CBHSSJB

Researcher's GUIDE

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CONSEIL CRI DE LA SANTÉ ET DES SERVICES SOCIAUX DE LA BAIE JAMES

CREE BOARD OF HEALTH AND SOCIAL SERVICES OF JAMES BAY

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INTRODUCTION

Miyupimâtisîun is the act of living well and Nishîyû is a term that reflects the growth of a Nation while remembering its ancestors.

The Cree Board of Health and Social Services of James Bay (CBHSSJB) Research Office oversees health and social services-oriented research for the population of Eeyou Istchee. The Research Office reviews, approves, and manages all research carried out under the auspices of the CBHSSJB.

We are mandated to ensure that research benefits the health and well-being of the Eeyouch in the spirit of Miyupimâtisîun reflective of Nishîyû.

This Researcher's Guide provides detailed information for researchers wishing to conduct research with our population on or outside the Eeyou Istchee territory.

For more information, please contact the CBHSSJB Research Office:

18tcr.research.committee@ssss.gouv.qc.ca

Or, visit us online at

www.creehealth.org/about-us/departments/research-office

1 What research falls under the auspices of the CBHSSJB?

The concept of research should be understood in a broad sense as covering any research activity involving humans, including the creation or use of a database or a biobank.

According to Ministère de la Santé et des Services sociaux (MSSS) guidelines, research on human participants includes research that involves personal information, biological materials of human origin, and information derived therefrom, whether or not it identifies the individual to whom it relates.[1]

As the regional health authority for Eeyou Istchee (Region 18), the CBHSSJB must approve health and social services-oriented research involving our population, whether they reside on the territory or not (i.e. under our auspices).

A research project falls under the auspices of the CBHSSJB if the study intends to:

- Recruit participants from any CBHSSJB facility;
- Use personal information that is housed by the CBHSSJB;
- Use CBHSSJB facilities;
- Use James Bay and Northern Québec Agreement (JBNQA) Cree beneficiary status as a variable at any stage of the research; and/or
- Use Cree of Northern Québec identification as a variable at any stage of the research.

1 - Art. 1.9, 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 (MSSS, 2016)

HOW WE DEFINE RESEARCH

The CBHSSJB views research as an inclusive and respectful process that balances scientific methods with an Eeyou worldview.

A research project must aim to extend or create new knowledge by testing a hypothesis and drawing conclusions.

Many activities share research-like methodologies but do not fall under the category of research, such as program evaluation, quality improvement, and surveillance.

According to the Public Health Act (CQLR, c. S-2.2), the following activities do not fall under research:

- Surveillance of the health status of the population and its determinants.
- Health portraits developed for the purpose of informing the population on its general state of health and of major health problems, groups most at risk, principal risk factors, and related matters.
- Regional surveys on health and social issues.

QUALITY IMPROVEMENT VS. RESEARCH

- Quality improvement (QI) initiatives are similar to research in that they seek to generate new knowledge to improve health care and social services.
- It can be difficult to distinguish between the two. Some research methodologies are like QI, relying on participant engagement in the development of the project. Some QI projects include a research component that might pose risks to participants.
- To help decide, the CBHSSJB may ask the researcher to complete the ***QI vs Research tool*** and if necessary seek the advice of an institutional research ethics board (REB).
- If the REB determines that a project is QI rather than research, it will issue an exemption letter.
- If a project is considered research or includes elements of research, it must be evaluated by the CBHSSJB and receive research ethics board approval.

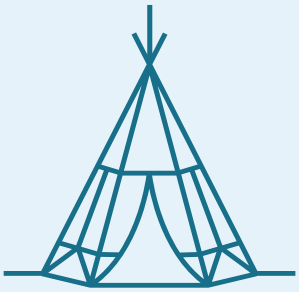
2 What is community-based participatory research?

The CBHSSJB only approves community-based participatory research (CBPR) projects.

CBPR is an approach that is grounded in collaboration, community wisdom, and co-ownership of research procedures, intervention design, evaluation, and application.[2] Participants collaborate with the research team in the process of defining the research objective, collecting and analyzing data, and producing final products.[3]

We favour this approach because it aligns with our commitment to engage in research that helps achieve Miyupimâtisîun reflective of Nishîyû.

The Miyupimâtisîun Research Principles ***Appendix A*** are the guiding principles of how research should be done with the CBHSSJB. These principles, created by Elders of Eeyou Istchee, must be respected and carried out at every step of a research project to ensure Cultural Safety.



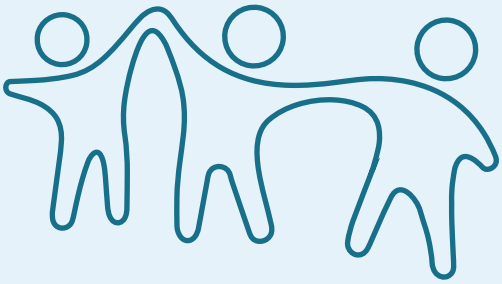
WHAT IS CULTURAL SAFETY?

"Cultural safety is about the experience of the patient [person]. It is an outcome based on respectful engagement that recognizes and strives to address power imbalances inherent in the healthcare system. It results in an environment free of racism and discrimination, where people feel safe when receiving health care."

(Source: BC First Nations Health Authority (2016). "Creating a Climate for Change – Cultural Safety and Humility in Health Services for First Nations and Aboriginal Peoples in British Columbia.")

2 *Israel B., Schulz A., Parker E., Becker A. (2001). Community-based participatory research: Policy recommendations for promoting a partnership approach in health research. Education for Health, 14(2), 182–197.* ***doi.org/10.1080/13576280110051055***

3 *TCPS-2, 2022, Art. 4.7*



WHAT IS A STRENGTHS-BASED APPROACH?

Strengths-based approaches in research refers to work that begins "by analyzing, not the deficits, but the strengths of both individuals and communities... [and aims to] profile potential solutions, positive programs and initiatives taking place in communities. It would seek out potential paths forward. Ultimately, such research will enhance the quality and level of data used for advocacy"

(Source: First Nations Information Governance Centre, 2015, p. 7).

There are many sources in the literature that identify different tenets of CBPR. In the context of the CBHSSJB, here are the most important ones to keep in mind:

- Recognizing and respecting Eeyou sovereignty and Cree First Nation governments
- Respecting collective Eeyou/Eenou knowledge
- Partnering and ensuring co-ownership with the community at every step of the project
- Using Eeyou/Eenou ways of knowing and doing
- Using a strengths-based approach throughout the project
- Promoting co-learning, capacity building, and empowerment of the Eeyouch
- Creating knowledge into practice through having Eeyou/Eenou people as active creators and implementers of the knowledge translation plan

If you would like to learn how to apply a CBPR approach to your project, please reach out to the Research Office. We are always open to discussions and reflection on ways to engage with communities.

