

**Research Office**

**University Human Research Ethics Board**

**Standing Operating Procedures (SOPs)**

**and Guidance Documents**

**Version: December 2021**

**ABOUT THE POLICY SUITE:**

This Policy Suite informs the review process for research involving human subjects at The University of Winnipeg. It combines a set of policies and procedures developed expressly by the Office of the Vice-President, Research and Innovation, as well as national standards codified in the Network of Networks/CAREB SOPs (hereafter, N2 SOPs) (http://www.N2Canada.ca). Use of the N2 SOPs facilitates the harmonization of ethics reviews with other Canadian jurisdictions. In operational terms, where a University of Winnipeg addendum is attached to the N2 SOP, both the SOP and the addendum define how the ethics board functions, and how researchers should understand the review process. Where there is no addendum, the N2 SOP defines the procedures followed by the ethics board.

Questions about the SOPs can be directed to the program officer of the Ethics Office at ethics@uwinnipeg.ca.

| **SOP#. Version** | **UNIVERSITY OF WINNIPEG POLICIES AND PROCEDURES** |
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| UW-UHREB 1.001 | Composition of the University Human Ethics Research Ethics Board (UHREB) |
| UW-UHREB 2.001 | Reconsideration and Appeal of UHREB Decisions |
| UW-UHREB 3.001 | Departmental Ethics Committees (DEC) |
| UW-UHREB 4.001 | Scholarly Review of Non-Peer Reviewed Research |
| UW-UHREB 5.001 | Responsibilities of Researchers |

| **SOP#. Version** | **N2/CAREB SOP TITLE** |
| --- | --- |
| **100 General Administration (101-108)** |
| 101.003 | Authority and Purpose |
| 102.003 | Research Requiring REB Review |
|  |  University of Winnipeg Addendum 001 |
| 103.003 | Training and Education |
| 104.003 | Management of REB Office Personnel |
| 105A.003 | Conflicts of Interest – REB Members and REB Office Personnel |
| 105B.003 | Conflicts of Interest – Researcher |
| 105B.003 | University of Winnipeg Addendum 001 |
| 105C.003 | Conflicts of Interest – Organization |
| 106.003 | Signatory Authority |
| 107.003 | Use and Disclosure of Personal Information |
| 108.003 | Standard Operating Procedures Maintenance |
| **200 REB Organization (201-203)** |
| 202.003 | **Management of REB** Membership |
| 203.003 | **Duties of the REB Members** |
| **300 Functions and Operations (301-303)** |
| 301.003 | REB **Submission Requirements and Administrative Review** |
| 302.003 | **REB Meeting Administration** |
| 303.003 | **Document Management** |
| **400 Reviews of Research (401-407)** |
| 401.003 | Delegated Review |
| 402.003 | **REB** Review Decisions |
| 403.003 | **Initial Review - Criteria for REB Approval** |
| 403.003 | University of Winnipeg Addendum 001 |
| 404.003 | Ongoing REB Review Activities |
| 405.002 | Continuing Review |
| 406.003 | **Research Completion** |
| 407.003 | Suspension or Termination of REB Approval |
| **500 Reviews Requiring Special Consideration (501)** |
| 501.003 | REB Review During Publicly Declared Emergencies |
| **600 REB Communication and Notification (601-602)** |
| 601.003 | Communication – Researcher |
| 602.003 | Communication – Research Participants |
| **700 Informed Consent (701)** |
| 701.003 | Informed Consent Form Requirements and Documentation |
| **900 Quality Management (901-903)** |
| 902.003 | Non-Compliance |

The N2 SOPs and corresponding University of Winnipeg addenda are authorized for use **effective ???? ??, 2021.**

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| **SOP#.Version** | **OTHER DOCUMENTS (update as required)** |
| 603.003 | Glossary of Terms |
| N/A | References |

|  | **UNIVERSITY OF WINNIPEG GUIDANCE DOCUMENTS** **FOR HUMAN PARTICIPANT RESEARCH** |
| --- | --- |
| GUID DOC 1 | Undertakings Requiring Review |
| GUID DOC 2 | Principles Guiding UHREB Review |
| GUID DOC 3 | Procedures Related to Faculty Research and Graduate Student Research |
| GUID DOC 4 | Procedures Related to Course Based and Independent Senior Undergraduate Research |
| GUID DOC 5 | The Consent Process (including Consent Form Examples and Checklist) |
| GUID DOC 6 | UHREB Review of the Assessed Risk of Observational Studies Involving Specific Vulnerable Populations |
| GUID DOC 7 | Post-Approval Activities |
| GUID DOC 8 | Using Student Subject Pools in Research |

|  | **UNIVERSITY OF WINNIPEG FORMS** **FOR HUMAN PARTICIPANT RESEARCH** |
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| FORM 1 | Conflict of Interest and Confidentiality Agreement (UHREB Members, Public Representatives, and *ad hoc* Advisors) |
| FORM 2 | Scholarly Review Form (Faculty) |
| FORM 3 | Scholarly Review Form (Graduate Student) |
| FORM 4 | Adverse Events Report |
| FORM 5 | Protocol Amendment Report |
| FORM 6 | Annual Report |
| FORM 7 | Final Report |