

Policies, Procedures and Guidelines

Complete Policy Title:

Policy Number (if applicable):

Policy on Research Participant
Confidentiality and the Retention of
Legal Counsel

n/a

Approved by:

Responsible Executive:

Senate /

Vice-President (Research)

Board of Governors

<u>Date(s) of Original Approval:</u>

Date of Most Recent Approval:

June 6, 2024

June 6, 2024

<u>Supersedes/Amends Policy Dated</u>:

Policy-Specific Enquiries:

n/a

Vice-President (Research)

PURPOSE

- The University is committed to providing financial and other necessary support for researchers to maintain
 assurances of confidentiality made to participants of a Research Ethics Board-approved study. Such
 support may include the retention of independent legal counsel ("Counsel") when there are challenges to
 the assurances of confidentiality previously provided to participants as part of the information and consent
 process.
- 2. The University, with the cooperation of the researcher and the Vice-President (Research), may take reasonable and lawful measures to prevent the disclosure of confidential participant information.
- 3. McMaster University, Hamilton Health Sciences Corporation, and St. Joseph's Healthcare Hamilton/Research St. Joseph's Hamilton (hereafter collectively referred to as "the Institutions") will work collaboratively to coordinate a response in relation to this Policy.

SUPPORT

- 4. Support will be provided through the Office of the Vice-President (Research) and the Office of Legal Services. Depending on the specific circumstances, support may include:
 - a) advice on the extent of assurances of confidentiality made to participants and on the identification of privacy and/or security risks;
 - b) investigation of and advice on current best practices bearing on the matter;
 - c) advice on whether to seek the support of the researcher's professional organization(s) whenever ethical obligations may also derive from professional obligations; and/or
 - d) legal action or support to respond to third-party action; for example, subpoenas, search warrants, requests for access to documents, and access to information requests.

Retention of Counsel

- 5. In cases where there is an irreconcilable conflict between the researcher's ethical obligations to safeguard the confidentiality of participant information and the researcher's legal obligations, the University will assist the researcher in retaining the services of Counsel.
- 6. The mandate given to Counsel will be to advise the researcher on the personal consequences of a possible decision to respect ethical obligations rather than legal obligations.
- 7. The purpose of the mandate will not be to provide advice on the potential consequences of the researcher's decision on the University or other parties.
- 8. If the protection of participant confidentiality requires a defence in court, the mandate to Counsel will include the researcher's representation.

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PROCEDURES

- 9. A researcher shall seek the assistance of the Office of the Vice-President (Research) as soon as possible after being presented with:
 - a) a request for access to confidential participant information; or
 - b) an action seeking to compel disclosure of confidential participate information.
- 10. In cases where the study involves cross-appointed researchers, researchers from multiple Institutions, the resources of multiple Institutions, and/or includes data from multiple Institutions, the Vice-President (Research) will communicate with the other relevant Institution(s) to coordinate the response and support of the researcher(s).
- 11. The Vice-President (Research) shall review the matter and seek relevant information from the researcher(s) and the relevant Research Ethics Board approval as appropriate, including details of what may be disclosed if the request or order is enforced and what promises of confidentiality were made to participants.
- 12. The Vice-President (Research), with assistance from the Office of Legal Services, shall determine if there is a conflict between the researcher's ethical obligations to safeguard the confidentiality of participant information and the researcher's legal obligations. If such a conflict exists, the University will assist the researcher in retaining the services of approved Counsel.
- 13. The Office of Legal Services will document and communicate the specific mandate of the legal advice and/or representation being provided by Counsel for the situation.
- 14. Any subsequent advice from Counsel shall be considered confidential and privileged and will not be shared with the University unless:
 - a) the researcher requests that such advice be shared;
 - b) the University requests that such advice be shared and has secured the express consent of the researcher.

COST FOR SERVICES OF COUNSEL

- 15. The costs for the services of approved Counsel will be paid for by the University, where appropriate. If the research involves more than one of the Institutions, the Vice-President (Research) will communicate with the other relevant Institution(s) to determine a cost-sharing strategy, where appropriate. The strategy employed will depend on the nature of the specific case in question.
- 16. In cases where the University bears the costs for services of Counsel, any potential providers must be preapproved by the Office of Legal Services. Such Counsel shall not be one from the roster of Counsel that normally provides advice to the University.

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17. The Office of Legal Services shall oversee and pay the approved legal costs to ensure that the services provided by Counsel are consistent with the communicated mandate and are necessary to protect participant confidentiality.

RELATED POLICIES AND LEGISLATION

- 18. This Policy is to be read in conjunction with the following policies, statements, and legislation. Any question of the application of this Policy or related policies shall be determined by the Vice-President (Research) as appropriate and in conjunction with the administrator of the other policy or policies. The University reserves the right to amend or add to this list. Please note that this is not a comprehensive list.
 - Freedom of Information and Protection of Privacy Act
 - Research Involving Human Participants, Policy Statement on
 - Tri-Council Policy Statement (TCPS 2)
 - Tri-Council Policy Statement (TCPS 2) Interpretations: Privacy and Confidentiality

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