18tcr.research.committee@ssss.gouv.qc.ca

3 Who reviews and evaluates research at the CBHSSJB?

Research is approved after a project has been reviewed by various committees.

At the CBHSSJB, research projects are subject to four reviews:

- *1 • Cultural Safety*
- *2 • Suitability*
- *3 • Scientific*
- *4 • Ethics*

The first two reviews are carried out internally by the CBHSSJB, and the last two are carried out by a MSSS network research ethics board (REB). Section 6.1 provides more details on each review.

WHO DOES WHAT?

The **Research Governance Committee** (RGC) is a subcommittee of the CBHSSJB Board of Directors. The committee is composed of four Board members as well as representatives from the Executive Committee; its chairperson is the Chair of the CBHSSJB. The mandate of this committee is to provide the overall vision for the Research Office and to manage matters related to the governance of research.

The **Research Advisory Committee** (RAC) is an operational committee that reports to the CBHSSJB Executive Director. It's composed of seven senior managers of the CBHSSJB and six Elders from the Nishîyû Council of Elders. The mandate of the committee is to carry out the suitability and cultural safety reviews of research projects, as well as reviewing projects throughout their life cycle.

The CBHSSJB works closely with the **Research Ethics Board** (REB) of the McGill University Health Centre (MUHC) our REB of record. This ensures that ethical review and approval procedures are aligned with the Miyupimâtisîun Research Principles *Appendix A*.

Each project is expected to have a **Steering Committee**. This committee is formed by patient partners, CBHSSJB employees working on the subject being researched, or other key partners. The committee provides advice to the research team throughout the lifecycle of the project and helps ensure that Eeyou/Eenou perspectives, interpretations, and ways of knowing and doing are integrated into each project.

The Research Office is the administrative hub. It coordinates the review and approval of research between all parties and maintains the research registry. The Research Office can be reached at:

18tcr.research.committee@ssss.gouv.qc.ca

4 What should I know before doing research with the CBHSSJB?

Research projects must be carried out in a manner that complies with the principles of responsible conduct of research with the Eeyouch, which includes, but is not limited to respect for:

- Cree language, values, customs, and cultural perspectives
- The Miyupimâtisîun Research Principles
  see ***Appendix A***
- The principles of Ownership, Control, Access and Possession (OCAP®) developed by the
  First Nations Information Governance Centre
- The MSSS Reference Framework for Research Involving Human Participants
  Cadre de référence ministériel pour la recherche avec des participants humains, 2020
- The FRSQ Standards
  frq.gouv.qc.ca/app/uploads/2021/03/standards_frsq_ethique_recherche_humain_2009.pdf
- The TCPS2 guidelines
  The Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans TCPS 2 2022 or a revised version, especially Chapter 9 covering "Research Involving the First Nations, Inuit and Métis Peoples of Canada".

Research projects are also governed by the following legal and organizational instruments:

- ***The James Bay and Northern Québec Agreement*** including Section 14, the Act and other applicable laws and regulations
- The CBHSSJB Strategic Regional Plan*
- CBHSSJB Research By-law, Research Governance Committee By-law and associated policies and procedures

** Available upon request*

WHO OWNS RESEARCH DATA AND RESULTS?

The CBHSSJB applies OCAP® principles to the governance of research data.

OCAP® and the Miyupimâtisîun Research Principles are rooted in the understanding that data is part of the sacred knowledge of the Eeyouch. Data can be shared under certain conditions, but it can't be given away; it belongs to the Eeyouch.

The Research and Data Use Agreement makes it clear that data collected, including biological samples, must be returned to the CBHSSJB, and not destroyed at the end of the project. Similarly, research results—the findings that emerge from data analysis—are considered joint results, co-owned by the parties to the agreement. As such, both parties own intellectual property emerging from research.

5 How can I engage in research with the CBHSSJB?

ENGAGE IN A PROCESS OF SELF-REFLECTION

Consider your position with regards to Indigenous communities. Ongoing self-reflection is key to engage in a meaningful research process. The following questions are examples of elements that should be considered:

- How does your identity influence how you see the world?
- How can you be vigilant to personal bias and the systemic bias of the healthcare and social services system in which research is conducted?
- How will your approach address the inherent power imbalance between researchers and research participants?

ENGAGE WITH COMMUNITIES

Every Cree First Nation in Eeyou Istchee, has its own culture, priorities, and ways of knowing and doing. Take the time to consult with a broad range of community members and other key partners. This will help establish local relationships and identify needs that could be met by research. Some research projects may require official support from the local Chief and Council.

ENGAGE WITH THE CBHSSJB

Consider how your project aligns with CBHSSJB Strategic Regional Plan (available upon request). This document captures organizational priorities based on consultations with communities. Seek guidance from CBHSSJB managers and clinical personnel who will be able to identify specific knowledge gaps.

ENGAGE WITH THE RESEARCH OFFICE

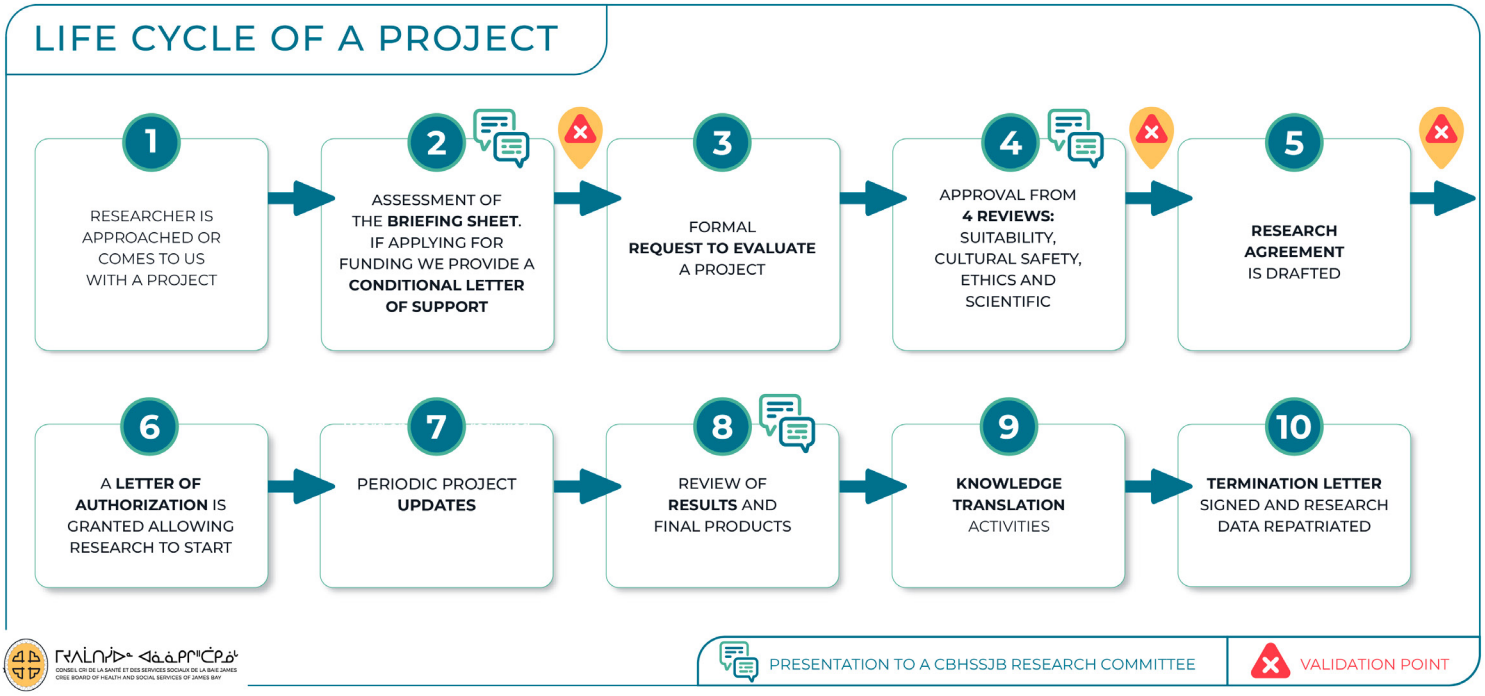
Once you have developed a project idea in collaboration with community members and CBHSSJB representatives, the Research Office will invite you to submit your idea for consideration. Feel free to connect with the Research Office at any stage for advice and guidance.

