*Body’s LOGO*

**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**

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| 1. **INSTRUCTIONS** |
| For more information about this form and how to complete certain sections, please refer to the document titled: *Guide explicatif facilitant la complétion du Formulaire EFVP et du Rapport EFVP dans le contexte de la LRSSS* [explanatory guide to facilitate completion of the PIA form and the PIA report in the context of the AHSSI] (hereinafter, explanatory guide).  **Privacy Impact Assessment (PIA):**  Under sections 44 to 48 of the *Act respecting health and social services information* (CQLR, c. R-22.1, hereinafter, AHSSI), a researcher attached to a body[[1]](#footnote-2) referred to in that Act may, under certain conditions, be informed of the existence of and have access to health and social services information (hereinafter, health information) held by a body to carry out a research project. Under those provisions, in order to be informed of the existence of and have access to health information, the attached researcher must, among other things, obtain authorization from the person exercising the highest authority within the body (or any person mandated for that purpose), carry out a PIA, and sign a communication agreement with the body to which he/she is attached. A copy of the agreement must be provided to each body consulted under section 46 of the AHSSI and to the Commission d’accès à l’information.  However, if access, collection, or communication of health information may **rely on a valid consent of the persons concerned** (s. 6 of the AHSSI), you do not have to complete this form.  **Research Context**  Please check the situations that apply to your research:  In the course of my research, I need access to personal information that is not health information (e.g., information available from human resources). In this regard, I understand that I must complete the form(s) requesting access to personal information for study, research or statistical purposes, which differ from this one. Refer to the explanatory guide for more information.  In the course of my research, I need to share health information outside Quebec. I must therefore complete Schedule 2 of this form.  For legal compliance purposes, several questions will need to be answered repeatedly, for example, in this form and in your application to the Research Ethics Board. **Please ensure that the information provided in all your applications is consistent.** |

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| 1. **IDENTIFICATION OF ATTACHED RESEARCHER** | |
| Name:    Title:    Department / Service: | Name of the body to which the researcher is attached:    Business address:    Email:  Telephone: |

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| 1. **BRIEF DESCRIPTION OF THE RESEARCH** |
| Research title:    Please provide a brief summary of the research goals, the population targeted by the research (including projected staff requirements for each of the bodies covered by this request), the proposed methodology, and timelines: |
| Nature of the request:  ☐ Research (with approval by the Research Ethics Board - REB)  Project number with the REB (e.g., 2022-5555) :  New request  Changes to an existing request  *Please complete only the sections of the form where changes are being made*  ☐ Request for access for teaching, training, or reflective practice purposes. For these specific situations, you may not need to complete this form. Please refer to the explanatory guide for more information. |

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| 1. **IDENTIFICATION LEVEL OF REQUESTED INFORMATION** |
| **To what identification level of information do you want to be informed or have access? Please check the most identifiable level to which you will have access.** (Please refer to the explanatory guide for more information)  Identifiable information  Information that can identify a specific individual through direct identifiers (e.g., name, social insurance number, or health insurance number) or that can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence, or unique personal characteristic);  De-identified information (coded, depersonalized, list of cases without identifiers)  Information for which direct identifiers have been removed and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., if the attached researcher retains a list that links the participants’ code name with their actual name so data can be re-linked, if necessary);  If the information is **anonymized** or **aggregated**, please refer to the explanatory guide for more information.  Should there be any difficulty in determining the level of identification, please contact the Research Ethics Board or the committee assessing PIAs within your body to obtain support. |

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| 1. **USE OF INFORMATION** |
| 1. **For what purpose do you want to use the information?**   Verification of eligibility criteria  Retrospective study  Prospective study  Other, please specify: |
| 1. **What is the period covered by the health information you wish to collect or consult (e.g., January 1, 1980, to December 31, 1985)?**          to  Please provide a rationale for this period: |
| 1. **How long (e.g., weeks, months, years) do you plan to retain the health information collected for the research?**   Anticipated information retention period:  Please provide the reason(s) for the health information retention period for your research:  Please note that the retention period is necessary in order to prepare the communication agreement. |

