*Body’s LOGO*

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| **AGREEMENT ALLOWING TO BE INFORMED OF THE EXISTENCE OF AND HAVE ACCESS TO HEALTH AND SOCIAL SERVICES INFORMATION[[1]](#footnote-2) NECESSARY FOR CARRYING OUT A RESEARCH PROJECT WITHOUT THE CONSENT OF THE PERSONS TO WHOM THAT INFORMATION RELATES (“AGREEMENT”)** |
| **BETWEEN:**   |  |  | | --- | --- | | **IDENTIFICATION OF THE BODY THAT AUTHORIZES THE ATTACHED RESEARCHER TO BE INFORMED OF THE EXISTENCE OF AND HAVE ACCESS TO HEALTH INFORMATION FOR RESEARCH PURPOSES** | | | Name of body to which the attached researcher is affiliated:    Address of headquarters: | Represented by:  If different:  Business address:    Email:  Telephone : |   **(hereinafter referred to as the “Body”)**  **AND**   |  |  | | --- | --- | | **IDENTIFICATION OF ATTACHED RESEARCHER[[2]](#footnote-3)** | | | For the Attached Researcher with research privileges within the Body  Name:       ,  Business address:    Email:  Telephone: |  |   **(hereinafter referred to as the “Researcher”)**  **(The Body and the Researcher** are hereinafter referred to jointly as the “**Parties**” and individually as a “**Party”**.)  **PREAMBLE**  **WHEREAS** the Body is responsible for the protection of the health information in its possession;  **WHEREAS** the Researcher has developed a research project titled[[3]](#footnote-4):       (“Research”);  **WHEREAS** in order to carry out the Research, the Researcher and any persons on his/her team[[4]](#footnote-5) (hereinafter, team) require to be informed of the existence of and, where necessary, have access to health information held by the Body;  **WHEREAS** pursuant to sections 44 to 48 of the *Act respecting health and social services information*, CQLR, c. R-22.1 (“AHSSI”), there is an exception to the general rule of consent whereby a researcher attached to a body referred to in the act may be informed of the existence of and have access to health information held by the body for the Research, subject to certain conditions.  **WHEREAS** in the context of the Research, it may be necessary for health information to be accessed and/or collected through an authorization granted to the Researcher in order for him/her to be able to access the medical record(s) of a user or users;  **WHEREAS** the Researcher has submitted to the Body a *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 the Information Relates[[5]](#footnote-6)* (“PIA Form”), attached to this Agreement as Schedule A;  **WHEREAS** a Privacy Impact Assessment has been completed and a *Privacy Impact Assessment Report[[6]](#footnote-7)* (“PIA Report”) has been prepared and attached to this Agreement as Schedule B;  **WHEREAS** the evaluation of this authorization request submitted by the Researcher has taken into account, among other things, the information provided in the PIA Form and the favourable opinion presented in the PIA Report;  **WHEREAS** the Body, by entering into this Agreement, authorizes the Researcher to be informed of the existence of and have access to health information necessary for carrying out a research project, without the consent of the persons to whom that information relates;  **WHEREAS** it is the prerogative of the Body, which is responsible for the protection of health information, to mandate the Researcher to carry out the de-identification of the health information collected in the course of the Research, where applicable;  **WHEREAS** a copy of this Agreement, including Schedules A and B, must be provided to each body consulted under section 46 of the AHSSI and to the Quebec Commission d’accès à l’information (“CAI”), in accordance with section 48 of the AHSSI;  **WHEREAS** the Researcher will not be able to access health information until the institutional suitability letter has been received authorizing Research within the Body;  **WHEREAS** the Parties wish to agree on the terms and conditions applicable to access, use, communication, retention, and destruction of health information collected for the Research;  **WHEREFORE, THE PARTIES AGREE AS FOLLOWS**:   1. RESPONSIBILITY OF THE RESEARCHER 2. As the Researcher is responsible for the proper conduct of the Research, he/she undertakes to comply with the policies, procedures, and any other rules in force within the Body and, where applicable, within the bodies consulted under section 46 of the AHSSI, as regards the processes to be followed to determine the existence of and/or access the health information covered by this authorization request.[[7]](#footnote-8) The Researcher undertakes that the team, where applicable, will also comply therewith. 3. The Researcher and his/her team, where applicable, undertake to determine the existence of and/or have access only to the health information authorized by the authorization request submitted for the Research. The Researcher further undertakes to ensure strict confidentiality of such information in accordance with the applicable legal requirements for the protection of personal information at all stages of its life cycle, that is, during its consultation, collection, use, communication, retention, and destruction. The Researcher also understands that he/she may be held responsible in the event of a leak of information. 4. Without limiting the scope of the following, the Researcher also undertakes that the information provided to him/her through this request: 5. will only be made accessible to persons for whom knowledge of the information is necessary for the performance of their duties, which persons have signed a [confidentiality agreement](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.cai.gouv.qc.ca%2Fdocuments%2FCAI_FO_engagement_confidentialite_Loi25.docx&wdOrigin=BROWSELINK);[[8]](#footnote-9) 6. will only be shared with a third party (external collaborator) if a written agreement has first been entered into; 7. will not be used for purposes other than those set out in the authorization request submitted for the Research, the details of which are outlined in the associated PIA Form and PIA Report, appended to this Agreement; 8. will not be linked to any other personal information or health information file not intended for the Research; 9. will not be communicated, published, or otherwise disseminated in a form that enables identification of the persons concerned; 10. will be retained