To learn more about the ethics of research in an Indigenous context:

- ***Read TCPS 2 (2022) – "Chapter 9: Research Involving the First Nations, Inuit, and Métis Peoples of Canada"***
- ***Consider taking OCAP training offered by the First Nations Indigenous Governance Centre***

6 What are the steps in the life cycle of a research project with the CBHSSJB?

THE LIFE CYCLE OF THE RESEARCH PROJECT



6.1 RESEARCH REVIEW AND APPROVAL

Below you will find the steps to follow for a research project to be approved:

1. COMMUNITY ENGAGEMENT

We encourage anyone looking to do research with the Eeyouch to spend time in Eeyou Istchee to engage with the people, learn their history, and understand their context. All of the above need to be carried out with the utmost respect and humility, while remaining open to a change of paradigm and to embracing different world views.

2. CO-DEVELOPMENT OF A RESEARCH QUESTION

All research project ideas must follow CBHSSJB research priorities or be developed in collaboration with the CBHSSJB. Proposals must also include the expected direct benefits to the communities.

3. SUBMISSION OF AN INTENT PACKAGE WITH A PRELIMINARY PROPOSAL

Once you have a research question and an outline for the project you can submit an intent package. Please note that a full protocol is not required at this stage.

The intent package includes the following documents, which should be submitted to the Research Office by the principal investigator:

- Commitment to the Miyupimâtisîun Research Principles and Good Collaborative Research Practices: An ethical declaration signed by the principal investigator.
  See Template 1.1
- Briefing Sheet: A summary of research objectives and how the project will benefit the community.
  See Template 1.2
- Research vs Quality Improvement Tool: This tool can help determine if the project is research (i.e. generating new scientific knowledge and therefore requiring full approval) or seeking to improve an existing program or service. This should only be submitted upon request of the Research Office.
  See Template 1.3
- After a favourable initial review, the Research Office will grant the researcher a Letter of Support, which can be used as proof of conditional support from the CBHSSJB when applying for funding.

4. DEVELOPMENT OF THE FULL PROPOSAL AND SUBMISSION FOR FORMAL EVALUATION.

Having engaged with the community and the CBHSSJB to develop the project, the researchers will be invited to submit their project for evaluation.

The Research Office will require the researcher to submit the following documents along with a completed Formal Request for Evaluation Checklist:
See Template 2.1

- Final research protocol
- Informed consent forms
- Data collection forms
- CBHSSJB and community collaboration plan
- Knowledge translation plan
- Researcher Status Form, signed
  see Template 2.2

Please note that all project documentation must be in English.

6.1 RESEARCH REVIEW AND APPROVAL

5. EVALUATION PROCESS

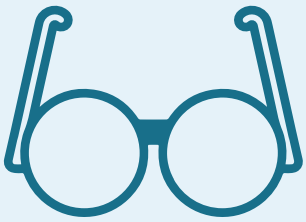
The evaluation process includes cultural safety and suitability reviews, carried out by the CBHSSJB, followed by the scientific and ethical reviews conducted by a network REB.

For the cultural safety and suitability reviews, the research team will be asked to present to either the RAC or the RGC. Feedback from this presentation will be provided to the research team with the expectation that changes may need to be integrated into the project. Once the project successfully completes the suitability and cultural safety reviews, a Letter of Satisfactory Review will be issued. The researcher will need this letter to support their application for REB approval.

Application for REB approval will follow the guidelines established by the MSSS. The research team is expected to submit the documentation that has been approved by the CBHSSJB.

Keep in mind that the review process is iterative, and the researcher should be prepared to modify their protocol at any stage.

See Template 2.1, the Formal Request for Evaluation Checklist for more information about the evaluation process.



Projects under the auspices of the CBHSSJB are subject to review by a network REB pursuant to Québec provincial law and to ministerial action plans, circulars (“circulaires”), directives, guidelines or similar instruments of the MSSS. Please note that certificates or letters from other REBs will not be valid.

6.2 RESEARCH AGREEMENT & AUTHORIZATION

Once all four reviews are complete (suitability, cultural safety, scientific and ethical), the Research Office will draft a Research and Data Use Agreement.

The Research and Data Use Agreement is a legally binding contract between the researcher, the academic institution and the CBHSSJB. It operationalizes the Miyupimâtisîun Research Principles and defines the disposition of data and joint results.

The following documents are attached to the agreement as appendices and must be kept up to date for the duration of the project:

- Final protocol
- REB letter/certificate of approval
- Contact information for the principal investigator(s)
- Statement of Assent Form
- Personal Commitment Concerning Data Use Form
- List of Co-investigators and Collaborating Researchers Form
- Model Consent Form
- DPS Authorization Form, if applicable
  see Template 3.2

The Research Office will provide a blank agreement, a Research Agreement Checklist & Instructions and relevant forms to be completed by the research team. ***See Template 3.1 & 3.1.1***

Once the agreement has been finalized and signed by all parties, the CBHSSJB issues a Letter of Authorization. The letter is valid until the termination date set out in the REB letter/ certificate of approval. The principal investigator is responsible for taking steps to extend or renew this letter/certificate and must inform the CBHSSJB Research Office at least 30 days in advance of any renewal date. Once the new REB letter/certificate is received the authorization will be renewed automatically.