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| 1. **CONSULTATION WITH BODIES HOLDING THE HEALTH INFORMATION AND COVERED BY THE REQUEST** |
| **Please identify the individuals and bodies that must be consulted before granting this authorization request.**  Only one authorization request addressed to the attached researcher’s body is required for a research project. However, before granting your request, the bodies concerned must be consulted. Please list these bodies where indicated. For more information, please refer to the explanatory guide.  ☐ None  Body(ies) referred to in the AHSSI, please specify:  Ministère de la Santé et des Services sociaux:  Other department(s) or body(ies) of the government of Quebec, please specify:  University(ies), please specify:  Other, please specify: |

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| 1. **NEED TO OBTAIN INFORMATION THAT ALLOWS THE PERSONS CONCERNED TO BE IDENTIFIED DIRECTLY OR INDIRECTLY** |
| **Why do your research goals require health information to be shared in a form that would enable identification or re-identification of the persons concerned?**  Quality control / assurance mechanism (data entry validation)  Assurance of the safety of research participants  Tracing mechanism for adding or linking data to file  Verification of eligibility criteria with a view to requesting participation  Other, please specify:  **If you have checked that you wish to verify the eligibility criteria, will the collected information be used to reach out directly to the persons concerned in view of their participation in the research activity?**  Yes  **Please specify the information to be communicated to these persons:**  Recruitment script approved by the Research Ethics Board  Consent form approved by the Research Ethics Board  Other, please specify:  No |

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| 1. **DEMONSTRATION OF THE IMPOSSIBILITY TO OBTAIN CONSENT** |
| **Why is it impossible for you to obtain the consent of the persons to whom the information relates? You can select more than one item.**  There is a risk of introducing bias into the research owing to (please select applicable situation(s)):  High proportion of potential participants with out-of-date contact information since initial data collection;  ☐ Use solely of data for individuals willing to consent. Please provide justification:  Proportion of potential participants who are likely to have died since initial data collection, or whom it is not appropriate to contact;  The research relies on de-identified information held by the body;  The purpose of collecting information (e.g., verifying eligibility for a clinical trial);  The human, material, financial, organizational and other resources required to obtain consent would place a burden on researchers or the body such that the research would be unworkable. Please elaborate on the reason below. Note that the high number of targeted participants falls into this category;  Other, please specify:  **If necessary, please add any information needed to justify your response:**    *(Please note that reasons such as the ease of the access without consent process, the administrative burden of obtaining consent, the fear of refusal (or any other similar rationale) are not sufficient to justify the impossibility of obtaining consent.)* |

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| 1. **PROJECT’S PUBLIC INTEREST VALUE** |
| **In your opinion, how do your project’s goals meet public interest needs (social relevance) and, in light of the public interest, outweigh the protection of individual privacy? Please check all that apply.**  Research to improve knowledge of a disease or disorder  Research to develop or improve diagnostic practices  Research to develop treatments, programs, or intervention methods to improve the health or quality of life of the Quebec population  Research to improve the well-being of future users of the health and social services network in Quebec  Research to address a public health need or a need for prevention or health promotion  Research to improve the delivery of health care or social services  Research to facilitate the delivery of one or more other public services  Research to guide decision-making in the area of public policies  ☐ Other, please specify:  Please provide a brief rationale for your response(s) and any additional details necessary for completion of Section 3 of the PIA Report: |

