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Research Ethics Board

**Secondary Data Application, Supplement**

**Access to Health Care Records without Patient/Client Consent but with Permission of Health Information Custodian (Alternatively: Access to Health Care Records with Permission of Health Information Custodian but without Patient/Client Consent)**

Context: The Ontario Personal Health and Information Protection Act (Section 44) permits sharing of confidential health information without the consent of the patient/client under specific circumstances. Under PHIPA, patient/clients are the owners of their health care information, while health care providers are considered custodians of the information. The principles and guidelines set out Tri-Council Policy Statement, 2nd edition (2014) are consistent with PHIPA.

The PHIPA act can be located at: https://www.ontario.ca/laws/statute/04p03

Use of health care information for research without consent from the individual who owns the health care information includes three components:

1. A written application submitted to the health information custodian that addresses the criteria set out in PHIPA Section 44.
2. Clearance from the Research Ethics Board.
3. A copy of the signed agreement with the health information custodian which stipulates all conditions placed by the health information custodian on the use of the information.

“Before a health information custodian discloses personal health information to a researcher… the researcher shall enter into an agreement with the custodian in which the researcher agrees to comply with the conditions and restrictions, if any, that the custodian imposes relating to the use, security, disclosure, return or disposal of the information. (PHIPA.44.5).

The information requested in Section 2 below is gathered in order to meet the criteria set out in PHIPA, and may be included in the written application to the health care custodian. The REB will review this information, in conjunction with the information provided on the Secondary Data Application. It may be necessary to repeat information provided in the Secondary Use application in this supplement.

The REB notes that the health information custodian is legally responsible for the conditions under which the information is released and used, and may choose to place additional conditions or restrictions on the use of the information.

The REB requires that a signed copy of the final agreement (Point 3) that stipulates the conditions of use for the health care information is filed with the REB prior to conducting the research. This agreement may be filed prior to clearance; or the REB will provide conditional clearance based on the information provided below, pending receipt of the final agreement.

**1. Name and contact information for the health care information custodian:**

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| Title:        | Name:       |
| Department (or organization if not affiliated with U of Windsor):       |
| Mailing address:       |
| Phone:        | Email:       |

**2. Research plan**

a) Name, title, and affiliation of each person involved in the research (44.2.a)

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| --- | --- | --- |
| Name | Title | Affiliation |
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b) The nature and objectives of the research and the public or scientific benefit of the research that the researcher anticipates (44.2.b)

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c) Describe why the objectives of the research cannot reasonably be accomplished without using the personal health information that is to be disclosed (44.3.a)

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d) Describe the safeguards that will be in place to protect the privacy of the individuals whose personal health information is being disclosed and to preserve the confidentiality of the information (44.3.b)

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e) Describe why it is impractical to obtain the consent of the individuals whose personal health information is being disclosed. (44.3d)

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**3. Access to Health Care files**

a) Describe how the health care information will be extracted for the research purpose (E.g., provided to the researcher by the custodian in anonymized form; extracted from the health care file by a custodian researcher; extracted from the health care file by a non-custodian researcher under the supervision of a custodian; other).

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b) Will any non-custodian member of the research team have direct access to the health care file?

Yes [ ]  No [ ]

If Yes,

Describe how access to the health care information will be supervised by the custodian:

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**4. Conditions of use of health care information**

The researcher / research team agrees to abide by the conditions set out in PHIPA Section 44.6.

A researcher who receives personal health information about an individual from a health information custodian shall (as stipulated in PHIPA):

1. comply with any conditions specified by the research ethics board;
2. use the information only for the purposes set out in the research plan as approved by the research ethics board;
3. not publish the information in a form that could reasonably enable a person to ascertain the identity of the individual;
4. not disclose the information except as required by law and subject to the exceptions and additional requirements, if any, that are prescribed;
5. not make contact or attempt to make contact with the individual, directly or indirectly, unless the custodian first obtains the individual’s consent to being contacted;
6. notify the custodian immediately in writing if the researcher becomes aware of any breach of this subsection or the agreement;
7. comply with the agreement established with the health care custodian