6.3 DATA COLLECTION AND INTERPRETATION

In keeping with the notion of CBPR, a steering committee is appointed to advise the research team on data collection and interpretation activities.

The steering committee is made up of individuals, ideally community members, who have personal and/or professional knowledge on the research topic.

- They facilitate community consultations to ensure local issues and concerns are built into the project plan;
- Ensure that all parties are properly involved in the project planning and logistics from the beginning of each fieldwork phase;
- Identify those responsible for various tasks among the partners involved in the fieldwork;
- Review research results prior to publication; and
- Provide input in the knowledge translation activities and products.

The final composition of this steering committee will be decided in consultation with the CBHSSJB and the Cree First Nation(s) authorities.

6.4 KNOWLEDGE TRANSLATION

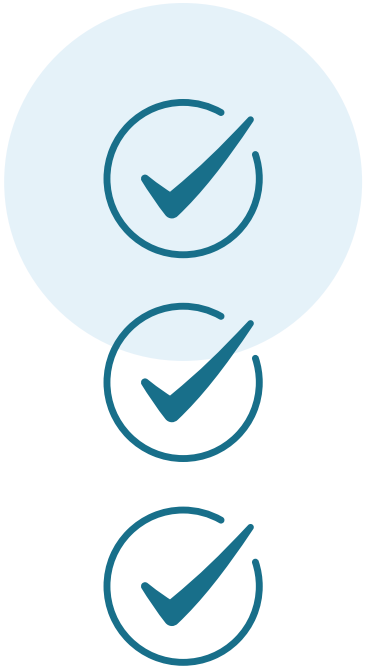
Good knowledge translation (KT) can lead to significant improvements in the health of the population and service delivery. For this reason, the CBHSSJB encourages researchers to consider KT throughout the life of the project.

Depending on the nature of the project, we encourage the research team to consider how knowledge translation can be integrated into project activities from the start. Throughout the project life cycle, knowledge holders, knowledge owners and knowledge producers contribute to the evolution of a project and the KT strategy.

Initial research project submissions are expected to include a knowledge translation plan; however, as with other aspects of the project, the specific details of the plan are developed in consultation with the community members and other key partners.

Knowledge translation should be developed with key partners who will provide input on products and activities that return study information and address specific challenges identified by participants. This will help the community see the value of research and enable researchers to strengthen relationships with all key partners, paving the way for future research opportunities.

6.5 PROJECT TERMINATION



The project is considered formally complete when the original data and joint results have been disposed of according to the terms of the Research and Data Use Agreement.

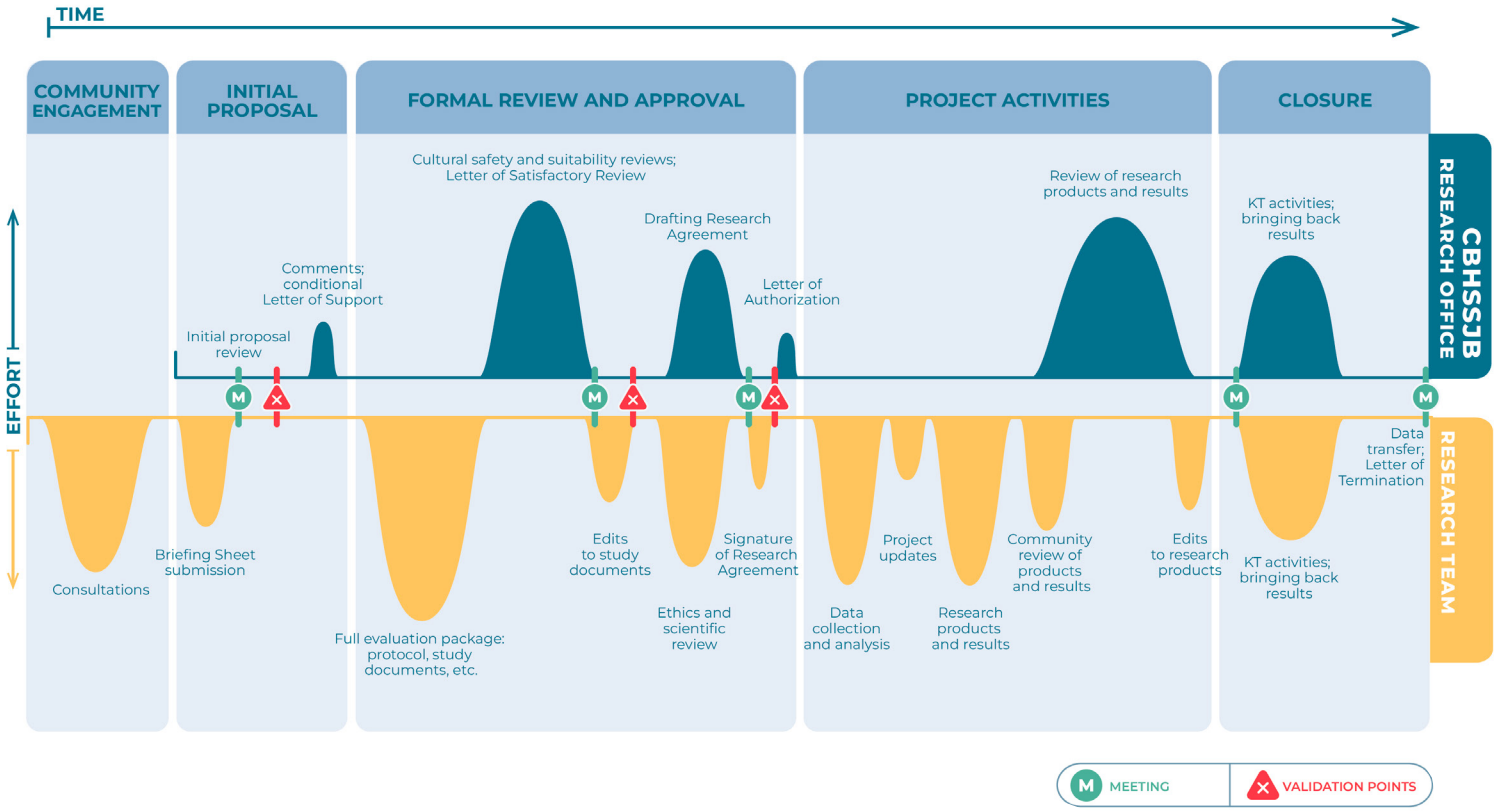
The CBHSSJB sends a Termination Letter with a Declaration Form (***see Template 4***) reiterating the terms of the agreement with regards to the return of data and use of joint results.
The Declaration must include a list of scientific publications, published or pending.

7 How long does it take to start a project?

It's important to consider that this is a lengthy process that can take approximately six to eight months to complete.

