CIHR Policy Guide - Requirements for Registration and Disclosure of Results from Clinical Trials

Introduction and background

In October 2020, CIHR joined some of the world's largest funders of health research and international non-governmental organizations by signing the World Health Organization's Joint Statement on Public Disclosure of Results from Clinical Trials ("WHO Joint Statement"). By aligning with international best practices for clinical trial reporting, CIHR is proud to demonstrate its ongoing commitment to advance open science and research excellence.

Improving the timely disclosure of clinical trial results will increase value and efficiency in the use of research funds, reduce reporting biases and waste in research, and contribute to better decision-making in health. CIHR's signing of the WHO Joint Statement affirms the agency's commitment to improving transparency and reducing publication biases in the Canadian health research enterprise by ensuring clinical research findings are available to those who can benefit from and build upon them.

Accordingly, CIHR endorses all the requirements of the WHO Joint Statement to ensure ethical and quality standards in clinical trial research and has updated the requirements for CIHR funded clinical trials, as outlined below.

The implementation of these new policy requirements and an associated monitoring plan for CIHR's role as signatory to the WHO Joint Statement is a year-one commitment within CIHR's Strategic Plan Action Plan. As such, successful implementation of this Statement will contribute to the achievement of CIHR's 10-year vision for Advancing Research Excellence in all its Diversity that "Canadian health research will be internationally recognized as inclusive, collaborative, transparent, culturally safe, and focused on real world impact."

Requirements for CIHR-funded clinical trial researchers

In accordance with existing tri-agency policies (Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans (TCPS2), the Tri-Agency Responsible Conduct of Research Framework and the Tri-Agency Open Access Policy on Publications):

- **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

The following new requirements apply to all clinical trial grants funded **on or after January 1, 2022:**

- Public disclosure of results must be done within a mandated time frame:
    - publications describing clinical trial results must be **open access from the date of publication**;
    - **summary results must be publicly available within 12 months** from the last visit of the last participant (for collection of data on the primary outcome); and
- All study publications must include the registration number/Trial ID (to be specified in the article summary/abstract).

Nominated Principal Investigators receiving CIHR grant funds for clinical trial research after January 1, 2022, must comply with the above requirements in order to remain eligible for any new CIHR funding.

Monitoring & Reporting

CIHR will monitor compliance with these policy requirements on an annual basis, by asking impacted researchers to provide clinical trial registration identifiers, and links to summary results and open access publications.

CIHR is committed to working with researchers in support of achieving compliance. While individual circumstances may be taken into consideration when interpreting compliance, **the conduct of activities that purposely contravene clinical trial policy will result in the withholding of new CIHR funds until outstanding requirements have been met**.

CIHR will annually publish aggregated data indicating the degree of compliance with these requirements.

Additional information is available within the Frequently Asked Questions.

Please direct all inquiries related to these policy guidelines to the CIHR Contact Centre.