*Body’s LOGO*

**PRIVACY IMPACT**

**ASSESSMENT (PIA) REPORT**

Project title:

Research project goal(s):[[1]](#footnote-2)

Name of attached researcher responsible for the PIA:

Date of assessment:

Date of review, if applicable:

The Privacy Impact Assessment (PIA) results from an analysis of the *Request Form for Authorization to Be Informed of the Existence of and Have Access to Health and Social Services Information Necessary for Carrying Out a Research Project Without the Consent of the Persons To Whom That Information Relates* (“PIA Form”). The PIA Form and this report are appendices to the written agreement signed between the researcher and the body[[2]](#footnote-3) to which the researcher is attached. This PIA Report should be consistent with the information provided through the submission forms in Nagano (if any) and the research protocol. If, despite the analysis of these documents, there is still some need for clarification, the committee on access to information and the protection of personal information  (AIPPI committee) or any other authority responsible for PIAs (hereinafter, the committee) may contact the attached researcher (and his/her team) to obtain further details or changes. For some bodies, the Nagano *Discussions* tab is the preferred tool to support traceability and project documentation.[[3]](#footnote-4)

At the [name of body], the committee that reviews PIAs is composed of the following individuals:[[4]](#footnote-5)

[Names and titles of individuals; generally includes a person responsible for the protection of personal information, a person responsible for information security, a person with knowledge of the applicable legislation, etc.]

If necessary, please consult your body’s Research Ethics Board (REB) or committee (AIPPI or other) for more information.

**Section 1: Assessment of criteria identified in sections 44 to 47 of the AHSSI[[5]](#footnote-6)**

An assessment of the criteria below is also part of the REB’s mandate to ensure the protection, safety, and well-being of research participants, including their privacy and the confidentiality of their health and social services information (hereinafter, health information).[[6]](#footnote-7) The assessment is made by analyzing all submitted documentation, including the research protocol, based on the applicable legislation and ethical standards. In this regard, the committee that reviews PIAs performs a second assessment of these criteria, with the collaboration of the attached researcher.

1. **The goal being sought can only be achieved if health information is communicated in a form that allows the persons concerned to be identified.**

Yes  No

Rationale:

Please check all that apply.

The collected information will be de-identified

In order to be informed of the existence of and have access to health information that is necessary to carry out a research project and identified in the PIA Form (Question 12 and Schedule 1), the attached researcher (and his/her team) must have access to health information about an individual that allows the individual to be identified directly or indirectly.

However, the nature of the research allows the subsequent use of such information in a de-identified form for more secure use (“working file”). This file includes the collected information and reference numbers (or codes). The nominal file[[7]](#footnote-8) is kept in a separate secure record (restricted and limited access) under the responsibility of the attached researcher. It may be necessary for quality control reasons or potential additions of information.

The collected information will not be de-identified

The nature of the research does not allow the subsequent use of such information solely in a de-identified form for the following reasons:

*(Please justify your choice. The use of non-de-identified information requires a compelling demonstration that the research cannot be carried out without “direct or indirect identifiers.” )*

1. **It is unreasonable to require the attached researcher to obtain the consent of the persons concerned.**

Yes  No

Rationale:

Since this is an exception to the principle of concerned persons’ consent in the area of the protection of personal information and their right to privacy, it is imperative to demonstrate that it is unreasonable to require the consent of persons whose information is necessary in order for the research project to be carried out.

Please check all that apply.

In this case, the attached researcher confirms:

Exhaustive size of population under study

According to the information provided in this authorization request, the research project targets a large number of persons. As a result, the human, material, financial, organizational, and other resources required to obtain consent would place a burden on the attached researcher or his/her team or body such that the project would be unworkable.

Missing or obsolete contact information

According to the information provided in this authorization request, the information being sought concerns a high proportion of individuals for whom the available contact information is no longer up to date. Consequently, there is a risk of introducing bias into the research for a segment of the population whose consent is impossible to obtain, which could affect the validity of the research results or be incompatible with the research goals.

Deceased persons

According to the information provided in this authorization request, the information being sought concerns a high proportion of deceased persons. Consequently, there is a risk of introducing bias into the research because of the loss of information concerning the portion of the population whom it is impossible to contact in order to obtain their consent. This could impact the validity of the research results or be incompatible with the research goals.

Other situations, please specify:

1. **The research goal outweighs the impact of using or sharing health information in the public interest on the privacy of the persons concerned.**

Yes  No

Rationale:

It is important to mention here that the field of health is a founding pillar of our civil society and that it is consequently recognized as an area of public interest. Furthermore, health research can improve life, and heal and save lives, not to mention the fact that it can also help improve the trajectory of care and social services for citizens.