The proportionality principle is applied to the review of projects. Higher risk projects will be subjected to additional scrutiny, which may take more time. The notion of risk is evaluated by taking into account the potential impact on individuals, communities, and the organization. Some research projects will require the approval of the Board of Directors. The Research Office will inform you if your project requires Board approval.

DISTRIBUTION OF TIME AND EFFORT OVER THE LIFE OF A PROJECT



8 Is there funding available for research at the CBHSSJB?

The CBHSSJB does not provide financial support in the form of grants. In exceptional cases, in-kind contributions may be considered.

We highly encourage researchers to seek public funding through grants provided by CIHR or FRQS. If a research project is funded by a private enterprise, the CBHSSJB must bill for the four reviews and for the institutional authorization. [4] The billing must comply with the billing schedule of the MSSS and it must use the rates in effect at the time the billable activity was carried out. Furthermore, the CBHSSJB must make sure the research budget provides for a contribution to the payment of the research project's indirect costs (infrastructure, administrative services, REB, facilities, equipment, etc.), which are calculated using the project's total direct cost.

4 *Circular 2016-029 (Québec, Ministère de la Santé et des Services sociaux, 2016b); Circular 2003-012 (Québec, Ministère de la Santé et des Services sociaux, 2003a)*

9 How can I hire Eeyou-Eenou research assistants for a project?

As part of the CBHSSJB mandate to foster Eeyou research capacity, every project should include Eeyou-Eenou research assistants.

The CBHSSJB Human Resources (HR) works with the researcher to determine the nature and terms of the position. The job is posted on CreeHealth.org and LinkedIn.

Once a candidate is identified, HR develops an employment contract. Salary, hours, and the period of employment are determined by HR and the researcher. More information is available upon request.

The Research Assistant is employed by CBHSSJB, but their salary is reimbursed with funds from the research project.

The research team is encouraged to search for a suitable candidate during community consultations; however, the Research Office can help find a candidate.

10

Can a graduate student carry out research with the CBHSSJB?

Students are welcome to carry out research projects with the CBHSSJB. The same review and approval processes as described above will apply and the authorization to conduct the research must be requested from the CBHSSJB by the person acting as the student's research supervisor at a college or university in Québec or in another Canadian province.

11

Questions?

You can reach out to us and we'll be happy to answer any of your questions:

18tcr.research.committee@ssss.gouv.qc.ca

APPENDIX A

Miyupimâtisîun Research Principles

Approved by the CBHSSJB Board of Directors on March 6, 2024

These Miyupimâtisîun Research Principles must be followed by anyone conducting research involving the Cree Board of Health and Social Services of James Bay (CBHSSJB).

Prior to beginning any research, research projects must obtain formal approval from the CBHSSJB Research Office. The entire research team, including any student researchers and research assistants, must provide written statements affirming that they will respect the following principles:

1. The Eeyouch have a unique worldview, culture and history that are different from Western science and practices. This should be considered and respectfully acknowledged during all stages of research, including in the interpretation of findings and any publications or oral presentations.
2. The Eeyouch have an inherent right to self-determination and self-governance. This is also affirmed in the Cree Constitution, the James Bay and Northern Quebec Agreement, s. 35 of the Constitution Act, 1982, and the UN Declaration on the Rights of Indigenous Peoples. This includes the right to determine and control research involving Eeyouch, and sovereignty over Eeyou/Eenou data.
3. Research should be governed by the important Eeyou/Eenou values of truth, respect and reciprocity. Transparency is essential to building and maintaining trust in research partnerships.
4. Collective Eeyou/Eenou knowledge* in and of itself cannot be owned by an individual, under the Eeyou worldview. Rather, the Eeyouch are collectively the guardians of this knowledge, for the benefit and use of Eeyouch. Documenting or researching Collective Eeyou/Eenou knowledge should only be carried out by Eeyouch.
5. Research must focus on local and regional Eeyou/Eenou needs and priorities. Research should be conducted in a culturally safe manner, in the best interests and for the benefit of the Eeyouch.
6. Research objectives should promote the Eeyouch attaining Miyupimâtisîun, or living well. Miyupimâtisîun includes physical, emotional, mental and spiritual health and social well-being, within the context of land, identity and the Eeyou/Eenou traditional ways of life. Encouraging and respecting Nishîyû mînwâchihîhkûsîwin (traditional healing approaches) is also essential.

** Collective Eeyou/Eenou knowledge refers to knowledge that the Creator has entrusted the Eeyouch with, which is intrinsically linked with Eeyou/Eenou traditional lands and resources and is passed on collectively from generation to generation (Eeyou Chischâyihtimuwin), as well as the practices associated with that knowledge (Eeyou Iyihtuwin).*

7. Eeyouch have the inherent responsibility and right to protect their knowledge, practices, data and biological samples. Their sharing for research involving the CBHSSJB is restricted to the research objectives and scope approved by the CBHSSJB and subject to conditions set out in the required research agreement with the CBHSSJB, as well as OCAP® principles and any applicable policies or laws. Eeyou/Eenou values and practices, especially in the community where the research is taking place, must always guide the research process.
8. Research should be planned, executed and interpreted collaboratively, unless the CBHSSJB and researchers mutually decide otherwise. The CBHSSJB should be kept informed at every stage of a project. Researchers should aim to strengthen research capacity within the CBHSSJB and within communities, and this objective should be reflected in any research grants. Researchers should be aware that collaborative and participatory research may take more time.
9. Prior and informed consent, without pressure, must be obtained from research participants prior to their participation in any research activity. For consent to be informed, project objectives, methodology, confidentiality of personal information, projected use of data and potential positive and negative impacts on Eeyouch, must all be addressed in the consent form. Consent forms should be available in îyiyû ayimûn (Eeyou language). Consent must also be obtained if data will be used for new purposes, other than the original objectives consented to.
10. All results must be interpreted prior to publication with Eeyou/Eenou input through the CBHSSJB to ensure accuracy and culturally appropriate interpretations. Publication review processes must be followed to ensure that the Eeyou perspective is integrated and given the appropriate weight, including co-authorship. The ultimate goal of creating new knowledge is to share it with communities, key partners and those who participated in the research, more so than creating publications.
11. Any interpretation of data and any creation, including intellectual property, developed during a research project involving the CBHSSJB shall be jointly owned by the CBHSSJB and the researcher. Eeyou/Eenou input and knowledge shared must be appropriately acknowledged, including in publications and oral presentations, and by having Eeyou/Eenou co-presenters.
12. The CBHSSJB may decide to withdraw from a research project at any time. In such a case, research must cease, as well as the use of Eeyou/Eenou data or of any results created, unless the CBHSSJB determines otherwise, including in view of valid and appropriate Eeyou/Eenou consent.

APPENDIX B
List of Forms & Templates

In the sections below, you will find the following forms and templates. These are examples of the documents the Research Office will provide to the research team as a project advances from initial review and approval to termination.