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| 1. **TO BE INFORMED OF THE EXISTENCE OF AND HAVE ACCESS TO HEALTH INFORMATION** |
| 1. **Who will find out about the existence of and allow access to health information? Please check all that apply.**   The body’s resource persons  Archives team  Team responsible for management of the data lake or warehouse  The body’s clinical service, please specify:  Other authority of the body, please specify:  Research team:  Remote access with username and password authentication  On-site access with username and password authentication  On-site access to physical records  Other, please specify:  **If necessary, please add any information needed to clarify your answer, for example, who will have access and how:**  **Name all individuals on the attached researcher’s team who will have access to the original source of health information (e.g., user records):**   |  |  |  |  | | --- | --- | --- | --- | | Last/First Name: |  | Title: |  | | Last/First Name: |  | Title: |  | | Last/First Name: |  | Title: |  | | Last/First Name: |  | Title: |  | | Last/First Name: |  | Title: |  | | Last/First Name: |  | Title: |  |   *Here, the body specifies its requirements for updating the list (with the body) while the project is being carried out.*  Please note that this list must be kept up to date throughout the research project and made accessible to the appropriate authorities, if necessary (refer to the explanatory guide for more information). |
| **10. (b) If health information is accessed by the body’s resource persons (other than the research team), by what means or method will they transfer this information to the attached researcher?**  Encrypted data transferred via a secure communication protocol  Transfer via a web-accessible, collaborative platform, authentication by username and password (e.g., RedCap)  Remote access with username and password authentication  On-site access with username and password authentication  By the method preferred by the body’s archives  Other, please specify:  Please specify any relevant information on how health information will be communicated to the attached researcher by the body (e.g., method, frequency, etc.): |
| **10. (c) What means will be used by the attached researcher and his/her team to process and retain information? Please check all that apply.**  Secure IT systems of the attached researcher’s body  IT systems of a body other than the attached researcher’s (e.g., multi-centre research), please specify and justify:  Personal secure IT systems, please specify and justify:  Personal IT systems, please specify and justify:  Cloud services, please specify where hosted (province, country):  Backup copies, please specify and justify:  Other: </3795><3824/  *As attached researcher, I undertake to have a confidentiality agreement signed by any individual to whom health information will be made accessible.[[2]](#footnote-3)*  *(Note: Use of the body’s secure system is mandatory unless the need to use another system and the security of that other IT system are demonstrated.)[[3]](#footnote-4)* |

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| 1. **SHARING AUTHORIZED INFORMATION WITH THIRD PARTIES** |
| 1. **Will a researcher or a collaborator external to the attached researcher’s body be informed of the existence of or have access to information in the course of this research project? Please check all that apply.**   No (project carried out solely by the attached researcher and his/her team). If No, go to question 12.  Yes, please specify:  ☐ A researcher attached to one of the bodies in the health and social services network referred to in the AHSSI (e.g., INSPQ, Héma-Québec, etc.),please specify:[[4]](#footnote-5)  ☐ A university researcher or a government collaborator external to the health and social services sector located in Quebec, please specify:  ☐ A university researcher or a government collaborator located outside Quebec, please specify:  ☐ A private company; please specify the name of the company, the name of the collaborator, and the location where the information is hosted (Quebec or outside Quebec):  ☐ Other, please specify:  ☐ If the information sought through this request must be shared with a researcher or a collaborator external to the attached researcher’s body, a communication agreement must be entered into with the attached researcher’s body in advance. Please insert here the name of the body’s authority to be contacted and its contact information:  ☐ If the information sought through this request must be shared with a researcher or a collaborator located outside Quebec, please complete Schedule 2 of this form.  If you answered Yes to the previous question (11a):   1. **What identification level of information will be shared with or accessed by this third party? Please check the most identifiable level to which this third party will have access.**   Identifiable information  De-identified information (coded, depersonalized, list of cases without identifiers)   1. **How is information transferred to the external researcher or collaborator?**   Encrypted data transferred via a secure communication protocol  Transfer via a web-accessible, collaborative platform, authentication by username and password (e.g., RedCap)  Remote access with username and password authentication  On-site access with username and password authentication  Other, please specify:   1. **What type of IT system or workstation will be used by the external researcher or collaborator to process and retain the information?**   Secure IT systems of another body referred to in the AHSSI  IT systems of another body/private company, please specify:  Cloud services; please specify the type of service and where hosted (province, country):  Backup copies, please specify:  Other, please specify:  *Please note that the use of personal IT systems is not possible to process and retain health information.* |

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| 1. **SOURCES OF ACCESS AND/OR COLLECTION OF HEALTH INFORMATION** |
| 1. **From which source(s) will the information come? Please check all that apply.**   Information from a biobank (sample analysis data)  Information from a patient registry (e.g., Quebec cancer registry)  User information from the body’s information systems or from clinical service databases reported or not in a collection form or Case Report Form (CRF)  Please specify:[[5]](#footnote-6)  PACS software </4862  Document management software (digitized physician/nurse notes, pathology reports, surgical reports, etc.)  Hospital appointment scheduling software  Lab results software  Microbiology results software  Pharmaceutical orders management software  Emergency user management software </4886  Bed/services occupancy management software  Surgery planning and management software  Cancer/tumour board registry and software (e.g., SARDO)  Cancer treatment management software  Blood/transfusions bank software  User information from physical records, please specify:  Information from sources other than the body (e.g., medical/administrative files held by the Régie de l’assurance-maladie du Québec), please specify:  Other, please specify:  Does your research require cross-referencing multiple sources of information (e.g., data coupling)?  No  Yes, please specify: |
| 1. **What is the approximate number of users/participants of the body subject to this request for information? Please itemize these numbers of participants by body in the event of such a need.** |
| 1. **How many variables per user/participant will be included in the list of requested information including repeated variables\***)**?**   Fewer than 100 variables  100 to 500 variables  More than 500 variables  **Please complete Schedule 1 with details of the information sought through the authorization request.**  \*) Example of a repeated variable: the follow-up date variable for daily follow-up over seven (7) days. |

