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Canada's interim clinical trial policy: What sponsors and investigators need to know

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Health Canada's September 14, 2026 interim policy introduces flexibility in ethics reporting, investigator qualifications and informed consent for drug trials. It does not bring the proposed Clinical Trials Regulations into force. Sponsors remain responsible for good clinical practice and applicable ethical, legal and institutional requirements.[1]

Streamlining ethics reporting

For sites using coordinated ethics review, sponsors may omit repeated research ethics board (REB) contact details from the Clinical Trial Site Information form when the same board has already approved other sites in that trial and its previously submitted details remain current. The board's name and approval date are still reported.[2] Sponsors must retain evidence of all required site approvals, including signed and dated REB attestations, for inspection.[1]

Broadening investigator eligibility

The policy permits investigators whose education, training and experience qualify them to conduct the trial, even if they are not physicians or dentists. Where an investigator is not a physician or dentist, medical decisions outside their licensed scope must be made by a qualified physician or dentist on the trial team, licensed in the site's province or territory and responsible for medical oversight and participant care.[2] Sponsors should document both investigator competence and medical oversight arrangements.[1]

Documenting informed consent

The policy recognizes remote discussions, electronic signatures and documented oral consent, provided the process meets good clinical practice and applicable consent laws.[1] TCPS 2 describes consent as voluntary, informed and ongoing. Researchers should provide understandable information, allow questions and document how consent was established; collecting a signature alone does not demonstrate understanding.[3]

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Applying the policy at a new site

Consider a hypothetical drug trial adding a site whose investigator is neither a physician nor a dentist, with consent obtained remotely. Before opening, the sponsor could use the questions below to test its procedures. The review should establish who is accountable for each decision and where supporting records are kept.

Area	Practical review question
Ethics	Do approval records cover this site and its consent process?
Oversight	Who makes medical decisions, and how can site staff reach them?
Consent	How will staff assess understanding and record the participant's decision?

These checks translate policy flexibility into assigned responsibilities and verifiable records. Teams should resolve gaps before enrolment and revisit arrangements when personnel, procedures or consent information change.

References

1. Health Canada. Interim policy for the modernization of the clinical trial framework. September 14, 2026.

2. Health Canada. Instructions for completing the Clinical Trial Site Information Form. September 14, 2026.

3. TCPS 2 (2022). Chapter 3. The Consent Process. Articles 3.1-3.3 and 3.12.

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