1. INITIAL REVIEW

1.1 Commitment to the Miyupimâtisîun Research Principles and Good Collaborative Research Practices (Ethical commitment)

1.2 Briefing Sheet

1.3 Research vs. Quality Improvement

2. EVALUATION

2.1 Formal Request for Evaluation Checklist

2.2 Researcher Status Form

3. RESEARCH AGREEMENT

3.1 Research Agreement Checklist & Instructions

3.1.1 Full Research Agreement *(template available upon request)*

3.2 DPS Authorization Form

4. TERMINATION

4.1 *Termination Letter/Declaration*

TEMPLATE 1.1

Commitment to the Miyupimâtisîun Research Principles and Good Collaborative Research Practices

I, the undersigned, acknowledge that I have read the Miyupimaatisiiun Research Principles and that I have carried out the necessary self-reflection and have adapted the research methods to undertake respecting the aforementioned principles. I will also undertake to respect the measures, directives, policies and procedures of the Cree Board of Health and Social Services of James Bay (CBHSSJB) governing research activities; the standards relating to generally applicable ethics and responsible conduct in research.

I commit to:

- Respect and enact the Miyupimâtisîun Research Principles;
- Respect the laws and standards in force in the field of research, particularly in terms of responsible conduct of research with Indigenous peoples, research ethics, good research management practices and good clinical practices in research;
- Respect the regulatory framework for research in force at the CBHSSJB, including the provisions relating to the confidentiality of users' personal information;
- Respect, within the framework of each research project to which I contribute or supervise, the decisions of the person formally mandated to approve research and Research Ethics Board, as well as the committees responsible for the cultural safety evaluation and ethical monitoring of research project in question;
- Declare any conflict of interest, apparent or real, actual or potential, direct or indirect;
- Declare my corporate affiliation(s) within the framework of each research project that I implement or in which I collaborate;
- Notify the competent authorities (e.g., Research Ethics Board, Research Office, person formally mandated to authorize the carrying out of research projects, etc.) of any investigation or any sanction of which I would be the subject;
- Notify the Research Office of any change regarding my research activities;
- Maintain my scientific skills and knowledge necessary to carry out my research activities;
- Regularly update my knowledge regarding cultural safety, Indigenous methodologies, research ethics, responsible conduct in research as well as, where applicable, good clinical practices and standard operating procedures;
- Ensure the competence of the members of my research team;
- Acknowledge the CBHSSJB in my publications and communications.

In addition, I declare that I have read the Tri-Council Policy Statement 2, Chapter 9 (TCPS2, 2022) and have familiarized myself with the First Nations Principles of Ownership, Control, Access, Possession (OCAP®).

Finally, I hereby consent to the communication to the competent authorities of information enabling my identity to be established when an allegation of failure to conduct responsible research involving me proves to be founded.

Signature of applicant	Date	Full name of applicant

TEMPLATE 1.2

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	
SUBMISSION DATE	
MAIN OBJECTIVE(S)	
EXPECTED SCIENTIFIC OUTCOME(S)	
EXPECTED BENEFITS FOR THE COMMUNITY	
PRINCIPAL INVESTIGATOR(S)	
CBHSSJB COLLABORATOR(S)	
COMMUNITY PARTNERS	
CBHSSJB INVOLVEMENT	
TIMEFRAME	
FUNDING	
DOCUMENTATION	

Please return this form to this email, with the proposed project.

18tcr.research.committee@ssss.gouv.qc.ca

TEMPLATE 1.3

Research vs. Quality Improvement

DEFINING RESEARCH, EVALUATION AND QUALITY IMPROVEMENT

The following document is adapted from the "Research versus quality improvement screening tool" designed by the Center for Applied Ethics at the MUHC. It is designed to help you determine if your project is considered research requiring REB review or an evaluation or quality improvement (QI) project that is exempt from REB review and approval. It also describes the process that must be followed when a project is research, evaluation, quality improvement or when you are unsure what category your project belongs to.

1 Why is deciding if a project is research, evaluation or quality improvement important?

Research involving human subjects must undergo REB review and approval; evaluation and quality improvement projects do not.

2 What is the difference between research, evaluation and quality improvement?

RESEARCH is defined as: "an undertaking intended to extend knowledge through a disciplined inquiry and or systematic investigation. The term disciplined inquiry refers to an inquiry that is conducted with the expectation that the method, results and conclusions will be able to withstand the scrutiny of the relevant research community."[1] Research aims to produce generalizable knowledge by answering a specific research question or testing a hypothesis via scientific methods.

EVALUATION is a systematic and objective assessment of a given object, its design, its implementation, and its results.[2] It uses collected information to determine what the value of something is and based on that there can be changes or improvements.

QUALITY IMPROVEMENT PROJECTS aim to introduce changes that will lead to improved patient outcomes (health), system performance (care) and/or professional development. Often, quality improvement projects seek to implement already established best practices. Quality improvement projects may use established quality improvement methods (e.g. PDSA cycles) and generally don't place any additional burdens on participants other than what is expected during standard care or practice.

Research, evaluation and quality improvement exist on a continuum. Some projects may contain features of all, which can make it difficult to clearly distinguish research from evaluation and quality improvement initiatives. The Research Ethics Screening Tool was designed to help you make this determination.

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. (2014) p. 13-14.
2. Organization for Economic Co-Operation and Development. Glossary of statistical terms. https://stats.oecd.org/glossary/detail.asp?ID=7097

3 What can I do if I'm not sure whether my project requires REB review?

The Centre for Applied Ethics has created a Research versus Quality Initiative Screening Tool to help you determine whether a project requires REB review.

This tool may help you if:

1. You are uncertain as to whether your project needs to be submitted for REB review
2. If you believe it is evaluation or QI and you require an exemption from REB review letter to provide at time of publication.

4 Do I automatically need REB review if I intend to publish?

No, intent to publish does not determine whether or not a project requires REB review.

5 How do I use the tool?

Carefully read the 12 questions, answer them accurately and act in accordance with the instructions on the tool.

6 Who is responsible for the decision?

The REB is ultimately responsible for determining whether REB review is required. However, you are responsible for the accuracy and completeness of the responses that will be used in the determination of whether a project requires REB review. Regardless of whether the project is determined to be research, evaluation or QI, fundamental principles of respect for persons, welfare and justice apply and should be upheld. Ethical concerns related to evaluation or QI projects may be directed to the MUHC Centre for Applied ethics rather than the REB.

7 What if my evaluation or QI project evolves into a research study?

If you substantially change your evaluation or QI project and you think it is moving towards research, you are responsible for obtaining REB review and the exemption letter will not apply to the new aspects of the study.

8 What do I do if the tool says my project is research?

Submit your project to an appropriate REB and review the Miyupimâtisîun Principles of Research.

