Research Trial Submission and Approval Process

Research Trial Standards/Medical Directives

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Emergency Health Regulatory and Accountability Branch
Ministry of Health

Ontario

Document Control

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Document Purpose

This document outlines the process for the submission and approval of research trials to the Emergency Health Regulatory and Accountability Branch (EHRAB) of the Ministry of Health (MOH). Questions regarding the applicability of this process to specific proposed trials may be directed to EHRAB.

Document Scope

This process is limited to research trials submitted to EHRAB that include patient care practices that differ from those set out in the Basic Life Support Patient Care Standards and Advanced Life Support Patient Care Standards (as set out in the respective Research Standard).

Submission and Approval Process

Submission Process

In order for a research trial to be evaluated for approval by the Director, EHRAB, the interested base hospital(s) or ambulance service operator(s) shall submit an application package to EHRAB that includes:

1. an overview of the research trial, including:
    a. a description of the trial (aims, objectives, etc.),
    b. a recommendation of when the research trial should be initiated and be halted[1] (e.g. upon target enrollment, upon preliminary results, upon published findings, etc.),
    c. the name/contact information of the principal investigator,
    d. funding and equipment considerations[2],
    e. how the proposed trial differs from the current standards, and
    f. alignment with government and/or ministry priorities;
2. a draft research trial standard or medical directive that includes, but is not limited to, the specific Indications, Conditions, Contraindications and Treatment (e.g. practices, dose, route, etc.) for each controlled act or other advanced medical procedure;
3. a letter of support or a request to participate from the interested base hospital(s) (if applicable);
4. a letter of support or a request to participate from the interested ambulance service operator(s);

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[1] This does not include considerations for halting research based on adverse events, recommendations from the DSMB, research trial futility, *etc.*

[2] This may not include use of ministry funding provided under the auspices of the *Ambulance Act*.

5. a letter of endorsement from the Ontario Base Hospital Group Medical Advisory Committee (OBHG MAC), which includes, but is not limited to, confirmation that, in the opinion of the OBHG MAC, the research trial:
    a. the Medical Directives/Standards to be used in the research trial is/are endorsed by OBHG MAC,
    b. includes the appropriate patient consent for participation in the research trial (including documentation/notification),
    c. includes appropriate educational objectives for paramedics that include, but are not limited to:
        i. the knowledge, skills and judgment required to provide the care provisions of the research trial;
        ii. considerations for the elements of consent set out in section 11 of the *Health Care Consent Act, 1996*, as they apply to the care provisions of the research trial, and
        iii. considerations for emergency treatment set out in section 25 of the *Health Care Consent Act, 1996*, as they apply to the care provisions of the research trial;
6. confirmation of Research Ethics Board (REB) approval, and a letter indicating:
    a. the composition of the REB (i.e. members, affiliations, etc.),
    b. that the research trial abides by and is consistent with the version of the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, current at the time of submission, and
    c. that the REB meets the requirements for an REB set out in section 15 of O. Reg. 329/04 made under the *Personal Health Information Protection Act, 2004*;
7. a copy of the Research Protocol;
8. supplemental documentation, as required (e.g. Health Canada support letter, Data and Safety Monitoring Board [DSMB] information, etc.); and
9. any other materials or documentation that may be required by the Director, EHRAB.

Review

Upon receipt of a complete application package submission, EHRAB will review the materials and contact the applicant(s) in writing with any follow-up, as required. Please note, the length of the review will depend on complexity of the proposed research trial.

Approval

The decision to approve a research trial is at the sole discretion of the Director, EHRAB.

Research trials approved by the Director, EHRAB will:

1. be communicated to the applicant(s) in a memorandum, which outlines:
    a. the research trial which has been approved,
    b. the date of approval,
    c. the date and/or conditions at which use of the research trial shall be halted,
    d. approved ambulance call report codes, and
    e. any other terms or conditions pursuant to the approval; and

2. be listed on the EHRAB portion of the MOH public website, including the name and contact information of the principal investigator.

General

The Director, EHRAB may, at any time, and at his or her discretion, revoke his or her approval of a research trial.

Upon written notification of the Director, EHRAB's revocation of his or her approval of a research trial, the ambulance service operator base hospital, and any affected paramedics shall forthwith cease participation in the research trial and shall ensure that patient care is provided in accordance with the applicable standard(s).

Requests to modify approved research trials must be submitted in writing to the Director, EHRAB for review and approval.

Conclusion

EHRAB is committed to ensuring excellence in ambulance services for Ontarians. Clinical research is fundamental to the practice of medicine and the development of safer, more effective treatment options for patients. The process detailed above standardizes the submission process for research trials to EHRAB.

For further information on the Research Trial Submission and Approval Process, please contact:

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