The purpose of this test is to balance the anticipated benefits of the research project, as outlined in Section 9 of the PIA Form, against the risks associated with access, use, communication, and retention of health information over individual privacy. This test thus pits the public interest against individual privacy rights. It must be able to demonstrate that the research goals are important enough to justify that the public interest takes precedence over individual privacy rights.

So, taking into account the arguments outlined in Section 9 of the PIA Form and the measures taken by the attached researcher and his/her team to protect individual privacy, please justify why the public interest trumps individual privacy rights:

For more information on how to conduct a proportionality test, please refer to the explanatory guide.

1. **Health information is used in a way that ensures its confidentiality.**

Yes  No

Rationale:

Please check all that apply.

The information is stored in a secure space specific to the attached researcher on the institution’s secure server, which belongs to the *Réseau de la santé et des services sociaux (RSSS)*, Quebec’s public health and social services network).[[8]](#footnote-9)

This secure space is part of the body’s IT system, which obtained certification or approval from the Bureau de certification et d’homologation before being able to be used. This procedure aims in particular to strengthen governance of the RSSS’s information technologies, to ensure the fairness and transparency of the processes, and to promote the autonomy and accountability of the various players within the limits of their responsibility. <2189/[[9]](#footnote-10)

In addition, the Direction générale des technologies de l’information of the Ministère de la Santé et des Services sociaux (MSSS) has the largest number of RSSS security specialists. This expertise enables it to control and oversee the security of the IT network and to quickly resolve any incidents that are detected.[[10]](#footnote-11)

Access to the body’s secure system is logged and requires unique user authentication.

The information will be saved in a secure space specific to the attached researcher and not belonging to the RSSS. In these circumstances, the attached researcher must provide the committee with all the necessary information so that it can assess the risks associated with this secure space. This information is attached to and forms part of this report.

To be able to carry out research activities within the body, the attached researcher has researcher status or research privileges. In this regard, he/she must attend various training sessions and comply at all times with the laws, regulations, and good practice applicable to research, including those arising from the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Good Clinical Practice* of the International Conference on Harmonisation (ICH) and the MSSS document titled *Cadre global de gestion des actifs informationnels – volet sécurité* and those relating to the responsible conduct of research.[[11]](#footnote-12) These documents frame the importance of maintaining the protection of personal information.

The information will be destroyed within the timeframes specified at the time of this authorization request, taking into account the applicable legislation and internal policies in effect. The attached researcher is responsible for destroying the information stored in his/her secure IT space as soon as it is no longer required or no longer than the maximum retention period specified in the PIA Form and the agreement. The attached researcher must also notify the body of its destruction. The agreement signed between the body and the attached researcher (as required by law) imposes, among other things, this obligation on the attached researcher and the body.

The body has put in place a registry listing authorization requests under sections 44 to 48 of the AHSSI as a control measure. The registry includes a retention schedule that allows for a reminder to be sent to the attached researcher at the end of the specified period to verify that he/she has actually destroyed the health information at the end of the retention period indicated in the PIA Form or, if not done, demand him/her to do so as soon as possible and notify the body following destruction.[[12]](#footnote-13) Where necessary and justified, the attached researcher may also take steps to renew the agreement with the body.

An attached researcher is a physician or, if a member of a professional order, subject to the same rules of confidentiality, whether practising in a clinic or taking part in a research activity. Professional secrecy must be maintained in the performance of his/her professional activities, in any body or in private practice.

The attached researcher plans to share health information with an external researcher or collaborator. He/she must take the necessary measures to govern the sharing of this information, including signing a communication agreement with the body, where necessary, which must outline the protection and security measures to be respected. Those measures must be as restrictive as those imposed by law.

In the event that health information is shared outside Quebec, the attached researcher must complete Schedule 2 of the PIA Form. The researcher must also participate in the privacy impact assessment depending on the country in which the health information will be shared, taking into account the method of transfer, the frequency of transfer, the form of shared information (e.g., de-identified), the medium on which the information will be retained by the external collaborator, and the safeguards used to maintain the confidentiality of the information shared within the recipient institution.

1. **Only the necessary information is disclosed.**

Yes  No

Rationale:

Please check all that apply.

In the course of the research, only health information necessary to meet the goals presented by the attached researcher when requesting authorization to be informed of the existence of and/or have access to the information will be consulted and/or collected by the attached researcher. Where possible, all of this information will be de-identified.

In the course of the research, the attached researcher will inevitably have access to health information included in the research participants’ clinical records in order to extract the information sought through the authorization request. However, as previously mentioned and where possible, the information will be de-identified and only the working file will subsequently be used to carry out the research.

The various documents received, including the Nagano submission forms where applicable, the research protocol, and the PIA form, have been analyzed and cross-referenced to ensure that only the information needed for the research will be consulted and/or collected.

