College of Physicians and Surgeons of British Columbia

Position Statement

Clinical Research in Non-Hospital Facilities

DETAILS

Department/program: Non-Hospital Medical and Surgical Facilities Accreditation Program

Date: June 28, 2019

PURPOSE

Position statements from the College provide background information and express or clarify the College's intent on a particular matter. They are intended as guidance for stakeholders in areas where events are evolving or changing rapidly, the implementation of processes and procedures may be premature, the implementation of a guideline or standard may not be necessary, another credible body (i.e. professional association) has already established guidelines or standards, or it is timely to communicate the College's broad intent before or as policies and procedures are developed.

This document addresses 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.

Clinical research in non-hospital facilities may only be conducted under a properly constituted clinical trial with research ethics board oversight. Before any research involving human participants and/or human biological materials commences at a non-hospital facility, a NHMSFAP Clinical Trial Application form must be submitted to the NHMSFAP Committee.

POSITION

The Non-Hospital Medical and Surgical Facilities Accreditation Program (NHMSFAP) Committee is responsible for establishing accreditation standards, policies, rules, procedures and guidelines for the NHMSFAP to ensure the delivery of high-quality and safe services in the facility and for determining the medical, surgical, dental and anesthesia procedures that are appropriate for the non-hospital setting.

In accordance with section 5-17(2) of the Bylaws, a clinical trial may be conducted at a facility if:

(a) The investigative procedure is conducted under a properly constituted clinical trial with ethical oversight.

(b) There is no opportunity for the clinical trial to be conducted in an accredited hospital.

(c) The NHMSFAP Committee has approved the procedure to be performed in the facility under the clinical trial.

The NHMSFAP Committee recognizes that clinical research is important as it provides answers to scientific questions and leads to better ways to prevent, diagnose and treat health conditions and diseases. The NHMSFAP Committee also recognizes that the rights, safety and well-being of study participants need to be protected through appropriate ethical and regulatory oversight.

Clinical trial review responsibilities

The NHMSFAP Committee is responsible for the following:

- Determining whether the procedures, as outlined in the study protocol, are appropriate for the non-hospital setting.
- Verifying the completeness of the NHMSFAP clinical trial application.
- Acknowledging the medical director's recommendation for granting of privileges to a named physician(s) to perform a procedure at a non-hospital facility as part of the conduct of the clinical trial.

The medical director is responsible for the following:

- Determining that there is no opportunity for the clinical trial to be conducted in an accredited hospital.
- Ensuring that the clinical trial has been reviewed 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 physician investigator(s) comply with the study protocol, monitor adverse events and obtain informed consent of the study participants.
- 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 a responsibility of the physician investigator(s), IRB/IEC, and study sponsor.

NHMSFAP clinical trial application

The following constitutes a complete document submission and confirms the appropriate ethical and regulatory oversight:

- NHMSFAP Clinical Trial Application form
- Ethics board approval (and amendment, renewals as applicable)

- Study 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)

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 should 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, an NHMSFAP Clinical Trial Application form must be submitted to the NHMSFAP Committee. Study-related activities should not be performed until the facility has received written confirmation from the NHMSFAP Committee acknowledging the medical director's granting of privileges to a named physician(s) to perform a procedure 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 procedures at the facility.
    - Applicable when facility participation involves only a procedural encounter with the study participant (e.g. biopsy, surgery). 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

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CONTACT

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