

POLICY

Clinical Research in Non-Hospital Facilities

Purpose

This policy sets out the requirements for conducting clinical research in accredited non-hospital medical and surgical facilities.

Background

Clinical research is any study (trial) that involves the administration or testing of drugs, medical devices, medical imaging or diagnostic techniques, the taking of blood or other specimens, and/or the analysis of data obtained from physical interventions, medical records or clinical studies involving the linkage of data from existing databases.

CPSBC Bylaws under the *Health Professions and Occupations Act (HPOA)* Part 13.1 - Non-hospital Medical and Surgical Facilities Accreditation Program (NHMSFAP), Division 11 - Clinical trials outline the requirements for clinical trials in non-hospital facilities which are:

Division 11 - Clinical trials

Notice of proposed clinical trial

13-31 A medical director must provide written notice to the NHMSFAP Committee in the specified form at least 90 days prior to permitting a facility to conduct or participate in a clinical trial together with:

- (a) records that verify the clinical trial will be conducted under the oversight of a research ethics board acceptable to the NHMSFAP Committee,
- (b) information that verifies the procedure or technology to be used in the clinical trial falls within the scope of procedures and/or technology authorized by the facility's certificate of provisional or full accreditation, as applicable,
- (c) information that confirms the medical director has approved the privileges of the licensee(s) who will perform the clinical trial, and
- (d) such additional information or records the medical director is directed to provide.

Prohibition on conducting clinical trial

13-32 The NHMSFAP Committee may, in its discretion, deliver a notice to the medical director of a facility prohibiting the facility from conducting a proposed clinical trial if the written notice and/or supporting records and information do not comply with section 13-31 of these Bylaws.

Policy

Clinical trial review responsibilities

The **NHMSFAP Committee** is responsible for:

- Determining whether the procedure(s) or technology to be used in the clinical trial, as outlined in the study protocol, is appropriate for the non-hospital setting.
- Verifying that the procedure(s) or technology to be used in the clinical trial, as outlined in the study protocol, falls within the scope of procedures and/or technology authorized by the facility's certificate of accreditation.
- Verifying the completeness of the specified NHMSFAP clinical trial form and supporting documentation.
- Confirming the medical director has approved the privileges of named licensee(s) who will perform a procedure or use a technology at the non-hospital facility as part of the conduct of the clinical trial.

The **medical director** is responsible for:

- Ensuring that the clinical trial has been reviewed and approved by an institutional review board (IRB) or independent ethics committee (IEC) to ensure the ethical acceptability of the study (e.g., scientific merit, the protection of the rights, safety and well-being of study participants).
- Ensuring that the clinical trial procedure(s) or technology to be used are only conducted under current IRB/IEC approval (e.g., annual approval renewal, amendment approval) until such time as it no longer involves human participants and their research data.
- Ensuring that the licensee investigator(s) comply with the study protocol, monitor adverse events and obtain informed consent of the study participants.
- Ensuring that the clinical trial records and essential documents list the non-hospital facility as a study site, as required by the study sponsor and any legislation and/or regulation.
- Maintaining complete and accurate clinical trial records and essential documents for the conduct of the clinical trial (i.e., protocol and amendments, ethics approvals, curriculum vitae evidencing qualifications of the investigator(s)) as required by the applicable ethical and regulatory authorities. Review of these records and essential documents to verify completeness and accuracy is the responsibility of the study sponsor (i.e., the individual, company or organization managing the clinical trial).
- Ensuring compliance with the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guideline. "GCP is an international ethical and scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected and that clinical trial data are credible." This is also the responsibility of the licensee investigator(s), IRB/IEC, and study sponsor.

Clinical trial notification and supporting documentation

A medical director must provide written notification to the NHMSFAP Committee in the specified form at least 90 days prior to permitting a facility to conduct or participate in the clinical trial together with:

- current IRB/IEC approval of the clinical trial.
- clinical trial protocol (version and date, as approved by the ethics board)
- informed consent form (version and date, as approved by the ethics board).
- regulatory authority (or authorities) authorization/approval, where required (e.g., Health Canada letter of no objection) **or** a study sponsor letter confirming that Health Canada approval is not required.
- information on the clinical trial procedure(s) or technology to be used at the facility.
- information which confirms the licensee(s) who will perform the clinical trial procedure(s) or technology and the medical director's approval of the privileges of the named licensee(s) who will perform a procedure or use a technology at the non-hospital facility as part of the conduct of the clinical trial.
- additional information as directed (i.e., investigator's brochure, product monograph, reprocessing instructions).

Prohibition on conducting clinical trial

The NHMSFAP Committee may, in its discretion, deliver a notice to the medical director of a facility prohibiting the facility from conducting a proposed clinical trial if the written notice and/or supporting records and information do not comply with section 13-31 the Bylaws.

Clinical trial conduct

All research involving human participants and/or human biological materials requires approval by an institutional review board (IRB) or an independent ethics committee (IEC). The IRB or IEC must be one that complies with Health Canada's membership requirements for a research ethics board and function in a manner consistent with GCP.

Before any research involving human participants and/or human biological materials commences at the facility, a NHMSFAP Clinical Trial form must be submitted to the NHMSFAP Committee. Study-related activities are not to be performed until the facility has received written confirmation from the NHMSFAP Committee verifying that the procedure(s) or technology to be used in the clinical trial, as outlined in the study protocol, falls within the scope of procedures and/or technology authorized by the facility's certificate of accreditation and acknowledging the medical director's granting of privileges to named physician(s) to perform the procedure and/or technology at a non-hospital facility as part of the conduct of the clinical trial.

Study-related activities (e.g. procedures, blood work, follow-up assessment) may only be conducted under a valid research ethics board approval certificate.

When facility participation in the clinical research is complete, the medical director should inform the NHMSFAP Committee. Notification of study completion should occur when:

- There will be no further study participants undergoing a procedure and/or use of technology as part of the conduct of the clinical trial at the facility.
 - Applicable when facility participation involves only a procedure and/or use of technology encounter with the study participant (e.g. biopsy, surgery) and the ongoing data collection and participant follow up is the responsibility of another facility, office or hospital institution.
- Data collection from all study participants is complete.
 - Applicable when facility participation involves continued recruitment of and/or data collection from study participants (e.g. blood work, imaging, follow-up assessment).

References

1. Government of Canada. Clinical trials [Internet]. Ottawa: Government of Canada; 2009 [cited 2019 Jan 29].
2. Government of Canada, Health Canada. Guidance document: applications for medical device investigational testing authorizations [Internet]. Ottawa: Health Canada; 2018 [cited 2019 Jan 29].
3. Government of Canada, Health Canada, Health Products and Food Branch. Guidance document: good clinical practice: integrated addendum to E6(R1)ICH topic E6(R2) [Internet]. Ottawa: Health Canada; 2017 [cited 2019 Jan 30].
4. Health Canada. Notice - Interim implementation of International Council for Harmonisation (ICH) integrated addendum to ICH E6(R1): guideline for good clinical practice E6(R2) [Internet]. Ottawa: Health Canada; 2018 [cited 2019 Jan 29].
5. University of British Columbia, Office of Research Ethics. About human research ethics [Internet]. Vancouver: University of British Columbia; 2016 [cited 2019 Jan 30].
6. University of British Columbia, Office of Research Ethics. Clinical research ethics [Internet]. Vancouver: University of British Columbia; [cited 2019 Jan 30].
7. World Health Organization. Clinical trials [Internet]. Geneva: World Health Organization; 2019 [cited 2019 Jan 30].

Contact

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