

CONJOINT HEALTH RESEARCH ETHICS BOARD (CHREB)

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ClinicalTrials.gov Registration Temporarily Unavailable

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The National Institute of Health has posted a notice on the ClinicalTrials.gov website to indicate that due to a lapse in U.S. government funding, information on the <u>ClinicalTrials.gov</u> website and registry may not be up to date, and the agency may not be able to respond to inquiries in a timely manner. Researchers are unable to register new trials on the registry.

While the trial remains offline, this will impact research teams planning to initiate recruitment into a clinical trial.

Public registration of clinical trials is a regulatory and ethical requirement. In Canada, this is mandated by:

- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), which states, "All clinical trials shall be registered before recruitment of the first trial participant in a publicly accessible registry that is acceptable to the World Health Organization (WHO) or the International Committee of Medical Journal Editors (ICMJE).... Researchers shall provide the REB with evidence of registration (e.g., registration number)." (TCPS2, Ch. 11.10)
- Health Canada's <u>guidance on public disclosure of clinical trial results</u>, which states, "Sponsors should register their Health Canada-authorized clinical trials with a clinical trial registry that complies with WHO international standards."
- <u>CIHR's Policy Guide</u>, which states, "clinical trials must be registered in a publicly available, free to access, searchable clinical trial registry complying with WHO's international agreed standards before the first visit of the first participant"

Researchers should be aware that registries may have specific criteria or priorities to comply with. Researchers aiming to launch recruitment during this period are advised to consult with the <u>University of Calgary's Clinical Trials Office</u> at the Calgary Centre for Clinical Research (<u>cccr@ucalgary.ca</u>)