

# Guidelines for the Recruitment of Incompetent Subjects

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## Research involving incompetent subjects

The Tri-Council Policy Statement on Ethical Conduct of Research Involving Human Subjects refers to an ethical duty to allow those who are incompetent to consent to participate in research “which is potentially beneficial to them as individuals, or to the group that they represent.” (Article 3.9)

There are, however, some legal issues which must be borne in mind when contemplating participation in research by subjects who are not competent to consent. Research protocols might refer to the need to obtain consent from the potential subject’s “legally accepted representative” and/ or their caregiver. It might not be clear, however, that the meaning of “legally accepted representative” varies, and is not identical in all jurisdictions. In addition, in some, but not all, cases the caregiver and the legally accepted representative may be the same person. What follows is a brief explanation of some of the legal issues around incompetent subjects and consent to research in Alberta.

*This document does not constitute legal advice.*

Most adults are competent to make their own decisions about whether or not to participate in health research, and consent must be sought from the individual subject. Where the picture becomes somewhat less clear, however, is where the potential subject’s mental health has deteriorated to the point where there are significant doubts about the individual’s ability to make such decisions for him or herself. As a general rule, unless a substitute decision-maker has been appointed by the courts (a guardian, appointed under the *Dependent Adults Act*) or the individual him or herself (an agent under the *Personal Directives Act*), then there is no “legally accepted representative” for that person. In the clinical context, the individual’s family members are generally consulted as the need to make health care decisions arises, but these individuals, unless they are either the person’s court-appointed guardian or PDA-appointed agent, do not have legal capacity to provide or withhold consent.

In the research context, the issues are still more complex. A guardian appointed under the DAA is permitted to make decisions only in respect of matters specified in the guardianship order. One of the matters relating to which a guardian may exercise authority, provided that this is specified in the order, is “to consent to any health care that is in the best interests of the dependent adult” (s.10(3)(h)). There is no mention in the Act of a guardian’s authority to consent to participation in research, although arguably, a guardian who has the authority to consent health care that is in the best interests of the dependent adult also has the authority to consent to participation in research with potential benefit to the dependent adult. What amounts to potential benefit is of course subject to interpretation, but could include either the possibility of benefit from the study drug itself, or from participating in the research itself.

Where an individual has appointed an agent in their Personal Directive, that agent is the substitute decision-maker for all personal decisions (subject to any limitations set out in the Directive itself). Even where someone has appointed an agent pursuant to their personal directive, however, unless they specify, via clear instructions, that the agent may make decisions relating to their participation in “research or experimental activities, if the participation offers little or no potential benefit to the maker”, then the agent has no authority to consent to such research (s.15(d)). The agent would, however, be able to consent to research that provides a potential benefit to the subject.

In cases where the subject’s caregiver is not the same person as the substitute decision-maker, then the consent of the caregiver is neither necessary nor sufficient for valid consent. There may be value in directing the caregiver’s attention to the importance of their role in assisting the subject to participate, but unless they themselves are a research subject (ie. part of the purpose of the study is to collect personal information about the caregiver), then their consent need not be obtained.