

Title	Research with Eeyou/Eenou (Cree) Communities
SOP Code	REB-SOP 410.001
N2/CAREB SOP CODE	NA
Effective Date	2025-01-23

Status	Name and Title	Date
Authors	MUHC REB, CBHSSJB Research Office	2024-11-06
Approved	MUHC REB Full Board Meeting CBHSSJB Research Office	2024-11-06 2025-01-23
Approved	MUHC Board of Directors CBHSSJB Executive Director	2024-12-13 2025-01-23

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1 PURPOSE

This standard operating procedure (SOP) describes the multicentre review and approval process between the Cree Board of Health and Social Services of James Bay ('CBHSSJB') and the McGill University Health Centre ('MUHC') Research Ethics Board ('the REB') for research involving human participants.

2 BACKGROUND

The CBHSSJB has requested that the REB acts, for the time being, as its REB of record for multicentre research involving human participants conducted under the auspices of CBHSSJB,¹ as contemplated by the *Cadre de référence des établissements publics du réseau de la santé et des services sociaux pour l'autorisation d'une recherche menée dans plus d'un établissement*.²

First Nations and Inuit communities continue to be impacted by **colonization and oppression**, both at the individual and system level.³ Indigenous people have a right to access a healthcare system in which they feel **safe** when receiving care or participating in research. Indigenous communities in Canada have mobilized to reaffirm their sovereign right to self-determination and self-governance through greater involvement and decision-making in research involving their communities.⁴ In this context, to ensure that the research reviewed by the REB is culturally safe and respectful, and that it meets the needs and priorities defined by the CBHSSJB, further to its engagement and collaboration with Eeyou/Eenou (Cree) communities and other Cree organizations, the REB's process of review is adapted to the extent possible given resources to promote the involvement of the CBHSSJB, and by extension Eeyou/Eenou communities and other Cree authorities through the CBHSSJB.

This SOP therefore builds on the *Policy on the Research Ethics Board of the McGill University Health Centre* and the REB's SOPs. It also recognises specific principles and processes to support Eeyou/Eenou agency over research projects through the involvement and collaboration with the CBHSSJB.⁵ If a process is not addressed in this SOP, then the usual REB SOPs apply. Ongoing modifications to this SOP are expected over time.

Research conducted under the auspices of the CBHSSJB requires the formal institutional authorisation of the relevant research project by the "mandated person" of the CBHSSJB ("MP"). Additional authorisation from each participating site must be obtained when researchers are affiliated with sites other than the CBHSSJB, the whole in accordance with the MSSS Multicentre Framework (2016).

¹ For simplicity, for the purpose of this SOP, any such research is referred to as "under the auspices of the CBHSSJB".

² Ministère de la Santé et des Services sociaux, *Cadre de référence des établissements publics du réseau de la santé et des services sociaux pour l'autorisation d'une recherche menée dans plus d'un établissement*, 2016, hereafter "MSSS Multicentre Framework" (2016).

³ Truth and Reconciliation Commission of Canada. Honouring the Truth, Reconciling for the Future: Summary of the Final Report of the Truth and Reconciliation Commission of Canada, 2015.

⁴ The First Nations Information Governance Centre. Ownership, Control, Access and Possession (OCAP™): The Path to First Nations Information Governance, May 2014.

⁵ Policy on the Research Ethics Board of the McGill University Health Centre (MUHC REB), August 2024, hereafter Policy on the MUHC REB; MUHC Research Ethics Board (REB) Standard Operating Procedures (SOPs), hereafter "REB SOPs", <https://muhc.ca/cae/muhc-research-ethics-board-reb-standard-operating-procedures-sops>.

3 SCOPE

For the purpose of this SOP, research projects will be subject to the reviews outlined below if the project falls under the auspices of the CBHSSJB, including if the project plans to use, **as a variable** and at any stage of the research (e.g., eligibility screening, recruitment, data analysis, publication):

- James Bay and Northern Quebec Agreement (JBNQA) Cree beneficiary status; and/or
- Cree of Northern Québec identification; and/or
- a catchment area that includes the Québec socio-sanitary region 18 (e.g., postal code).

