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Reconsenting paediatric research participants for use of identifying data

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ABSTRACT

When a minor research participant reaches the age of majority or the level of maturity necessary to be granted legal decision-making capacity, reconsent can be required for ongoing participation in research or use of health information and banked biological materials. Despite potential logistical concerns with implementation and ethical questions about the trade-offs between maximising respect for participant agency and facilitating research that may generate benefits, reconsent is the approach most consistent with both law and research ethics.

Canadian common law consent requirements are expansive and likely compel reconsent on obtaining capacity. Common law doctrine recognises that children are entitled to decision-making authority that reflects their evolving intelligence and understanding. Health consent legislation varies by province but generally either compels reconsent on obtaining capacity or delegates the ability to determine reconsent to research ethics boards. These boards largely rely on the Canada's national ethics policy, the Tri-Council Policy Statement, which states that, with few exceptions, reconsent for continued participation is required when minors gain capacity that would allow them to consent to the research in which they participate. A strict interpretation of this policy could require researchers to perform frequent capacity assessments, potentially presenting feasibility concerns. In addition, Canadian policy and law are generally consistent with the core principles of key international ethical standards from the United Nations and elsewhere.

In sum, reconsent of paediatric participants upon obtaining capacity should be explicit and informed in Canada, and should not be presumed from continued participation alone.

INTRODUCTION

Long-term cohort studies are powerful health research platforms.[1 2] Paediatric cohort studies, for example, have provided helpful insights about human development and paediatric diseases and disorders.[3] However, paediatric cohorts are also associated with a range of legal and ethical challenges.

One significant concern is the question of reconsent. Minors often lack legal decision-making capacity and, as a result, participate in health research without providing informed consent, which is typically given by a parent or guardian. When a minor participant reaches the age of majority or, depending on the jurisdiction, the level of maturity necessary to be granted legal decision-making capacity, reconsent could be required for ongoing participation in research or use of health information or banked biological materials. Informed consent is a key pillar of international research ethics policy.[4] The question of when an individual is competent to give, withhold or change their consent should be considered throughout the research process. Here, we analyse the relevant law and research ethics policy relating to reconsent for paediatric health research and related biobanking in Canada.

REASONS TO RECONSENT

Many have suggested that reconsent is necessary and/or best practice when a paediatric research participant obtains capacity.[5–10] Some note, for example, that children must be reconsented because they 'should be given the opportunity to develop their own autonomy' and to 'express their values'.[10] Likewise, participants should be able to decide whether to accept ongoing or additional risks, such as emerging or intensifying privacy concerns (especially given new technologies that can be used to reidentify anonymised data).[11–14] Various possible forms of recontact policies have been noted, ranging from thin 'opt-out' (participants can withdraw but are not actively recontacted) to strict 'opt-in' (samples and data are destroyed if recontacted participants with capacity do not reconfirm their consent).[15]

Reconsenting is the approach most consistent with both law and research ethics. Brothers *et al* present, among other arguments, the idea that when a research activity 'continues after the participant reaches the age of majority, the authorisation for participation must be updated. This is because the person legally empowered to authorise participation has changed, from the parent to the young adult participant'.[16] Some have also argued that researchers and clinicians play a 'surrogate 'guardian' role' in paediatric research, because it is possible that guardians may make decisions that are counter to the participant's best interests.[17] A requirement to recontact participants when they obtain capacity would flow from this framing of relationships, as recontact respects the participant's emergent capacity and autonomy.

The initial consent provided by the parent(s) or guardian may have also included ethically and/or legally challenging decisions that competent minors should have the right to revisit. For example, if a broad consent was used for participation—a mode of consent that continues to stir controversy[18 19]—it is clear that a now autonomous decision-maker should be able to revisit the scope of that consent. This seems equally true for decisions about the return of incidental findings, another topic that has

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divided scholars.[20] Decisions made about the return of results at the time of initial consent can pose a potential conflict between 'the current or future desires of the child and those of the parents'.[17]

DEBATES ABOUT COST AND HARM TO RESEARCH

Despite the existing legal and ethical foundation, there remains controversy about whether minor research participants must or should be recontacted and reconsented when they obtain capacity. Opposition stems mostly from practical concerns rather than arguments grounded in consent law or research ethics. Some argue, for example, that recontact policies can be unnecessarily onerous and introduce selection bias if those who grant reconsent are a materially different population from those who do not.[21] Even proponents of recontacting note significant concern around the costs and feasibility of recontact.[9]

