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Guidance Document
Research Consent and Requests for Waiver of Consent

The Board requires that all investigators obtain the informed consent of all research participants as part of the conduct of their research. Investigators must also obtain the consent of research participants for access to and research use of personal health or other information collected initially for some other purpose. This default rule applies to the conduct of all research except where the Board has explicitly approved a waiver of the requirement for such consent. In all cases, it is the responsibility of the investigator to justify all requests for waiver of or delay in obtaining consent to research participation or research access to personal health information (Chapter 3, TCPS2).

Surrogate or Third Party Consent

The Board may approve research that involves unconscious individuals or those who lack capacity. In such cases, the Board must determine that the research cannot proceed without enrolling such participants and ensure that the research poses no more than minimal risk to participants or some demonstrable potential benefit. In such cases, the Board may approve enrollment of participants based on consent of the participant's authorized representative. Where a research participant may regain capacity at some point during the research, the Board will require the investigator to obtain his/her consent to continued participation in the research protocol. (Articles 3.9, 3.10, TCPS2)

Research Participants who are Minors: Consent/Assent

For research protocols involving the participation of minors (<18 yrs), the Board will typically require the consent of the parent or legal guardian for the minor's participation. Investigators should work to ensure that the minor/participant is informed about the research and has the opportunity to express assent to his/her participation as part of the consent process.

When a participant is enrolled in a study as a minor but reaches the age of majority during the research project, investigators should obtain the participant's consent to continued participation in the study at that point or as soon as possible thereafter (Article 3.10, TCPS2).

Consent to Research in Emergency/Urgent Circumstances

Research conducted in emergency or urgent circumstances sometimes requires time-limited implementation of research procedures. In such circumstances, a requirement for individual or surrogate consent may render the research impossible. The Board may approve enrolling research participants in such protocols without consent. The Board will make this determination

upon consideration of the importance of the research, the risks and benefits to the individual associated with the research, and the feasibility of obtaining individual or surrogate consent in the circumstance. Again, 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, consistent with Article 3.8 of the Tri-Council Policy Statement (TCPS 2).

Waiver of Consent for Research Access to Personal Health Information

Researchers must obtain the consent of patients for any secondary use of personal health information. This includes all prospective or retrospective chart reviews of patients who have been in care, including reviews of charts or other records to determine potential eligibility for a research protocol.

The Board may approve a waiver of consent for access to personal health information for research. In such cases, the investigator must formally request a waiver of consent and must demonstrate to the satisfaction of the Board 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. (*Health Information Act*, Section 50)

The onus is on the investigator to establish that these conditions are met, not on the Board to establish that they have not been met.

The circumstances that make obtaining consent unreasonable, impractical, or not feasible are matters of Board judgement in the individual case. In practice, the Board applies various criteria to make this determination. The numbers of research participants involved, for example, in large-scale epidemiologic research protocols, may make it a priori unreasonable or not practical to obtain the consent of individuals to the research. The Board also recognizes that research on conditions with a high mortality rate, where many of the research subjects may have died in the interval, or research on populations of patients who are frequently lost to follow up (for example, patients with chronic mental disorders) may meet the standard of unreasonableness or impracticality. Thus far, the Board has not employed an explicit criterion number of subjects or proportion of populations who may be unavailable for contact as grounds for its determinations. The Board does not accept as grounds for waiver of consent that the researcher may find it inconvenient to contact potential subjects for consent or that the researcher may feel that he/she does not have the human or fiscal resources to contact subjects. In all cases, the onus is on the investigator to establish that the required conditions for waiver of consent are met under the provisions of the Health Information Act, not on the Board to establish that they have not been met.

Oral/Written Consent

Under ordinary circumstances consent requires written consent signed and dated by the subject or the legal representative of the subject. If a researcher proposes not to obtain signed written

consent, the onus is on the researcher to provide the board with justification for the board to dispense with the requirement for consent to be written (Article 3.12, TCPS2).

Translators and Interpreters involvement in Consent

If an interpreter or translator is involved in obtaining a subject's consent that must be indicated in the consent form. The details must include but are 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 subject before the subject signed it and that the interpreter faithfully translated any surrounding discussion that took place to facilitate the subject's understanding of the study and their potential role and involvements, including the potential risks and benefits;
- The date of the interpretation; and
- The relationship, if any, between the interpreter and the subject.

Opting In/Opting Out Consent Processes

In order to make sure consent is free and voluntary for all aspects of the study, any provision which is not essential to the study design ("a sub-study") must clearly be indicated as an optional component and the subjects consent to participate in those components must be sought. Researchers are expected to clearly indicate whether a subject expressly needs to opt-out or opt-in. Use of additional headings and paragraphs in consent forms is appropriate for these purposes. Consent for participation in genetic sub-studies and tissue banking sub-studies as components of main studies should conform to the CHREB consent form templates. A researcher who wishes to incorporate these into a single main consent must explain the preference to the satisfaction of the board.

Culturally Sensitive Consent Processes

It is recognized and accepted by the board that certain cultural and community circumstances might make it inappropriate for researchers to employ the methods described above for obtaining consent. A researcher who believes the ordinary methods would be inappropriate must provide a written explanation to the board setting out their reasons together with their understanding of culturally appropriate alternative methods and any supporting documentation from the community or cultural group. The board will take these matters into consideration in its review process.