In case of difficulty interpreting these criteria, the CBHSSJB Research Office can be contacted (18tcr.research.committee@ssss.gouv.qc.ca).

The REB promotes awareness of the *CBHSSJB Miyupimâtisiûn Research Principles*,⁶ as well as the promotion of culturally safe research. Should there be conflicting interests or conflicting practices, the REB will give precedence to the solution that supports cultural safety, consistency with the Principles, and respect for human rights.

Research done in collaboration with Eeyouch (Crees) through the CBHSSJB will be evaluated according to the following guidance documents:

- 1) [The CBHSSJB Miyupimâtisiûn Research Principles](#);
- 2) [The First Nations Principles of Ownership, Control, Access, and Possession \(OCAP®\)](#);⁷
- 3) [Tri-Council Policy Statement, Chapter 9 \(2022\)](#);⁸
- 4) [Cadre de référence ministériel pour la recherche avec des participant humains](#).⁹

⁶ The Miyupimâtisiûn Research Principles, as approved by the board of directors of the Cree Board of Health and Social Service of James Bay, 2024, hereafter “Miyupimâtisiûn Research Principles”.

⁷ The First Nations Principles of Ownership, Control, Access and Possession (OCAP®), First Nation Information Governance Centre (FNIGC), 2024, henceforth “OCAP® Principles”; OCAP® is a registered trademark of the First Nations Information Governance Centre (FNIGC), <https://fnigc.ca/ocap-training/>.

⁸ Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022, hereafter “TCPS 2”, ch 9.

⁹ Ministère de la Santé et des Services sociaux, Cadre de référence ministériel pour la recherche avec des participant humains, October 2020, hereafter “Cadre de référence”.

4 RESPONSIBILITIES

Researchers must commit to respect the CBHSSJB Miyupimâtisîun Research Principles. Researchers are responsible for engaging in necessary self-reflection (i.e., being aware of one's history and how it affects one's current decision-making) and being open to learning different worldviews of health and well-being. Under the guidance of the CBHSSJB, researchers must demonstrate a commitment to promoting cultural safety throughout the life cycle of the project. All members of the research project must strive to restore and maintain trust. Once a project has received REB approval as described in the present SOP, the Researcher is responsible for continuing to comply with other SOPs of the REB.

The CBHSSJB is responsible for authorizing research under its auspices, which, among other things, includes carrying out reviews of institutional suitability and reviews of cultural safety to ensure consistency with the CBHSSJB Miyupimâtisîun Research Principles.

REB members are responsible for reviewing projects that are subject to this SOP in a manner consistent with the guidance provided by the CBHSSJB. Due to the review process outlined in this SOP, timelines for the review of projects may be variable.

All REB members and designated REB staff are responsible for ensuring that the requirements of this SOP are met. The REB is committed to working collaboratively with all parties to further goals set forth in this procedure.

5 DEFINITIONS

Letter of Support: Document issued by the CBHSSJB Research Office to a Researcher when their preliminary research proposal has been accepted, as contemplated by subsection 6.1.2.4. It is provided to facilitate funding applications. The letter of support does not constitute formal approval of the project.

Letter of Satisfactory Review: Document issued by the CBHSSJB Research Office to a Researcher once the full research proposal has undergone cultural safety and suitability review and has received approval, as contemplated by subsection 6.1.3.4. This document is needed for the Research to proceed to review by the REB.

Research Agreement: An agreement developed by the CBHSSJB, to be signed between the Researcher and the CBHSSJB in relation to a given project and setting out the responsibilities of each party, including provisions to ensure consistency with the CBHSSJB Miyupimâtisîun Research Principles and that research practices promote cultural safety, as contemplated by subsection 6.1.3.4. This agreement is signed once all four reviews set out in the regulatory research framework of the CBHSSJB (suitability, cultural safety, scientific, and ethics) have been completed in a satisfactory manner.

Suitability: The institutional suitability review ensures that the research is feasible locally given the capacities of the CBHSSJB, that it aligns with the priority areas identified in the Strategic Regional Plan of the CBHSSJB, and that it has support from the CBHSSJB departments that will be impacted by the project.