9 What do I do if the tool says my project is evaluation or QI?

You are responsible for following any procedures regulating evaluation and QI initiatives in your department and at the CBHSSJB.

Please note: quality improvement projects requiring access to medical records or use of hospital resources must obtain authorization from the DPS.

If you require an REB exemption letter, please email the completed tool to

18tcr.research.committee@ssss.gouv.qc.ca

and write “request for REB exemption letter” in the subject line.

10 What do I do if I use the tool and it is still unclear if my project is research, evaluation or quality improvement (e.g. the difference between the sums is small, i.e. one or less?)

Submit your protocol or a project summary including your goal and methods and the completed tool to the appropriate REB. The project will be reviewed and the REB will make a determination.

11 Who can I contact if I have questions or need help?

Please contact the CBHSSJB Research Office:

18tcr.research.committee@ssss.gouv.qc.ca

TEMPLATE 1.3 | **Research vs. Quality Improvement**
DEFINING RESEARCH, EVALUATION
AND QUALITY IMPROVEMENT

Title of your project

Project leader

Target population, process, program or system

Please provide a brief description of your project including your project's specific objective, method, risks entailed and how the results of the project will be used:

1	Does the project involve the use of an experimental medical device, drug or natural health product which requires approval from Health Canada or an off-label use of an existing drug?	Yes ◯	No ◯
2	Is the project funded by, or being submitted to, a research funding agency for a research grant or award that requires research ethics review	Yes ◯	No ◯

***IF YES** to either of the above, the project should be submitted to a Research Ethics Board.*
***IF NO** to both questions, continue to complete the checklist.*

3	Is the goal of the project to create new generalizable knowledge by answering a question or testing a hypothesis?	Yes ◯	No ◯
4	Is the project design and methodology adequate to support generalizations that go beyond the particular population the sample is being drawn from? (If a pilot study or proof of concept designed to support a future larger scale research project, say "yes".)	Yes ◯	No ◯
5	Does the project seek to control for variables or confounders to promote generalizability?	Yes ◯	No ◯
6	Does the project impose any additional risks on participants beyond what would be expected through a typically expected course of care or role expectations?	Yes ◯	No ◯
7	Will you determine the number of participants via formal statistical justifications, power calculations or expected thematic saturation levels?	Yes ◯	No ◯

LINE A: SUBTOTAL Questions 3 through 7 = (Count the # of YES responses)

8	Is the goal of the project to assess or promptly improve a process, program or system, or improve performance as judged by accepted practice standards?	Yes ◯	No ◯
9	Do you expect the results of your project to be quickly integrated into local practices?	Yes ◯	No ◯
10	Is the project intended to evaluate or implement a best practice within your organization?	Yes ◯	No ◯
11	Would the project still be done at your site, even if there were no opportunity to publish the results or if the results might not be applicable anywhere else?	Yes ◯	No ◯
12	The knowledge sought is expected to directly benefit a process, program or system at the CBHSSJB?	Yes ◯	No ◯

LINE B: SUBTOTAL Questions 8 through 12 = (Count the # of YES responses)

- If the sum of Line A is greater than Line B, the most probable purpose is research. The project should be submitted to the appropriate REB.
- If the sum of Line B is greater than Line A, the most probable purpose is quality/evaluation. If you require an REB exemption letter, email this form to:

  ✉ **18tcr.research.committee@ssss.gouv.qc.ca**
- If the difference between the sums are ≤1, email this form and a copy of your protocol (or projects summary) to the appropriate REB to obtain an REB determination as to whether it should be treated as Research, Evaluation or as QI.

Please note the REB retains the right to make the ultimate determination regarding the need for REB review, regardless of the results implied by use of this screening tool.

TEMPLATE 2.1

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
- ◯ Informed Consent Form(s)
- ◯ Data Collection Forms
- ◯ CBHSSJB and Community Collaboration Plan
- ◯ Knowledge Translation Plan
- ◯ Researcher Status Form, signed (CBHSSJB will provide this)

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 a network approved research ethics board (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.

TEMPLATE 2.2

Researcher Status Form

CONTACT INFORMATION

Name

Department

Job Title

Telephone

Establishment

Email

Are you part of a professional order?

◯ Yes ◯ No

Indicate the professional order of which you are a member and your registration numbaer:

Professional order

Registration number

List of documents required to make your request:

- ◯ This form, completed and signed
- ◯ Signed Commitment to the Miyupimâtisîun Research Principles and Good Collaborative Research Processes
- ◯ Curriculum vitae
- ◯ OCAP® certification or equivalent

Research with Indigenous peoples

If you have carried out research with Indigenous peoples, please provide a summary of those projects. If applicable, please include a description of any past research you have carried out in Eeyou Istchee.

Which disciplinary field(s) does your research cover?

Your research intentions with the CBHSSJB over the next three (3) years

What themes will your research activities address?

If known, briefly describe the research project(s) in which you plan to collaborate in the coming years. Furthermore, indicate, for each of these research projects, the position you intend to occupy (principal investigator, co-researcher, etc.).

What data collection methods do you anticipate will be used as part of your research activities?

Are you considering participating in one or more clinical trials?

Research with other populations/institutions

If known, briefly describe the research project(s) in which you plan to collaborate. Furthermore, indicate, for each of these research projects, the position you intend to occupy (principal investigator, co-researcher, etc.).

Please indicate if you hold researcher status in one or more institutions (include the name of the institution and the date of status expiry).

◯ **I certify that the information contained in the present application is accurate**

Signature of applicant | *Date* | *Full name of applicant*

CBHSSJB RESEARCH OFFICE AUTHORIZATION

◯ *I, the undersigned, support this request.*

Reasons or reservations for support:

Signature of person formally mandated to review and approve re-search: | *Date* | *Print name of person formally mandated to review and approve research*

TEMPLATE 3.1

Research Agreement

CHECKLIST

Once the research project has gone through the evaluation phase, a Research and Data Use Agreement will be drafted between the parties. The purpose of the research agreement is to operationalize the Miyupimpâtisîun Research Principles as well as OCAP® principles. The agreement sets out the responsibilities of the parties.

Please submit the following documents which together will form the agreement:

- ◯ Research and Data Use Agreement*
- ◯ Final protocol (Appendix A)
- ◯ Ethical approvals (Appendix B)
- ◯ Contact information for the principal investigators (Appendix C)
- ◯ Statement(s) of Assent (Appendix E-1)
- ◯ Personal Commitment Concerning Data Use (Appendix E-2)
- ◯ List of co-investigators and collaborating researchers (Appendix E-3)
- ◯ Consent Form(s) (Appendix F)
- ◯ DPS Authorization Form, if applicable*

**Forms will be provided by the Research Office.*

Once the agreement has been signed by all parties, the CBHSSJB will issue a Letter of Authorization allowing the research project to begin.

