

Waiver of Consent – Impracticability and Other Considerations

Free and informed consent is a fundamental principal in the ethical conduct of research involving humans. But Canadian regulations and ethical guidelines acknowledge, under specific circumstances, it may be reasonable and appropriate to waive some or all of the elements of consent. To do so, it must be demonstrated to the REB that:

- (i) The research cannot be conducted without the use of the PHI
- (ii) PHI is strictly limited to that necessary to accomplish the research
- (iii) PHI is in the most de-identified form possible for the conduct of the research
- (iv) It must be used in a manner that ensures its confidentiality.
- (v) It is impracticable to obtain consent

Impracticability is an important concept in evaluating requests for waivers of consent in clinical research, but it is difficult to define with either precision or simplicity:

- The Nova Scotia Personal Health Information Act (PHIA) has described impracticability as a “degree of difficulty higher than inconvenience or impracticality but lower than impossibility.”
- The Department of Health and Wellness’ PHIA toolkit adds “undue hardship or onerousness that jeopardizes the conduct of the research.”
- Macquarie Dictionary: “not practicable: that cannot be put into practice with available means”
- The Merriam-Webster Dictionary: “not practicable: incapable of being performed or accomplished by the means employed or at command”

Regardless of the definition used, the REB can be guided by the PHIA toolkit which describes the intent of the legislation as ensuring that the researcher “consider and/or attempt all available means of requesting consent” (*PHIA Toolkit*). This guidance is key, but the examples given are neither exhaustive nor comprehensive and will not cover all the circumstances in which a waiver of consent may be requested. The REB will consider each.

The REB reviewer is therefore faced with the need to determine an individual contextual decision on “impracticability”, and in doing so must weigh carefully the opposing interest of the patient (potential research participant) in maintaining privacy and control over Personal Information (PI) and Personal Health Information (PHI), and the community’s interest in promoting what may be very valuable research.

The REB can provide ethical approval for access to personal information without consent when the REB is satisfied that it would be impracticable to require the researcher to obtain consent from involved individuals. In this context, these general factors should be taken into consideration:

- Is the research scientifically valid and likely to yield information truly important to clinical practice?
- How sensitive is the information to be gathered under this waiver? Would authorized disclosure of this

information constitute more than a minimal risk for the participant? For example, inspection of diagnostic indices by a researcher without any previous relationship to the patients, extracting contact details in order to offer individuals the opportunity to take part in a research project, and facilitating the appropriate full informed consent process must be considered in balance against the sensitivity of the diagnostic details in question.

- Would seeking consent for disclosure be likely to adversely affect the well-being (including psychological health) of the participants?
- Are there concrete and substantial obstacles rather than mere inconvenience to seeking out each potential participant to obtain consent?
- Is the target population for the research so great in number or scattered in place or time that finding each individual would so overwhelm available resources that the research would have to be abandoned?
- Are the barriers to contacting each individual participant so great as to impose fatal resource demands on the project budget? (Examples might include sheer size of the population; impossibility of regenerating lost contact details; passage of time meaning that a proportion of the participants may have died).
- Would financial and organizational costs of attempting to contact each potential participant be such as to make it impossible for the research to be done at all? (Assuming that the researchers have made every reasonable effort to amass the required resources)
- Is there intent on the part of the researcher to provide retrospective information to participants after participation?
- Would limitation of recruitment to those potential participants who can be easily contacted so bias the research as to make the project scientifically invalid?

References:

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3. *CIHR Best Practices for Protecting Privacy in Health Research*. Ottawa (ON): Canadian Institutes of Health Research; 2005. Available from: http://www.cihr-irsc.gc.ca/e/documents/et_pbp_nov05_sept2005_e.pdf
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