6 PROCEDURES

All research that falls under the scope of this SOP should meet the criteria outlined below before institutional authorisation may be granted. These elements are in addition to those listed in REB SOP “[Initial Review - Criteria for REB approval](#)”.

6.1 CBHSSJB Research Approval¹⁰

Researchers should complete the procedures for CBHSSJB cultural safety and institutional suitability review before submitting to the REB for the review process. The researcher must contact the CBHSSJB for current information on their processes (18tcr.research.committee@ssss.gouv.qc.ca). See Figure 1 for a flow diagram of the CBHSSJB and REB joint review process.

6.1.1 Engagement with the community

6.1.1.1 Before any steps are taken towards the creation of the project, the Researcher and their team should engage with the CBHSSJB as an initial step towards collaborative participatory research. This should include the process of co-identifying research objectives, methodological design, and community members as part of the research team. The CBHSSJB may also indicate other Eeyou/Eenou stakeholders to engage with as part of this initial step. The CBHSSJB Research Office and the researcher must agree on an initial outline for a proposed research project.

6.1.1.2 All ideas for a proposed research project must be aligned with existing CBHSSJB research priorities or be developed in collaboration with the CBHSSJB through its Research Office.

6.1.2 Preliminary research proposal

6.1.2.1 Once the CBHSSJB Research Office and the Researcher have agreed on an initial outline for a proposed research project, the Researcher will submit a preliminary research proposal (study objectives) using the briefing sheet template (found in appendix A) to 18tcr.research.committee@ssss.gouv.qc.ca.

- Submission of the preliminary research proposal should be done before developing a complete protocol and associated study documentation (i.e., full research proposal).

6.1.2.2 The CBHSSJB will invite the Researcher to give a presentation of the preliminary research proposal, including to the internal and external stakeholders identified by the CBHSSJB.

6.1.2.3 The CBHSSJB will assess the research proposal and advise the Researcher if the request is considered

¹⁰ In the case of a student project, the procedures apply with the necessary adaptations to the supervisor of the student, as per the Cadre de référence 2020, s. 2.3.3.

6.1.3.3 The CBHSSJB requires that all research projects undergo four reviews: (i) institutional suitability; (ii) cultural safety and Miyupimâtisîun Research Principles; (iii) scientific; and (iv) ethical. Following the presentation of the full research proposal, the CBHSSJB will conduct the cultural safety/Miyupimâtisîun Research Principles review and the institutional suitability review of the project.

6.1.3.4 If the project is granted cultural safety and suitability approval by the CBHSSJB, its Research Office will issue a Letter of Satisfactory Review to this effect.

- The Letter of Satisfactory Review is needed to proceed to the REB review (see Section 6.2)

6.2 REB review process

6.2.1 Initial Submission

6.2.1.1 Studies must be submitted to the REB using the Nagano platform.

6.2.1.2 In addition to the documents listed in the REB SOP “[REB Submission Requirements and Administrative Review](#)” the following documents must be submitted:

- The CBHSSJB Letter of Satisfactory Review (institutional suitability and cultural safety/Miyupimâtisîun Research Principles);
- The cultural safety and suitability reviews conducted by the CBHSSJB, along with the responses provided by the research team (as applicable); and
- The knowledge translation plan reviewed by CBHSSJB.

6.2.2 Determination of Qualification for Delegated Review

6.2.2.1 Studies that qualify as “minimal risk” by the REB are eligible for delegated review (i.e., review by REB members without full-board quorum).

6.2.3 Delegated Review Process

6.2.3.1 For research that meets the REB criteria for delegated review, the review may be conducted by the REB Chair, or by one or more qualified REB members as designated by the REB Chair or designee, with input, whenever possible, from a designated representative of the CBHSSJB or Eeyou/Eenou community member designated by the CBHSSJB.

6.2.4 Full Board REB Review Process

6.2.4.1 To promote the inclusion of an Eeyou/Eenou community member even when they are not available for a Full Board meeting, research projects can undergo a pre-review with at least one REB member with experience with research with Eeyouch/Eenouch and the REB Chair and/or one or more qualified REB members as designated by the REB Chair or designee.

