Subject:

Clinical Trial Registration During U.S. Government Shutdown

Message:

The University of British Columbia (UBC) is aware that registration of clinical trials on <u>ClinicalTrials.gov</u> are currently impacted by the United States government shutdown.

UBC Research Ethics Boards recognize the necessity to comply with CIHR as well as The International Committee of Medical Journal Editors (ICMJE) requirement for such registration. Given the extent of the circumstances of the U.S government shutdown, UBC suggest the following:

Researchers may use other registries to meet Canadian requirements. Current acceptable alternatives to ClinicalTrials.gov include:

Primary registries in the WHO registry network ICMJE approved registry

For researchers needing to comply with US Regulations, research teams who have initiated but cannot complete trial registration in <u>ClinicalTrials.gov</u> due to the shutdown may begin participant enrollment provided they retain clear documentation of attempted registration (e.g., screenshots, error messages, or email confirmations).

- 1. Attempt to initiate registration in ClinicalTrials.gov as per normal process.
- 2. Document any errors, access issues, or confirmation notices as evidence.
- 3. Maintain this documentation as a **Note-to-File*** in the Trial Master File (TMF) or Investigator Site File (ISF).

Once ClinicalTrials.gov functionality is restored, trial registration must be completed without delay, with records updated to reflect accurate enrollment dates.

Resources to follow:

CIHR Clinical trials registration and disclosure