Ontario Cancer Research Ethics Board
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Terms of Reference

PURPOSE

The Ontario Cancer Research Ethics Board (OCREB) was established in December 2003 in response to a need to improve and streamline ethics reviews of multi-centre oncology clinical trials. The creation of OCREB stemmed from extensive consultation, during which several key issues were identified. In particular, the large number of new cancer therapies entering clinical trials had considerably increased the workload of research ethics boards (REBs). Furthermore, complex and changing regulations were making the reviews more difficult and time consuming, and many local REBs identified the challenge of maintaining sufficient expertise.

OCREB is a central, oncology-specialized REB serving institutions in Ontario that conduct multi-centre cancer clinical trials/studies/research. The centralized model means that once a study is approved by OCREB, participating Ontario study centres can submit their abbreviated centre-specific applications, and typically receive OCREB approval to conduct the study within days. This includes centres joining studies that were originally approved by OCREB months or sometimes years earlier. All participating centres using OCREB must use the same consent form. The model not only provides a robust ethical review of oncology studies, but also streamlines the review process, minimizes redundancy, promotes consistency, and saves the time and cost of having the study reviewed by an REB at every participating institution/study site. Since its first meeting in January 2004, OCREB has been working with researchers, institutions and sponsors to safeguard the rights and welfare of research participants in Ontario, while advancing ethically sound cancer research.

OBJECTIVES

1. Provide uniform, high quality ethics review and oversight of multi-centre oncology research;
2. Ensure that the research meets current scientific and ethical standards for the protection of human research participants;
3. Streamline the review process, reducing the overall time to initiate the research at centres across Ontario;
4. Reduce the cost, workload and administrative burden on local REBs and investigators by eliminating redundant reviews;
5. Foster collaboration with the oncology research community through communication and exchange of information, essentially creating a community of practice.

AUTHORITY, ACCOUNTABILITY AND REPORTING

OCREB is an arms-length program of the Ontario Institute for Cancer Research (OICR), and accountable to the OICR Board of Directors through the OICR Governance Committee and the OCREB Advisory Committee. However, the deliberations of OCREB are independent of their authority.

OCREB serves as an REB to institutions in Ontario in accordance with the requirements of their Federal Wide Assurance and Clinical Trials Ontario (CTO) Participation Agreement. Institutions authorize OCREB to act as the REB of Record for research conducted under its auspices on a study-by-study basis. In this capacity, OCREB is accountable to the institution for initial and ongoing ethics review and oversight of the research.

As set out in its Standard Operating Procedures published online at https://ocreb.ca/, OCREB operates in compliance with, and is constituted in accordance with, the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Health Canada Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. OCREB is qualified through the CTO REB Qualification Program and registered with the U.S. Department of Health & Human Services (DHHS) Office for Human Research Protection (OHRP) - registration number IRB00003960.

OCREB reports to the OICR Board quarterly and publishes an annual report online.

MANDATE / SCOPE

OCREB is authorized to review research involving human participants within its established jurisdiction in accordance with the restrictions below:

1. OCREB's mandate is restricted to multi-centre clinical trials, where multi-centre is defined as more than one participating Ontario centre, and clinical trial is defined as any research that prospectively assigns human participants to one or more health-related interventions to evaluate the effects on health outcomes;
2. OCREB will accept a study with only one confirmed participating centre, providing the sponsor is actively looking for and is confident that a second centre will agree to participate;
3. OCREB will accept the submission of all cooperative group (e.g., CCTG, NRG) multi-centre trials even if a second centre has not been identified at the time of initial submission; cooperative group studies generally include more than one centre in Ontario.

MEMBERSHIP

The OICR Board of Directors appoints the OCREB Chair based on the recommendations of the OCREB Advisory Committee and the OICR Governance Committee. The OCREB Chair appoints the Vice-Chair(s) after ratification of the appointment by the OCREB Advisory Committee. The roles and responsibilities, recruitment and appointment of the OCREB Chairs and Vice-Chairs are outlined in their individual Terms of Reference.

OCREB appoints its members based on nominations from current OCREB members or the broader oncology research community, and following consultation with the OCREB Chair and its members and ratification by the OCREB Advisory Committee. Institutions that delegate to OCREB are encouraged to appoint representatives to serve as members. OCREB members serve for renewable terms of two to three years. Terms are overlapping to preserve experience and continuity.

OCREB is comprised of members from across Ontario representing many of the institutions from which clinical trial submissions are received. OCREB members collectively have the qualifications and experience to evaluate the ethics of the proposed research for both adult and pediatric oncology trials. Membership includes: medical, surgical and radiation oncologists and

hematologists; nurses and other professionals with oncology research experience; informed community members including people with cancer and family members of people with cancer; and members with expertise in research ethics, relevant law, privacy and members from other relevant disciplines such as pharmacy, pathology, and statistics. Details of OCREB's membership can be found in the 200 series SOPs.

FREQUENCY OF MEETINGS

Meetings are held in Toronto monthly or as called by the Chair. The REB office retains all minutes and administrative records related to the REB review activities. The agendas, meeting minutes and review documents are confidential and will not be made available unless required for inspection or auditing purposes.

DECISION PROCESS

OCREB decisions are based on the scientific and ethical merits of the research, and guided by the following core principles cited in the TCPS:

- Respect for Persons;
- Concern for Welfare; and
- Justice.

OCREB may approve, disapprove, propose modifications to, put on hold, or withdraw ethics approval of the research at its sole discretion. In the event of disagreement with OCREB's decisions, OCREB will follow the procedures outlined in SOP402.

QUORUM

OCREB decisions are made by a majority vote of the members present at a convened meeting. Inclusive in the determination of quorum will be the minimum membership representation required by applicable regulations, guidelines and SOPs. The Chair generally abstains from voting except to break a tie vote, unless he/she is fulfilling one of the required capacities to meet quorum.

CONFLICT OF INTEREST

All REB members shall be without conflict of interest in the review process and shall disclose actual, perceived or potential conflicts of interest. Only REB members who are independent of the investigator and the sponsor of the trial should participate in the initial or continuing review of any project, or provide opinion on a trial-related matter, except to provide information requested by the REB.

BUDGET AND RESOURCES

OICR provides appropriate administrative support (financial and human resources) to OCREB. The REB office personnel provide support to the Chair and for the work of the REB. The office personnel are integral to the operations of OCREB and serve as the primary liaison between the REB and the research teams and other stakeholders, facilitating the research ethics review process. The office is responsible for the storage and maintenance of REB documents in accordance with the applicable regulations, policies and guidelines.