for a period of ( the “Retention Period”), as indicated in the Body’s retention rules[[9]](#footnote-10) or the *Food and Drug Regulations*, if applicable:   ☐ 10 years  ☐ 15 years  ☐ Other, please specify and justify:   1. will be destroyed at the end of the Retention Period required for the Research. Upon expiration of the Retention Period, you must notify the Body that the health information has been destroyed. Consequently, should a need arise to extend the Retention Period, the Researcher undertakes to take the necessary steps to renew this Agreement; 2. where applicable, the health information collected for the Research will be de-identified by the Researcher and his/her team. 3. The Researcher further undertakes to: 4. immediately notify the *Body* and the CAI ([cai.communications@cai.gouv.qc.ca</1885><1891) of:></1891](mailto:cai.communications@cai.gouv.qc.ca)) :  * failure to comply with any condition of the Agreement; * any breach of the protection measures provided under the Agreement; * any event that could compromise the confidentiality of the information.  1. take appropriate security measures to ensure the protection of the health information consulted, collected, used, communicated, retained, or destroyed, including to:  * take the datasets prepared using the health information to the lowest level of identifiable information required to achieve the Research goals; * comply with the conditions set out in the PIA Form and the PIA Report with respect to the security measures surrounding access, collection, use, and retention of health information, including the retention of health information on the Body’s secure IT system or through another means provided for in the authorization request and approved by the Body; * take any other measures included in the PIA Report, issued by the committee responsible for the PIA, or by the Body, where applicable.  1. inform the Body of any request made to the Researcher by the CAI or in the course of an audit by the CAI. 2. RESPONSIBILITY OF THE BODY 3. As the Body is responsible for protecting health information, it shall respect the confidentiality of the health information in its possession and shall undertake to comply with the applicable laws and regulations; 4. In accordance with the established procedures in the area of access to health information, the Body undertakes to allow the Researcher to be informed of the existence of and have access, under certain conditions, to the health information in its possession and identified in the PIA Form, taking into account the information contained in the PIA Report, when necessary for the Research; 5. The Body undertakes to destroy any information under its control at the end of the period provided for its retention as detailed in the PIA Form and the associated PIA Report, if applicable; 6. The person exercising the highest authority within the Body may, without delay or formality, revoke this Agreement where he/she has reason to believe that the generally accepted standards of ethics and scientific integrity, the security measures, or any other measure provided for in this Agreement are not being complied with or that the protection of health information is compromised. In the event of such revocation, this Agreement will be terminated and the Researcher will lose the right to be informed of the existence of, or have access to and use, health information. During the term of this termination, the obligations set out in clause 1 of this Agreement will remain in effect for any health information accessed prior to the withdrawal of authorization; 7. In the event of termination of the Agreement, the Body undertakes to notify, without delay, the CAI, the Research Ethics Board, and, where applicable, each body consulted under section 46 of the AHSSI. 8. SIMILAR ACCESS REQUESTS WITH OTHER BODIES   Where applicable, for the purposes of the Research, the Researcher has identified in section 6 of the PIA Form the persons and bodies that must be consulted by the Body before granting this authorization request, as provided for in section 46 of the AHSSI.   1. VERIFICATION OF ELIGIBILITY CRITERIA   If the information is used to reach the persons concerned for the purpose of soliciting them to take part in the Research, the information in section 7 of the PIA Form will be provided to them.   1. EFFECTIVE DATE OF THE AGREEMENT   This Agreement will come into effect upon its signature by the Researcher and the Body to which he/she is attached. It is understood that a copy of this Agreement shall be sent to each body consulted, when required, and to the CAI. However, as indicated in the preamble to the Agreement, the Researcher may only be informed of the existence of and have access to health information following receipt of the authorization letter to carry out the Research signed by the Body’s formally mandated person (FMP).  **IN WITNESS WHEREOF**, this Agreement has been signed by the Researcher and an authorized representative of the Body  For the Researcher:   |  |  |  | | --- | --- | --- | |  |  |  | | Name (please print) |  |  | |  |  |  | | Signature |  | Date (dd/mm/yyyy) |  |  |  |  | | --- | --- | --- | | For the Body:  Name:  Title: |  |  | |  |  |  | |  |  |  | | Signature |  | Date (dd/mm/yyyy) | |

1. For simplicity, the term “health information” includes health and social services information as defined in the *Act respecting health and social services information* (CQLR, c. R-22.1, hereinafter AHSSI). [↑](#footnote-ref-2)
2. The use of the male form is in accordance with the SSRA, but it represents all genders. [↑](#footnote-ref-3)
3. Insert the project title. [↑](#footnote-ref-4)
4. These persons are as identified in section 10 of the PIA Form, and they will have access to authorized health information. These persons have signed a confidentiality agreement. [↑](#footnote-ref-5)
5. Title of the form to be adapted based on the Body’s reality. [↑](#footnote-ref-6)
6. Title of the report to be adapted based on the Body’s reality. [↑](#footnote-ref-7)
7. In certain circumstances, there may be associated costs. [↑](#footnote-ref-8)
8. The Body can refer here to the model document it suggests. [↑](#footnote-ref-9)
9. To be adapted based on the Body’s retention periods for the type of Research. See SOP or document approved by the BAnQ for the Body. [↑](#footnote-ref-10)