**Section 2: Assessment of risk posed to an individual’s privacy**

Include in this section your perception of the level of risk associated with this research. According to the Quebec Commission d’accès à l’information (CAI), the term “risk of a privacy breach” is defined as “*a situation or event that could cause harm to an individual in terms of privacy or another right, but in relation to his or her privacy. The risk is a potential threat to the right to privacy that may materialize in the future.”[[13]](#footnote-14)*

To assess this risk, an analysis grid proposed by the CAI is commented on in the explanatory guide. This assessment should consider the potential severity of the consequences of an adverse event (e.g., theft of health information, identity theft, etc.) and the likelihood of that event occurring (e.g., frequency of such events). So, assessing the level of risk is a subjective process, and it is preferable that this analysis be conducted by a committee. Research may entail more than one risk. Consequently, each risk needs to be identified and assessed.

In the table below, please indicate the risks identified for the research project. For each of these risks, please rate, on a scale of 1 to 4, the potential severity of the consequences of an adverse event and the likelihood that it will occur (1: very low; 2: low; 3: high; and 4: very high). For more information, please refer to the explanatory guide.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Risk identified | Health information being sought | Severity1  (1-4) | Likelihood2  (1-4) | Risk level3  (1-16) |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| Etc. |  |  |  |  |

1 Severity of potential consequences

2 Likelihood that the risk will occur

3 The risk level is the product of severity and likelihood (severity X likelihood).

Taking into account the risks identified and the values obtained for each of these risks, please rate the overall risk for this research.

Very low risk level (1 and 2)

Moderate risk level (3 and 4)

High (high or very high) risk level (6, 8, 9 and 12)

Unacceptable risk level (16)

Please justify this overall risk analysis and describe the means used to reduce these risks (mitigation measures):

|  |  |  |
| --- | --- | --- |
| **Conclusion** | | |
| Based on the information submitted for this authorization request and following the corresponding Privacy Impact Assessment, we recommend:  Approval[[14]](#footnote-15) of this request   * There is a very low risk that the research will have a minor impact on an individual or a small number of individuals; * The likelihood of a risk arising from access, use, and communication of health information is very low.   Conditional approval[[15]](#footnote-16) of this request[[16]](#footnote-17)  Please justify:  Refusal of this request  Any unfavourable decision must be substantiated and written notification sent to the researcher who submitted the authorization request. | | |
|  |  |  |
| Signature of PIA committee representative[[17]](#footnote-18)  Name (please print):  Email: |  | Date: |

Please note that authorization of this request will be official once a written agreement has been entered into between the researcher and the body to which he/she is attached.

1. Copy the goals(s) identified in the research protocol or Nagano forms. [↑](#footnote-ref-2)
2. In this report, the term “body” means any institution or body referred to in the *Act respecting health and social services information* (CQLR, c. R-22.1). [↑](#footnote-ref-3)
3. Procedure for requesting clarifications to be adjusted based on the body’s reality. [↑](#footnote-ref-4)
4. Composition to be adjusted by the body. [↑](#footnote-ref-5)
5. *Act respecting health and social services information* (CQLR, c. R-22.1). [↑](#footnote-ref-6)
6. Health and social services information is defined in section 2 of the AHSSI. [↑](#footnote-ref-7)
7. A nominal file may include information such as first and last names, the user’s file number, and the number cross-referencing to the de-identified file. [↑](#footnote-ref-8)
8. To be adapted based on the body’s reality. [↑](#footnote-ref-9)
9. <http://www.ti.msss.gouv.qc.ca/Familles-de-services/Bureau-de-certification-et-d-homologation.aspx>. [↑](#footnote-ref-10)
10. <http://www.ti.msss.gouv.qc.ca/Familles-de-services/Securite.aspx> [↑](#footnote-ref-11)
11. To be adapted based on the body’s requirements. [↑](#footnote-ref-12)
12. The body must submit an annual report to the Minister of Health and Social Services and to the Commission d’accès à l’information on research projects for which an authorization request has been submitted. [↑](#footnote-ref-13)
13. Quebec Commission d’accès à l’information. “Réaliser une évaluation des facteurs relatifs à la vie privée. Guide d’accompagnement à la démarche et à sa documentation.” Commission d’accès à l’information du Québec, April 2024, p.33. <https://www.cai.gouv.qc.ca/uploads/pdfs/CAI_GU_EFVP.pdf>. [↑](#footnote-ref-14)
14. Term to be customized by the body based on internal procedure [↑](#footnote-ref-15)
15. Term to be customized by the body based on internal procedure [↑](#footnote-ref-16)
16. If applicable, also detail the conditions at this location [↑](#footnote-ref-17)
17. Term to be customized by the body based on internal procedure [↑](#footnote-ref-18)