That said, new online tools and technologies may provide much more efficient and inexpensive avenues to complete recontact where it is required, decreasing the merit of these objections.[18] Some have argued that 'intuitively, it seems odd that a one-time sample donor remains a subject indefinitely'.[22] Given the burdens recontact can place on researchers and the research process, some argue that recontact should only be required if there is an 'important ethical justification for imposing it'.[22] Such thinking does not necessarily accord with key international research ethics standards like the World Medical Association's Helsinki Declaration on Ethical Principles for Medical Research Involving Human Subjects, which states that the goal to generate new knowledge 'can never take precedence over the rights and interests of individual research subjects'.[4 23]

There are other practical and scientific concerns associated with reconsenting. For example, a reconsent process in paediatric cohort research might result in the withdrawal of some participants such that it compromises the scientific usefulness of cohort data.[24] In addition, when a guardian consent is overridden by a mature minor it might create personal or family conflict.[24] And there is the issue of establishing a fair and efficient system for determining minor participants' legal capacity to consent, which we will see is not always based on age but rather on an assessment of mental maturity.[24] For some research, organising capacity assessments could be onerous. Though these issues are longstanding, none of them seem a justification—from either a legal or ethical perspective—for overriding the clear right of an autonomous individual with capacity to consent to participation in research.

Ultimately, the locus of bioethical controversy around the need to reconsent mature paediatric participants is in the trade-off between maximising respect for participant agency and minimising barriers to the advancement and completion of research that may or may not ultimately benefit the population to which participants belong. Though research is likely in aggregate and over time to provide significant benefits, this is not guaranteed on a study-by-study basis, and research ethics and consent law exist in part to prevent the erosion of rights in the name of unproven assumptions that the ends will justify the means. Regardless of these ethical controversies, as we will see below, existing law and policy does not always provide flexibility to engage in case-by-case consideration of these competing interests.

CANADIAN LAW

In Canada, the common law—that is, case law—is binding to the extent that it is not replaced or overridden by legislation. And the common law is key to understanding the issue of reconsent for minors. In Canada, the common law requires informed consent for medical research from participants with capacity, or guardians or substitute decision-makers on behalf of participants who do not have capacity.[25–27] The duty of disclosure in a clinical context is quite expansive and includes anything a reasonable person in the patient's position would want to know.[27] Defining capacity involves combining professional medical judgment with legal principles; the Canadian Medical Protective Association defines a patient's capacity to consent in a clinical context as understanding the nature of the proposed investigation or treatment, the anticipated effects of the proposed treatment and alternatives and the consequences for refusing treatment.[28]

Most relevant law relating to informed consent flows from the clinical context rather than from situations involving research. But the relevant case law that is available sets an even higher standard for obtaining informed consent for research participation.[29] It requires 'full and frank disclosure' of all relevant facts, probabilities and opinions that a reasonable person might be expected to consider before giving consent.[29] While the lack of research-focused case law injects a degree of uncertainty, it is hard to see how an interpretation of the existing jurisprudence would not embrace the view that reasonable participants who just obtained capacity would wish to have a say in continued participation in research that began when they were children.

The common law also addresses when a child is considered competent to consent. Under Canadian common law, there is no specific age of consent. In the healthcare context, consent from a minor is both necessary and sufficient if the minor is deemed competent. The doctrine of the 'mature minor'[30–32] recognises 'that children are entitled to a degree of decision-making autonomy that is reflective of their evolving intelligence and understanding'.[33] This likely applies to the research context.

In other words, regardless of age, capable adolescents can make decisions relating to medical treatment and research. However, mature minors' rights to autonomy and independent decision-making must be balanced against the common law welfare principle 'parens patriae' that requires the state to preserve the life and health of children.[33 34] As such, the application of the mature minor doctrine must be considered on a case-by-case basis, especially in circumstances where the research poses a significant risk to a child (a clinical example of this being where a minor attempts to refuse life-saving medical treatment).[33]

As noted, statutes layer further complexity onto determinations of capacity and reconsent. Since healthcare is largely within provincial jurisdiction, there is variation in standards across Canada. While several provinces have legislation setting requirements for informed consent for medical treatment, only British Columbia's *Healthcare (Consent) and Care Facility (Admission) Act* is clearly applicable to medical research where the goal is not primarily therapeutic.[35] Other similar statutes expressly exclude research from application or omit it from the definition of 'treatment' in relation to which the regulatory consent rights and requirements flow.[36 37]

Most provinces deal with informed consent for research largely through statutory provisions in health information legislation, and typically by offloading onto research ethics boards (REBs) the responsibility for determining both the need for informed consent and alternative protections when a waiver of consent is approved.[38–42] That is to say, in the provinces that rely on REB review, bypassing recontact may be permissible. However, certain requirements must be met, such as that it is unreasonable or impractical to obtain consent and that the research cannot be performed with deidentified data.[38 39 41 42] Since what is deemed

unreasonable and impractical is typically stated to be based on the opinion of the REB instead of being concretely defined in the legislation, these provisions leave an opening for the noted issues around cost and logistics of recontact to be used as a justification for REB-approved waiver of recontact. Indeed, the reliance on REBs means that, in Canada, we must turn to research ethics policy to better understand recontact requirements in most provinces.

