CONJOINT HEALTH RESEARCH ETHICS BOARD (CHREB)
Research Services Office
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Research Consent and Requests for Waiver of Consent

Participants should ordinarily consent to research participation before the research begins. They must also provide consent for research use of any personal health information that was initially collected for another purpose.

In certain circumstances, researchers may request that the Conjoint Health Research Ethics Board (CHREB) waive the requirement for consent for enrolment or for access to personal health information. Investigators are responsible for ensuring that the ethical standards for consent are met, including the conditions under which any alteration to prospective informed consent may be proposed (See Chapter 3, TCPS2 and Section 50, Health Information Act of Alberta - HIA).

Surrogate or Third-Party Consent

The CHREB may approve research that involves unconscious individuals or those who lack capacity to consent to participation. In such cases, the Board must determine that the research cannot proceed without enrolling such participants. The research must pose no more than minimal risk to participants and there must be some potential benefit either to the participant directly or to other people in the same circumstances. In such cases, the Board may approve enrollment of participants by consent of the participant's surrogate (e.g., a family member or legally authorized representative). When a research participant regains capacity at some point during the research, they must be asked for their consent for continued participation in the research. (Articles 3.9, 3.10, and 3.11 TCPS2).

Surrogate enrolment in research that will not benefit participants warrants special consideration. If a Personal Directive has been enacted and has come into effect, the maker of the Personal Directive (PD) cannot be enrolled in research unless the Directive explicitly allows for their participation in such research. (Personal Directives Act S. 15d)

Similarly, under HIA, surrogates cannot provide consent for researchers to access health information of potential participants unless such access has been authorized in a Personal Directive (Section 104, HIA). In such circumstances, where surrogates provide consent to study participation, the Board may grant a waiver for research use of personal health information.

Minors: Consent/Assent

TCPS2 permits minors to provide their own consent to research participation if they can demonstrate decision-making capacity (Section C, Chapter 3, TCPS). A parent or guardian must provide consent for the participation of minors who lack capacity. Should the capacity of minors evolve (i.e., be gained) during the study, the investigators should secure the minor's consent to continued participation. Research falling under US regulations does not permit minors to provide their own research consent.

For detailed guidance please see the CHREB's guidance document, "Assent, Consent & Decision-Making Capacity in Minors."

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Research in Emergency/Urgent Circumstances (Alterations to Consent Requirements)

Research conducted in emergent or urgent circumstances sometimes requires rapid implementation of research procedures. In such instances, requiring individual or surrogate consent may render the research impossible. TCPS2 permits the enrolment of participants in such protocols without consent (Article 3.8). Investigators must request and justify this enrolment approach, which typically includes a deferred consent requirement.

The CHREB's approval of such alterations considers several criteria:

- The importance of the research,
- the risks and benefits to the potential participant, and
- the feasibility of obtaining timely individual or surrogate consent.

The onus is on the researcher to demonstrate that the research cannot be conducted with a standard consent process and that the risks to the participants justify a waiver or delay of the requirement for consent (TCPS2).

Waiver of Consent for Research Access to Personal Health Information

Patients must consent to any secondary use of personal health information that is held by a data custodian such as AHS. This includes access to and use of this information to screen for study eligibility and abstracting data to address the research question.

Alberta's Health Information Act authorizes the REB to approve a waiver of consent for access to personal health information for research (See: https://oipc.ab.ca/legislation/hia/). In such cases, the investigator must formally request a waiver of consent and must demonstrate to the satisfaction of the REB that

- the research is of sufficient importance to justify a waiver of consent,
- adequate safeguards are in place to protect the privacy of personal information collected in the research, and
- obtaining consent for access to the personal health information is unreasonable, impractical, or not feasible.

Possible justifications for seeking a waiver of consent that the study team should establish are:

- a significant number of records is needed to accurately address the study question and seeking consent would overwhelm study resources and prevent research from taking place
- inability to contact people due to the passage of time and the inaccuracy of contact information
- loss to follow-up because of mortality and/or morbidity (i.e., loss of capacity)
- seeking consent might be traumatic to people (i.e., requires revisiting a distressing event)

- the number of cases is very small and data from all participants are needed to ensure scientific validity in addressing the research question

Consent Documentation

Studies regulated by Health Canada (e.g., clinical trials) generally require that the documentation of consent be written or electronic, other than in exceptional circumstances. The documentation of research consent may otherwise be written (i.e., wet ink), electronic, oral or implied (Article 3.12, TCPS) .

For more information about electronic consent, please review the CHREB's guidance, "Obtaining and Documenting Consent Electronically".

Certain cultural communities may prefer alternate means of documenting consent (Article 3.12, TCPS) . Investigators should be aware of, and respect, such cultural preferences. Investigators should provide sufficient information to the Board so that it may consider alternatives. Where possible, this should include supporting documentation from the community or cultural group.

Translators Involvement in Consent

If a translator is involved in obtaining a participant's consent, it must be documented in the consent process. Required information includes, but is not limited to, the following:

- Language of interpretation (including sign language);
- The name of the interpreter;
- Any official translation status or accreditation of the interpreter;
- A declaration that the interpreter faithfully interpreted the document for the participant before the participant signed it and that the interpreter faithfully translated any surrounding discussion that took place to facilitate the participant's understanding of the study and their potential role and involvement, including the potential risks and benefits;
- The date of the interpretation; and
- The relationship, if any, between the interpreter and the participant.

Impartial Witness Signature

Under the International Conference on Harmonization, Good Clinical Practice (ICH GCP 2.8.10), where a participant cannot read (e.g., visually impaired, illiterate) or cannot read the presented consent form (e.g. English second language), the signature of an impartial witness independent of the trial must be obtained. The witness must be present for the consent process. The witness' signature reflects that they believe the consent information was accurately presented to and understood by the participant, and that consent was freely given by the participant.

In some circumstances, it is permissible that the translator also be the witness. However, this must be considered on a case-by-case basis. Please consult with the CHREB if you have any questions.

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Consent Process for Opting In/Opting Out of Sub-Studies

Consent must be free and voluntary for all aspects of the study. Any study provision that is not essential to the main study objective(s) (e.g., substudy(ies) must be clearly indicated as optional. The participants' consent to participate in those components must be sought. This may be done using check-boxes (i.e., yes/no) in the main consent, or having sub-study specific consent forms. Consent for participation in genetic sub-studies and tissue banking sub-studies as components of main studies should conform to the CHREB consent templates (TCPS2 interpretation, Chapter 3, Article 3.13).

Re-Consent

The TCPS2 asserts that consent to research participation is an ongoing requirement. Investigators must bring to participants' attention any materially relevant changes to the study that may affect them. These changes may have ethical implications, may be pertinent to their decision to continue research participation, or may be relevant to the circumstances of individual participants. Investigators shall disclose emergent changes to the risks or potential benefits of the research and give participants the opportunity to reconsider their consent considering new information, time commitments, and/or inconveniences.

In the case of materially relevant changes, Health Canada advises that participants be presented with any REB approved amended consent forms at their earliest visit to the clinical trial site and they be asked to renew their consent to participate as soon as possible. A participant should sign an amended consent form no later than their next scheduled visit, if possible.

Please note that there is a distinction between having to renew the consent of a participant and keeping the CHREB updated with current versions/forms. Typically, renewed consent of participants is not required for minor administrative changes. Nevertheless, all revised forms should be submitted to the CHREB for review. The CHREB will consider the need for formal re-consent.