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| 1. **SIGNATURE OF THE ATTACHED RESEARCHER RESPONSIBLE FOR THE AUTHORIZATION REQUEST** | | |
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| Signature |  | Date |

**Schedule 1**

**List of Health Information Sought Through the Authorization Request**

Which of the following types of information would you like to be informed of the existence of (will be consulted) or have access to (will be collected) to carry out your research?

**Please check all that apply. You must justify for each checked item of information why it is necessary for your research. Also, please indicate if the information will only be consulted or if it will also be collected (or both).** When an item of information is identified in the second column, all other columns must be completed.

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| **Please identify the sources of access (software or files)** | **Please identify the health information necessary for the research** | **Please justify the need for to be informed of and/or have access to that information** | **Please check which applies** |
|  | ☐ Last/first names | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ User file numbers | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ Telephone or fax numbers | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ Email addresses | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ Social Insurance Numbers (SIN) | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ Health Insurance Numbers (HIN, RAMQ) | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ Biometric information, including finger and voice prints | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ All geographic subdivisions smaller than a country, including mailing address, city, county, neighbourhood, postal code, and their equivalent geocodes | Please specify which are required: | ☐ Consulted  ☐ Collected |
|  | ☐ Information regarding sex life or sexual orientation | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ Information about religious or philosophical beliefs | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ Socio-demographic information (e.g., gender, family status, occupation, income level, education) | Please specify the nature and justify: | ☐ Consulted  ☐ Collected |
|  | ☐ Facial or potentially identifiable images or photographs and any comparable images | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ Genetic information | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ Date elements directly linked to an individual (e.g., date of admission, date of death, date of diagnosis, etc.), and format (e.g., year, year and month, etc.) | Please specify the nature and justify: | ☐ Consulted  ☐ Collected |
|  | ☐ Device identifiers and serial numbers | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ Health plan beneficiary numbers | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ Any other unique number, characteristic, or identification code | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ Certificate/licence numbers | Rationale: | ☐ Consulted  ☐ Collected |
|  | ☐ Imaging information (e.g., MRI, CT scan) | Please specify the nature and justify: | ☐ Consulted  ☐ Collected |
|  | ☐ Recording or video information (e.g., ECG) | Please specify the nature and justify: | ☐ Consulted  ☐ Collected |
|  | ☐ Information on users with a rare condition or pathology | Please specify the nature and justify: | ☐ Consulted  ☐ Collected |
|  | ☐ Numerical or quantitative variables (e.g., laboratory value) | Please specify the nature and justify: | ☐ Consulted  ☐ Collected |
|  | ☐ Category or recoded variables (e.g., BMI category, ICD-10 diagnostic codes) | Please specify the nature and justify: | ☐ Consulted  ☐ Collected |
|  | ☐ Open-text variables (e.g., medical notes, report notes) | Please specify the nature and justify: | ☐ Consulted  ☐ Collected |
|  | ☐ Other | Please specify: | ☐ Consulted  ☐ Collected |

**Schedule 2**

**Communication of Health Information Outside Quebec**

This schedule is in development. It will need to include additional elements regarding the assessment of risk factors associated with the communication of health information outside Quebec.

1. In this form, the term “body” means any institution or body referred to in the *AHSSI*. [↑](#footnote-ref-2)
2. If the body has additional local requirements regarding disclosure of the identity of individuals with access to the information, its requirements are listed here. [↑](#footnote-ref-3)
3. *Note to be customized in line with the organizational reality.* [↑](#footnote-ref-4)
4. Clarification requests removed by the body if it feels the information is already provided in Nagano and does not need to be repeated here. [↑](#footnote-ref-5)
5. *Choice of responses to be customized by bodies (highlighting to be removed afterwards).* [↑](#footnote-ref-6)