CANADIAN RESEARCH ETHICS POLICY

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) is Canada's primary research ethics policy,[43] and compliance with it, as determined by the relevant REB, is required for federal funding. The TCPS2 requires that consent must be an 'ongoing process' (article 3.3) and notes that when minors gain a degree of maturity that would allow them to be competent to consent on their own, 'the researcher must seek the children's autonomous consent in order for their participation to continue'.[43] This research ethics policy is consistent with most Canadian legislation and jurisprudence.[44]

The TCPS2 states that the determination of capacity is not static but 'a process that may change over time'.[43] A capacity assessment involves 'determining, at a particular point in time, whether a participant (or prospective participant) sufficiently understands the nature of a particular research project, and the risks, consequences and potential benefits associated with it'.[43] Indeed, it is made clear that a potential participant may 'have diminished capacity in some respects but still be able to decide whether to participate in certain types of research'.[43] A strict interpretation of this guideline suggests a need for researchers to be in near constant contact with paediatric participants to assess and reassess their capacity, regardless of the type of research.

The TCPS2 also requires that voluntariness be maintained by ensuring participants are 'free to withdraw their consent to participate in the research at any time' and without reason.[43] This buttresses the obligation to recontact when legal authority changes as researchers should reaffirm that participation is voluntary and that rights of withdrawal are clearly understood. (Without reconsenting, how would this be assured?) In addition, consent from participants for secondary use of identifiable information can only be waived if it is 'impossible or impracticable' to seek consent.[43] Use of non-identifiable information does not require consent so it is not relevant here,[43] though the concept of non-identifiability is becoming increasingly tenuous, as we have explored elsewhere.[14]

The provisions noted above from the TCPS2, which guides REBs that have been granted legal decision-making authority to determine waivers of consent under most provinces' health information legislation, mean that in much of Canada,[38–42] mature minors must be reconsented unless an REB grants a waiver—which, given the language of the TCPS, should only rarely happen when specific conditions are satisfied.

INTERNATIONAL LAW AND POLICY

While Canada's reconsent law and policy are fairly clear, in other jurisdictions there is some variation with respect to the rights afforded to minors.[45] In the USA, for example, research consent requirements are set out in the regulation often referred to as the Revised Common Rule.[46–49] The Revised Common Rule allows for the use of broad consent—as opposed to specific consent—for future secondary research, but 'only with respect to the storage, maintenance and secondary research uses of identifiable private information and identifiable biospecimens'.[46] However, where samples and data are effectively de-identified (anonymised), the regulatory definition of human subject research is not met and recontact is not required on age of majority,[50 51] unless an REB determines technological advancements in reidentification allow the identity to 'readily be ascertained'.[52] Guidance from the United States' Office for Human Research Protections suggests reconsent at age of majority for continued use of identified paediatric samples is obligatory unless an REB grants a waiver of this requirement.[51]

A number of international policies are also relevant here. The United Nations Convention on the Rights of the Child states that 'Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child'.[53] Moreover, the Organization for Economic Co-Operation and Development's Guidelines on Human Biobanks and Genetic Research Databases 'specifically state that consent for continued sample storage and use should be obtained from minors once they gain the capacity to decide according to applicable law or ethical principles'.[54 55] While such guidelines are not necessarily binding on courts or REBs, they stand as powerful statements of international norms that further buttress the conclusion that reconsent is required from children who obtain capacity.

CONCLUSIONS

In Canada, continued participation in ongoing research by an individual who has newly obtained capacity requires reconsent. Interventions, new clinical data collection or even continued analysis of existing and linked data should not occur without a competent participant's consent. In paediatric cohort research there is often periodical and ongoing contact, but an explicit and informed reconsent should occur when the participant obtains capacity, and should not be presumed from continued participation alone. In addition, reconsent on obtaining capacity is generally required for use of identifiable samples and data in Canada, except where a waiver of reconsent is provided by an REB. Canada is arguably a leader in its protection of paediatric research participants' rights as there are strong and consistent policies and legal norms that favour ongoing consent and reconsent, such as those found in legislation, common law and the TCPS2.

While there is little policy or law that directly addresses reconsent in the context of paediatric cohort research, applicable guidance from policy and case law strongly suggests that reconsent will usually be required. Still, more direct policy guidance would be useful. Such guidance could help to clarify for researchers when reconsent of maturing paediatric cohort participants is required and how to minimise practical concerns, such as the ongoing need to assess participant capacity. Given the growing value of cohort studies, national clarity on the requirements of reconsenting would help researchers, REBs, and most importantly, research participants.

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