Fraser Health Research Ethics Board
Department of Evaluation and Research Services , FHA
400 – 13450 102 Avenue, Surrey, BC V3T 0H1
Phone: (604) 587-4436 Fax: (604) 930-5425

GUIDANCE NOTES ON CAPACITY TO CONSENT AND THE ASSENT PROCESS

INTRODUCTION

This document is intended to provide guidance on the assent process for research involving participants with diminished, diminishing, fluctuating, or developing capacity to consent. This document discusses considerations for determining capacity, requirements for obtaining assent and consent, and submission requirements to the FHREB for research involving participants with diminished, diminishing, fluctuating, or developing capacity to consent.

GUIDANCE NOTE #1: DECISION-MAKING CAPACITY

Decision-making capacity refers to the ability of prospective participants to understand relevant information presented about a research project and to appreciate the potential consequences of their decision to participate or not. Capacity is not static and may be diminished, diminishing, fluctuating, or developing. For instance, individuals with cognitive impairment may have diminished capacity, but may still be able to decide whether to participate in certain forms of research. Capacity to consent may vary depending on the complexity of the research project, the time at which the decision is being made, and numerous other factors.

Researchers are responsible for determining the capacity of potential participants to consent or assent to the research. Capacity should be assessed not only at the time of initial consent, but on an ongoing basis throughout the duration of the study. As such, researchers should have appropriate expertise with the populations they are researching to be able to assess capacity.

In the case of clinical interventional research, the determination of a potential participant's capacity to consent to research should align with the clinical determination of their capacity to consent to medical treatment. Researchers should also be aware of all legal or regulatory requirements that may impact determination of capacity to consent.

In keeping with the principle of fairness, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) recognizes that individuals who lack legal capacity to consent should not be inappropriately excluded from research. However, there are particular ethical considerations that must be addressed when a study seeks to involve individuals who do not have decision-making capacity in a study. Article 4.6 indicates states that the following criteria must be satisfied:

a) The research question can be addressed only with participants within the identified group; and

b) The research does not expose the participants to more than minimal risk without the prospect of direct benefits for them; and

c) Where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong.

In circumstances where potential participants do not have legal capacity to consent, an appropriate substitute decision-maker can consent on behalf of the participant. However, if the participant does not have capacity to consent but can still understand the significance of the research, researchers should obtain assent from such prospective participants in addition to substituted decision-maker consent.

Researchers are strongly encouraged to review Articles 3.9, 3.10, 3.11, and 4.6 of the TCPS 2.

GUIDANCE NOTE #2: CONDITIONS FOR RESEARCH WITH INDIVIDUALS WHO LACK CAPACITY

Researchers conducting research with adults who have diminishing or fluctuating capacity must describe how they will satisfy the conditions listed in Article 3.9 of the TCPS 2:

a) The researcher involves participants who lack the capacity to decide on their own behalf to the greatest extent possible in the decision-making process.

b) The researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned.

c) The authorized third party is not the researcher or any other member of the research team.

d) The researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the participation in research.

e) When authorization for participation was granted by an authorized third party, and a participant acquires or regains decision-making capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation.

GUIDANCE NOTE #3: ASSENT

In some circumstances, potential participants who have diminished, diminishing, fluctuating, or developing capacity to consent may still be able to understand the nature and consequences of the research. The TCPS 2 requires that the researcher involve such participants to the greatest extent possible in the decision-making process. Assent refers to the agreement of potential participants who do not have legal capacity to consent with the consent of their substitute decision-maker.

Assent may be expressed in various ways, such as verbally or physically. A participant's assent is not sufficient to permit them in the research in the absence of consent by a substitute decision-maker, however an expression of dissent will preclude their participation.

As with the consent process, assent should follow a face-to-face discussion with the Principal Investigator in which the participant has the opportunity to ask questions.

3.1 Assent Forms

In some instances, assent forms may be an appropriate means of documenting assent. For example, children who do not have capacity to consent but may still understand the nature and consequences of the study can be provided with an assent form to assist with the assent process.

An assent form must not be merely a bureaucratic device, but rather part of a meaningful process of seeking assent that describes the aims and procedures of the research using concepts and terms that are developmentally and cognitively appropriate. Assent forms should be as brief as reasonably possible.

Researchers are encouraged to consult the FHREB's assent form templates.

GUIDANCE NOTE #4: REQUIREMENT FOR REVIEW

Researchers proposing to conduct research with participants who may have diminished, diminishing, fluctuating, or developing capacity should clearly detail the following in their protocol:

1. The basis for determining potential participant's capacity to consent and/or assent;
2. How assent will be documented;
3. Who will administer the assent process, including what relationship that person has to the potential participant;
4. How prospective participants who neither clearly assent or dissent will be handled;
5. How substitute decision-maker consent will be obtained and documented; and
6. How consent will be obtained from participants who acquire or regain decision-making capacity during the course of the research.

All documents relating to the consent and assent processes should be submitted to the FHREB for review, including (as applicable):

1. Consent forms
2. Assent forms
3. Scripts for verbal consent/assent
4. Translated versions of consent/assent forms (these may be submitted to the FHREB as an acknowledgment request along with the translator's certificate of authenticity following the initial FHREB approval)

All documents must be clearly labelled with a version number and date. For specific guidance on the required content of consent and assent forms, please refer to the consent form templates on the FHREB website.

GUIDANCE NOTE #5: SUBSTITUTE DECISION-MAKERS

A substitute decision-maker, also known as an "authorized third party", refers to any person with the necessary legal authority to make decisions on behalf of an individual who lacks capacity to decide whether to participate or continue participating in a research project.

In accordance with Article 3.9 of the TCPS 2, substitute decision-makers should base their decision on their knowledge of the prospective participants and consideration for the prospective participant's welfare. Substitute decision-makers should not be in a position of conflict of interest when making their decision. Researchers and research team members are not permitted to be substitute decision-makers.

Substitute decision-makers should take into account any research directives about a potential participant's preferences.

GUIDANCE NOTE #6: CHILDREN

In accordance with the TCPS 2, the determination of whether children can consent to research should be based on their decision-making capacity rather than their age. While the age of majority in British Columbia is 19, minors may be able to consent to research if they have the capacity to understand the significance of the research as well as the risks and benefits.

In some circumstances, it may be necessary to obtain parental consent for a child's participation in a study even when the child has capacity to consent. For example, certain school boards may have requirements for parental consent for studies conducted within their schools. In these circumstances, researchers should seek consent from both the child in addition to the parents/legal guardians.

In other circumstances, informing parents about a capable child's participation in a study may be inappropriate or harmful, particularly with respect to studies addressing sensitive subjects. Researchers must consider the specific nature and context of the research in determining the appropriate communications with a child's parents.

Researchers conducting longitudinal studies with children should have a plan for ongoing assessment of capacity and consent/assent. Children who develop capacity to consent during the course of the study should be given the opportunity to consent for their continued participation as soon as possible. Similarly, infants and young children who were unable to provide initial assent should be given the opportunity to assent as soon as they develop the capacity to do so.