

DELEGATED RESEARCH ETHICS BOARD OF RECORD MODEL

Title	Delegated Research Ethics Board of Record Model
SOP Code	
Effective Date	01 April, 2023

Site Approvals

Name and Title	Signature	Date (dd/mmm/yyyy)

1.0 PURPOSE

This standard operating procedure (SOP) describes the process by Aurora College (AC) institutional officials for signing the delegated Board of Record (BOR) Agreement with the external investigator/their institution(s) engaged in research involving human participants in order to permit initial and ongoing ethics review and ethical oversight of a research study by AC Research Ethics Committee (REC).

The BOR agreement documents the respective authorities, responsibilities, and communication between the Aurora College, an organization/institution conducting the regulatory review of human subject research activities and the institution(s) relying on Aurora College for REC review.

2.0 SCOPE

Researchers are required to seek approval from the Aurora College REC for their funded and unfunded research study involving human participants (living or deceased individuals, their data, and their biological or reproductive materials) if:

1. They are a faculty, staff, or student of AC or an investigator collaborating with AC staff and/ or using AC's resources to conduct your research study. AC is eligible to hold research funds granted by the Tri-Council Funding Agencies.

2. If their research involves accessing health information of NWT residents as per the Health Information Act of the Northwest Territories (HIA, Sections 67-83). At the discretion of the NWT Department of Health and Social Services, they may be required to seek ethics approval from the AC REC.

3. External non-Aurora College affiliated researchers who do not have access to ethics review by a Tri-Council Policy Statement 2 (TCPS2) compliant Research Ethics Board (REB) within their own organization and need ethics review as part of the Northwest Territories research licensing process can apply to seek ethics approval from the Aurora College REC through a delegated Board of Record (BOR) agreement.

3.0 DEFINITIONS

For the purpose of this SOP, the following definitions apply:

“Affiliated” means individuals who: are Aurora College faculty, staff, students and research associates

“Delegated Board of Record” also known as delegated BOR, is the qualified Research Ethics Committee (REC) that has been delegated authority for the ethics review and ethical oversight of a research study. The BOR REC is responsible for the ethics review, approval, ongoing review, study consultations, monitoring and compliance oversight of the study. The Aurora College institutional senior leadership and/or the Aurora College REC Chair sign BOR agreement.

“REC” refers to the Research Ethics Committee authorized by the Aurora College.

“Principal Investigator (PI)” is the head of the research team who has overall responsibility for the ethical conduct of the study and for the actions of any member(s) of the research teams. The PI is responsible for communicating any changes to the study, material incidental findings, new information, and/or unanticipated events to their own REC as well as to local site researchers for multi-site studies.

“Research activity (ies)” involve participant enrolment and recruitment, research interventions, data collection and data analysis.

“Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans” referred to as “TCPS2” is the joint policy of Canada’s three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). This policy outlines ethical norms relevant to the conduct of research involving humans.

4.0 RESPONSIBILITY RESPONSIBILITIES

This SOP applies to the Aurora College REC Chair (or delegates), Institutional Representative(s), Manager, Research Ethics, Research Ethics Office staff, the study Principal Investigator (PI) and associated research staff to understand the basic principles of the delegated REB of record model, and when a study may be eligible for submission to a delegated Research Ethics review and approval.

The REC Chair and Manager, Research Ethics are responsible to monitor and review these Procedures.

5.0 PROCEDURES

5.1 The BOR shall be responsible for all aspects of the initial ethical review, ongoing review, monitoring and compliance oversight of the applications undergoing a delegated BOR review process. This includes the REC review decision letter, responses to the decision letter, issuing of study decisions and study consultations.

5.2 The Manager, Research Ethics functions as the principal point of contact for the researchers and shall provide administrative support for the delegated BOR coordinated review process. Any questions regarding the delegated BOR model and study eligibility should be directed to Manager, Research Ethics.

5.3 The Manager, Research Ethics will initiate the delegated BOR Study Agreement to be signed by the appropriate institutional representative(s). For example, the institutional representative responsible for signing the Agreement for AC are Vice President Research and Chair, Research Ethics Committee.

5.4 The REC review will not commence until the delegated BOR Study Agreement is signed by respective representatives from all participating institutions.

5.5 The PI shall submit an application for ethics review to the AC REC.

5.6 The AC REC will carry the responsibility for the initial review, approval and ongoing ethical review, monitoring and compliance and oversight of the study.

5.7 The PI will be responsible for obtaining any further approvals/permission that might be required to complete the study prior to initiation, for example, NWT research license.

5.8. The AC REC will communicate all decisions in writing to the PI. The AC REC shall manage and retain all documentation surrounding the initial and post-approval review activities.

5.9 The ongoing review, post-approval activities (e.g. change requests and yearly progress reports) monitoring and follow-up reporting of anticipated issues, adverse events and non-compliance will be overseen and managed according to AC REC's established SOP and policies.

5.10 Details of the qualification and scope of the DBOR model can be found on AC/ARI website. (Aurora College Research Ethics Committee (REC) | Aurora Research Institute (nwtresearch.com))

5.11 The determination of whether a research study falls within the scope of the DBOR model will be considered on a study-by-study basis.

5.12 A tally/ metric along with a decision tree will be maintained for all delegated BOR model requests.

5.13 These procedures will be reviewed as necessary and at least every three years (unless another timeframe is required for compliance purposes).

REF:

AC REC Policies I 04

AC delegated BOR Template

AC REC SOP for ethics review (ref to 5.6)