6.2.4.1.1 At its next Full Board meeting, the REB will be informed of the pre-review and will take it into consideration in rendering a decision.

6.2.5 Minimal Criteria for Approval of Research

6.2.5.1 In order for the research to receive REB approval, the REB will not only assess the usual criteria set out in the corresponding SOPs in light of the specific circumstances of the project, but also the following aspects:

6.2.5.1.1 Data management: The collection, use, retention, and stewardship of data will respect the OCAP® Principles and will be consistent with relevant, standard provisions of the applicable Research Agreement of the CBHSSJB. This includes the return of results.

6.2.5.1.2 Scientific methodology: The research methods will follow participatory collaborative research practices and integrate, wherever appropriate, Indigenous ways of knowing and knowledge creation. Where not possible, sufficient justification must be provided.

6.2.5.1.3 Participant-facing study documents: All participant-facing study documents and recruitment materials, including but not limited to social media strategies and study advertisements, will be provided in plain English, with the possibility of appropriate Cree translations (the latter to be arranged with the guidance of the CBHSSJB).

6.2.5.1.4 Compensation: Compensation offered to participants will take into consideration issues of local suitability (e.g., cost of living) and usability (e.g., if compensation is given through gift cards, then those gift cards should be provided for businesses accessible by participants).

6.3 Research Agreement

6.3.1 The Researcher and the CBHSSJB must conclude a Research Agreement before the project is initiated and as a condition of its formal authorization.

6.3.1.1 The Research Agreement is not needed to proceed with the submission of a project to the REB, but it is needed for research to be authorized by the MP of the CBHSSJB.

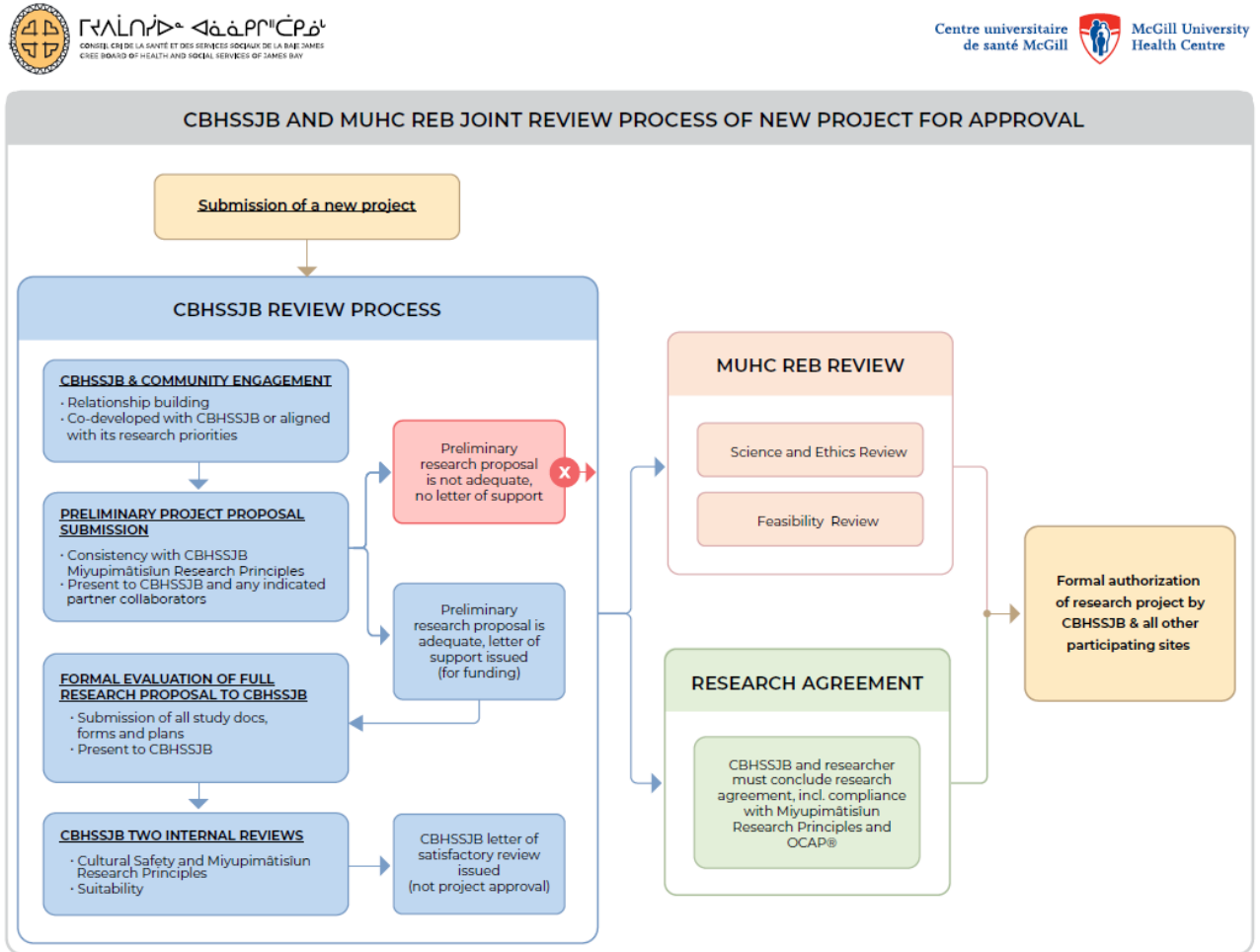
6.3.2 The study protocol approved by the REB and the REB approval letter must be appended to the Research Agreement, and form a part thereof, as a condition of its signature by the parties.