TEMPLATE 3.1.1

Instructions for Completing the Research Agreement Checklist

Once the project has completed the evaluation phase, a Research Agreement will be drafted between the parties. Please submit the following documents, which will be integrated into the agreement.

Research and Data Use Agreement*	The Research Office will provide a blank agreement. Please fill in project information where indicated. The template includes several appendices for the principal investigator (PI) and the Research Team to complete as per the instructions in each document. We've listed them here for your convenience.
Final protocol *(Appendix A)*	The final protocol, approved by the REB, will be attached to the Research Agreement as Appendix A.
Ethical approvals *(Appendix B)*	Appendix B will include the REB approval letter or certificate. The PI will be responsible for REB renewal. Each renewal will be appended to the original agreement along with the renewed CBHSSJB Letter of Authorization. If your project requires approval from the Board of Directors, the Board resolution will also be attached in this section.
Contact information for the principal investigator (Appendix C)	As the respondent for the project, the PI(s) must provide up-to-date contact information. If PIs join or leave the project, an updated contact list will be appended to the agreement.
Working Procedure Related to the Review of Publications *(Appendix D)*	No action is required at this stage of the process, but please ensure that all members of the Research Team read the procedure and understand their obligations if they intend to publish or present.
Statement of Assent *(Appendix E-1)*	This is a signed statement from each PI confirming that they hold no conflicts of interest in relation to the project. If they do have a conflict of interest, provide details.
Personal Commitment Concerning Data Use *(Appendix E-2)*	All members of the research team should sign a copy of this form to acknowledge the terms set out in the research agreement concerning data use and joint results.
List of Co-investigators and Collaborating Researchers *(Appendix E-3)*	Please provide a list of co-investigators and collaborating researchers, indicating their affiliations and dates of involvement. This list should be updated if there are changes to the team.
Model Consent Form *(Appendix F)*	The Model Consent Form, approved by the REB, will be attached as Appendix F and updated annually if necessary.
DPS Authorization Form*	If the project requires access to medical charts or other CBHSSJB databases, the researcher will need to apply for authorization. The Research Office will provide the form and facilitate the authorization process.

**Forms will be provided by the Research Office.*

Once the research agreement has been signed by all parties, the CBHSSJB will issue a Letter of Authorization allowing the research project to begin.

TEMPLATE 3.2

DPS Authorization Form

1. Applicant identification (to be completed by the applicant)

Name of the principal investigator and contact information including organization
Date of application

2. Research project description (to be completed by the applicant)

Title	
Main objective	
Name of approving Research Ethics Board (REB)	Approval number

3. File retrieval request (to be completed by the applicant)

Target period (years)	Duration of the research
Where will files be consulted	
Estimated number of files to be consulted	Manner in which files will be consulted (paper vs digital)
Data (variables) to be collected	Location where data will be stored
Duration of retention	Approximate date of destruction or repatriation of data
Platforms or software that will be used to store and process data	
Brief description of confidentiality mechanisms	
Name all the individuals and bodies to whom a similar request has been made for the purposes of this research project	

4. Confidentiality commitment (to be signed by the applicant)

I, the undersigned, commit myself and the individuals of my team or anyone working with the data collected through this form, to:

- Keep confidential, either verbally and/or in written form, any nominative information that I and my team may have become aware of during our consultation of the files.
- Use the data obtained solely for the purpose of the research project mentioned above.
- Ensure that any computer files or paper documents created for research purposes follow the same rules of confidentiality as the medical record.

Applicant's signature *Date*

5. Director of Medical Affairs and Services (DMAS)

Signature *Date*

6. Department of Regional Medical Archives (to be completed by Archives)

Date of reception of the request

Type of file search ◯ Digital databases ◯ Manual (paper-based registries/charts)

Number of files required

Access granted for one or multiple instances ◯ One ◯ Multiple

Location of files ◯ Physical place ◯ System

Formal agreement with the research team making the request (to be sent to the Commission on Access to Information) NOTE:

Once the request has been completed and signed by the researcher, it should be sent to the Research Office at **18tcr.research.committee@ssss.gouv.qc.ca**

Ref.: Article 125 Loi sur l'accès aux documents des organismes publics et sur la protection des renseignements personnels (chapitre A2-1) et article 19.2 Loi sur les services de santé et les services sociaux (L.R.Q. c. S4-2) (2006-10). Law 25 An Act to modernize legislative provisions as regards the protection of personal information.

TEMPLATE 4

Termination Letter/Declaration

Name | *Email*

SUBJECT:
TERMINATION LETTER FOR | **CBHSSJB reference:**

Title | *Project number*

DECLARATION

I, ..., hereby declare being an employee, student, trainee, coordinator, investigator or other individual involved in the project [TITLE].

I understand that a Research Agreement dated [DATE] governs the project and contains several sections with respect to confidentiality, publications, and the use of the data and results, during the agreement and once it has ended. I understand that the agreement is governed and construed in accordance with the laws of the Province of Quebec and the laws of Canada applicable therein.

I understand that the Research Agreement specifically provides that the Original Data will be given to the CBHSSJB for conservation. Original Data is identifiable and non-identifiable information about the Eeyou people used in the context of the project, whether in paper, electronic or other form, along with the indicators and their syntax, and includes nominal, numerical and categorical data.

I understand that any Joint Results I or my team have created based on the Original Data are co-owned with the CBHSSJB. Joint Results comprise synthesized data based on Original Data, as stated in the Research Agreement. I also understand that I may not use or transfer any Joint Results without obtaining the CBHSSJB's prior written consent, with the exception of results already published in the context of the project, which I may use for teaching purposes only.

I confirm that all publications have been finalized as listed in Annex A. [INCLUDE IF ANY PENDING].

I hereby declare that I, and my co-researchers, collaborators, employees and students will cease to use all Original Data on [DATE], as specified in the agreement. I will then transfer all the Original Data to the CBHSSJB. I will ensure that all copies in my possession or in the possession of my co-researchers, collaborators, employees and students, have been given to the Research Office of the CBHSSJB. I will not use the Joint Results after [DATE] unless I obtain consent from the CBHSSJB.

I will comply with the knowledge translation plan set out in the Research Agreement and will provide study results to the participating communities, with prior approval from the CBHSSJB Research Office.

Declaration signed on ..... before the designated representative of the research team.

DECLARANT WITNESS

Name | *Name*

Position | *Title* | *Role in the project*

Signature | *Signature*

All signed Declaration Forms must be returned to the CBHSSJB Research Office: **18tcr.research.committee@ssss.gouv.qc.ca**

ANNEX A

Please list title of the article, publication, date of publication or status.

Example: The Disproportionate Prevalence of Type 2 Diabetes Mellitus in Indigenous Females Compared to Males: DDT and Gestation as Potential Factors in the James Bay Cree of Subarctic Quebec, Canada (Submitted to "Scientific Reports", December 2020, Pending Acceptance for Publication)