of obtaining informed consent. Whenever possible and practical, the informed consent process should include a discussion between the research team and the potential participant, prior to the individual consenting to take part. There are limited circumstances in which the REB may approve a consent process that does not include such a discussion (e.g., a study of healthcare professionals involving low-risk longitudinal surveys). This would depend on the nature of the study, the study population, and the logistics of the study.

The REB must approve the consent process (i.e. obtaining an e-Consent) and any participant-facing materials.

A standard paper ICF should be submitted and the information included in the e-consent framework should be identical to the REB approved Consent Form.

Verbal Consent

In some cases, it may not be possible for the prospective participant to sign the ICF. However, a signed ICF still serves as the preferable method of documentation. Verbal consent requirements differ based on the type of research project.

In general, this process is not ideal because the participant does not personally sign the ICF. However, this is a low-tech, low burden option and may be particularly appropriate for some individuals or research populations.

The US federal funding agencies (e.g., National Institutes of Health, etc.) and US Food and Drug Administration (FDA) do not regard verbal consent as constituting the documentation of signed informed consent that is required by federal regulations (21 CFR 50.27; 45 CFR 46.117(a)). Verbal consent can only be used if the requirements for an REB waiver as outlined in 21 CFR 56.109(c) (for FDA regulated research) or in 45 CFR 46.117(c)(1) (for US federally funded research) are met. The researcher must identify the criteria that apply (i.e., the section of the regulations under which they are applying for a waiver) and justify this relative to the study in their REB application.

Verbal Consent - Observational Research

Once the consent discussion is complete and the participant verbally confirms their consent, the person conducting the consent discussion will complete the signature pages of the ICF by writing/printing the participant name, the date of the consent discussion, their own name, signature, and date of signature.

Verbal Consent – Interventional Research or Clinical Trials

Use of verbal consent for clinical trials is reviewed by the REB on a case-specific basis. REB review for this approach includes, at minimum, considerations of the risk of the study, the participation population, and whether participants will be seen in person during the conduct of the study.

When verbal consent is used for Health Canada regulated clinical trials, the consent discussion must additionally include a witness. **Please note that the provision of verbal consent for clinical trials by Health Canada is also a temporary measure as of this draft.** For other clinical trials, the need for a witness depends on the nature and risk of the study.

The witness should be impartial observer to the consent discussion. The witness cannot be the principal investigator/project lead, an individual with a clinical relationship to the participant, or the person conducting the consent discussion (additional institutional requirements may also apply). The witness cannot participate in the consent discussion (only observe) and must be able to complete the documentation requirements outlined below. The witness must be able to hear both the person conducting the consent discussion and the prospective participant. Researchers must identify who is permitted to act as a witness in their REB application.

Once the consent discussion is complete and the participant verbally confirms their consent, the person conducting the consent discussion will complete the consent form by writing the participant name, the date of the consent discussion, and their own name, signature, and date of signature (as above for observational research). In addition, the witness will separately sign (typically a separate page) to document that informed consent was appropriately obtained.

Please note that no one should ever sign or enter a signature on behalf of, or instead of, the person providing consent (the participant). An alternative and preferable approach is that separate tools such as verbal consent scripts and worksheets can be developed to document informed verbal consent.

Following Informed Consent

The participant should receive a fully signed, complete copy of the ICF as soon as possible and in a timely manner. A complete copy is all pages of the ICF, including the completed signature pages (with the exception of studies where consent is being obtained verbally).

The entire informed consent process including a detailed narrative of the informed consent discussion should be documented for each participant.

Consent is an ongoing process. It may be necessary to provide updated information to participants and obtain their ongoing informed consent. The above principles may be applied, or further alterations may be permitted depending on the nature of the changes. Above all, research teams must remain responsive to participant questions and concerns and ensuring that they remain informed throughout the course of the research project.

Additionally, researchers should consider and incorporate the logistical requirements of maintaining appropriate document and data management. Institutional policies around the secure storage and eventual destruction of identifiable data still apply.

Questions

Please direct questions about this document to the Research Ethics Office via email at researchethicsboard@hollandbloorview.ca.

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Appendix 1: Documentation of Verbal Consent

Instructions to study team: This page must be included as part of the informed consent form submitted to the REB and paginated as part of the main ICF document (i.e., all pages, including the witness attestation page as applicable, are numbered sequentially as page X of Y). When a study involves different methods of informed consent (such as e-consent and verbal consent), all ICF versions must be submitted to the REB.

Documentation of Verbal Consent

Study Title: (insert study title)

Do you have any questions?

☐ Yes

☐ No

Do you agree to take part in this study?

☐ Yes

☐ No

[Insert other specific questions as they pertain to the research such as confirmation of audio-recording, use of direct quotes, consent to future contact etc. as applicable]

We would like to provide you with a copy of what we've talked about today, which will include your name and the study title and the other information you have provided over the phone. Can we send this to you by email or mail? NOTE TO STUDY TEAM: the required text* around use of email and how it is not secure must be contained within the consent form. Email may only be used in research studies that are not related to a diagnosis and do not reference any potential Personal Health Information PHI within the ICF or study title, except when approved by the REB.

*Please note that email is not a secure way of communicating. An e-mail message that is sent through the public internet (using Gmail, Yahoo, or another non-Holland Bloorview provider) may be intercepted, delayed, altered, forwarded or used without authorization or detection. Giving us your email means that we will be sending you information through a non-secure form as compared to the mail.

☐ Mail
☐ Email
☐ Secure File Transfer

Name of Participant	Date of Participant Verbal Consent
Name of Substitute Decision Maker (SDM)	Date of SDM Verbal Consent

My signature means that I have explained the study to the participant named above. I have answered all questions,

Name of person obtaining consent	Signature of person obtaining consent	Date

For Interventional studies, include:

The completed consent form includes a witness attestation page (See Appendix 2).

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Appendix 2: Witness Attestation for Interventional Research and Health Canada Regulated Clinical Trials

Instructions to study team: This page must be included as part of the informed consent form submitted to the REB and paginated as part of the main ICF document (i.e., all pages, including the witness attestation page, are numbered sequentially as page X of Y). When a study involves different methods of informed consent (such as e-consent and verbal consent), all ICF versions must be submitted to the REB.

Study Title: (insert study title)

Name of Participant	Date of Participant Verbal Consent

The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, that any questions have been answered, and that the participant consented to participate.

Name of witness	Signature	Date