6.3.3 Once the required Research Agreement has been discussed, prepared and accepted in principle by all parties, the Researcher must obtain any necessary approvals and signatures from their institution and the Researcher must also sign the agreement.

6.3.4 No research activities can take place without a research agreement that is signed by all parties.

9 FIGURES

Figure 1: Flowchart of joint review process



10 APPENDICES

Appendix A: CBHSSJB RESEARCH OFFICE BRIEFING SHEET

Please complete the Briefing Sheet and append it to the proposed research project submission.

This form is intended to collect initial information about the project proposal. It does not need to capture all the details. These will be determined in collaboration with the CBHSSJB going forward.

PROJECT TITLE		Id.: (xxx)_202x-xx <small>Completed by Research Office</small>
SUBMISSION DATE		
MAIN OBJECTIVE(S)		
EXPECTED SCIENTIFIC OUTCOME(S)		
EXPECTED BENEFITS FOR THE COMMUNITY		
PRINCIPAL INVESTIGATOR(S)		
CBHSSJB COLLABORATOR(S)		
COMMUNITY PARTNERS		
CBHSSJB INVOLVEMENT	[Include equipment, personnel, installations, etc.]	
TIMEFRAME		
FUNDING		
DOCUMENTATION	(At a minimum, include the initial project proposal with methodology)	

Please return this form to 18tcr.Research.Committee@ssss.gouv.qc.ca with the proposed project.

Appendix B. CHECKLIST OF CBHSSJB DOCUMENTS FOR FORMAL PROJECT EVALUATION

FORMAL REQUEST FOR EVALUATION CHECKLIST

In the evaluation phase, the protocol will go through four reviews: suitability, cultural safety, scientific and ethics. At each stage, the project documents may need to be revised based on reviewer feedback.

Suitability and Cultural Safety Reviews

The suitability and cultural safety reviews are conducted by the CBHSSJB.

Please submit the following documents for evaluation:

- Final Research Protocol
- Consent Form(s)
- Data Collection Forms
- CBHSSJB and Community Collaboration Plan
- Knowledge Translation Plan
- Researcher Status Form, signed

Please send all documents by email: 18tcr.research.committee@ssss.gouv.qc.ca

If successful, a Letter of Satisfactory Review will be issued, permitting you to proceed with the scientific and ethical reviews, to be conducted by the REB.

Scientific and Ethical Reviews

Once the cultural safety and suitability reviews are complete, submit the approved documents to the REB with any other required documents. Please follow the instructions provided by the REB.