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POLICY

Clinical Research in Independent Diagnostic Accreditation Program (DAP) Facilities

Purpose

The purpose of this policy is to clearly define the actions required by the facility medical director to ensure the notification of clinical trial and required documentation is received in a timely manner to facilitate a review by the DAP Committee.

The DAP Committee is responsible for establishing accreditation standards, policies, rules, procedures and guidelines for diagnostic facilities and for ensuring facility conformance with its standards, policies, rules, procedures and guidelines and with the College of Physicians and Surgeons of BC (CPSBC) Bylaws.

Policy

As per s section 13-68 of the CPSBC Bylaws:

(1) A medical director of an independent facility must provide written notice to the DAP Committee in the specified form at least 90 days prior to permitting an independent 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 DAP 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 or participate in the clinical trial, and
- (d) such additional information or records the medical director is directed to provide.

The following are not considered clinical trials:

- (a) the provision of tests or procedures that are standard of care, or

(b) the provision of testing or procedures for patients involved in clinical trials that originate outside of the independent facility.

Notification

Notification is provided using the notification of significant change process, along with the provision of the following:

1. current Institutional Review Board (IRB)/Independent Ethics Committee (IEC) approval of the clinical trial;
2. clinical trial protocol (version and date, as approved by the ethics board);
3. informed consent form (version and date, as approved by the ethics board);
4. 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;
5. information on the clinical trial procedure(s) or technology to be used at the facility;
6. 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; and,
7. additional information as directed (i.e. investigator's brochure, product monograph, reprocessing instructions).

Upon review of the submission, written notice will be provided to confirm if the clinical trial complies with the Bylaws, or if the trial does not comply with the Bylaws, a notice prohibiting the facility from conducting or participating in a proposed clinical trial.

The DAP Committee may, in its discretion, deliver a notice to the medical director of an independent facility prohibiting the facility from conducting or participating in a proposed clinical trial if the written notice and/or supporting records and information do not comply with this policy or section 13-68 of the Bylaws.

Definitions

Clinical trial

A research study involving human (including human biological specimen) participants that evaluates the safety and/or effectiveness of a new diagnostic test or intervention on health outcomes.[1]

This definition excludes trialing of diagnostic tests or interventions and associated equipment which are new to the facility but have been validated by research as a standard of care. However, notification may be required to under the *New Technologies* policy, or as an expansion of scope of service.

Independent facility

A facility which is not operated by, or subject to regulatory oversight of, a health authority.

Standard of care

The diagnostic test(s) currently recommended in best practice guidelines as providing the most diagnostic value for a given diagnostic need.

These practice guidelines are provided by provincial, national or international medical speciality associations after extensive peer review of available literature. These guidelines often form the day-to-day standard practice of independent diagnostic facilities and inform DAP standard development.

Examples may include:

- American Academy of Sleep Medicine
- Association for Diagnostics and Laboratory Medicine
- Association of Molecular Pathology
- Canadian Association of Radiologists

Health Canada (role in clinical trials)

Health Canada takes an active role in protecting the health of Canadians who take part in clinical trials[2] and provides federal regulatory guidelines for conducting such trials.

Various directorates[3] within Health Canada may be involved in approving clinical trials[4], when Health Canada approval is required, each of these directorates issue a "letter of no objection" after approving an application.

Responsibility

Role	Responsibility
Medical director	Advise the DAP of the intention to conduct or participate in a clinical trial which is originated by the independent facility's organisation and is not that standard of care. Prepare the required documentation as outlined in the **notification** section of this policy.
DAP Staff	Review notifications and submissions for completeness and requirements. Communicate with the medical directors the outcomes of reviews of notifications, submissions and DAP Committee decisions.
DAP Committee	For notifications requiring decision, make an accreditation decision regarding the commencement of the clinical trial.

References

1. Canadian Institutes of Health Research
2. Health Canada
3. Health Canada Medical Devices Directorate
4. University of Waterloo