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Memo

To: Pediatric Clinical Trial Sites

From: Ontario Cancer Research Ethics Board (OCREB)

Date: June 10, 2026

RE: Change in Consenting Practices for Paediatric Clinical Trials

Purpose:

This memo outlines a change in consenting practice effective July 15, 2026. This change is to align with other paediatric trials, the TCPS2 and to reflect current thinking on team-based consenting.

Change in Consenting Practice for Paediatric Clinical Trials:

Treating physicians who are also study investigators may continue to explain the study and procedures to potential participants under their care to support informed consent.

This process must now also include a neutral person, who is appropriately trained, is outside of the potential participant's circle of care and is formally delegated on the site's delegation log (e.g. research coordinator) who obtains written consent (and assent as needed) from a participant/Substitute Decision Maker (SDM).

This memo also outlines the procedures required when, in extreme and extenuating circumstances, the treating physician obtains written consent from a potential participant under their care.

Rationale for the change:

a) Having a neutral person involved in obtaining consent can help to limit undue influence and role conflict with physician/investigator and potential study participant, ensure voluntariness, and reduce therapeutic misconception (TCPS2 Chapter 3 Article 3.1, 2022; Morain, Joffe & Largent, 2019; Wilfond & Porter, 2019).
b) Team based strategies for consenting, where the treating physician explains the study and then a neutral person is also involved in obtaining consent can help to

overcome concerns associated with investigator/physician consenting. This approach can also enhance receptivity to the trial and support informed decision making (Morain et al., 2023; Gutmann Koch & Sawicki, 2019; Kraft & Garrison, 2019).

c) This change ensures that consenting procedures align across adult and paediatric populations and reflect the TCPS 2 guidelines and principles.
d) This change will apply to studies that are currently open to enrollment (for initial consenting) and for ongoing studies that are submitting amendments with consent revisions (for re-consenting of current participants).

Extenuating circumstances:

In certain clinical situations, the time required to use a neutral person in obtaining written consent could pose risks to the potential participant. If it is unsafe or there is imminent risk of harm from waiting for a neutral person in the consenting(e.g. middle of the night), the treating physician may obtain written consent without the neutral person. A consent verification process to confirm initial and ongoing consent for study participation must be conducted by a neutral person on the next feasible day. Assent from the participant must also be obtained, if applicable.

Implementation/Next steps:

For studies currently open to enrollment:

While sites would ordinarily be expected to submit a Participating Site Amendment (PSAM) to update the initial application for this process change, OCREB is mindful of the administrative burden this will cause. To mitigate this, OCREB will work with sites to simplify the process while maintaining oversight.

For new study submissions:

Participating Site Initial Applications must reflect the consenting procedures described above.

References

T*ri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022). Chapter 3. Retrieved from https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html January 8, 2026.*

Grady, C. (2019). A Hybrid Approach to Obtaining Research Consent. *American Journal of Bioethics, 19*(4). P.28-30. doi-10.1080/15265161.2019.1574493

Gutmann Koch, V., & Sawicki, N. N. (2019). Everything in Moderation: Dual Role Consent and State Law Mandates. *American Journal of Bioethics*, *19*(4), 35–37. doi-10.1080/15265161.2019.1572814

Kraft, S. A., & Garrison, N. A. (2019). An Ethical Case for Dual-Role Consent: Increasing Research Diversity as a Matter of Respect and Justice. American Journal of Bioethics, 19(4), 44–46. https://0-doi-10.1080/15265161.2019.1572816

Morain, S. R., Barlevy, D., Joffe, S., & Largent, E.A. (2023). Physician-Investigator, Research Coordinator, and Patient Perspectives on Dual-Role Consent in Oncology: A Qualitative Study. *JAMA Netw Open,* 6(7):e2325477. doi:10.1001/jamanetworkopen.2023.25477

Morain, S. R., Joffe, S., & Largent, E. A. (2019). When Is It Ethical for Physician-Investigators to Seek Consent From Their Own Patients? *The American Journal of Bioethics : AJOB*, *19*(4), 11–18. https://doi.org/10.1080/15265161.2019.1572811

Wilfond, B. S., & Porter, K. M. (2019). Justifying Investigator/Clinician Consent When The Physician-Patient Relationship Can Support Better Research Decision-Making. *The American Journal of Bioethics*, *19*(4), 26–28. https://doi.org/10.1080/15265161.2019.1574496