

# REB#

REB Use Only

**Secondary Use of Data Research Application**

***(REB application Adapted from Baycrest, UHN, Mount Sinai and Ontario Shores Hospitals)***

**Instructions & Guidelines**

1. *Does this research study involve contacting patients?  Yes*  *No*

*If YES, then please complete the REB Application, Human Subjects Research Application Form (TAHSN)*

2. *Does this research study involve retrospective Chart Review and accessing client files?*

*If YES, complete the Retrospective Chart Review Application.*

3. *Does this research study exclusively utilize Secondary Data?*

*If YES, complete this form.*

**4.** All Investigators (including students) accessing an approved data base for conducting research are required to provide evidence of training for privacy protection of human subjects prior to submission of this Application.

**This requirement for training may be met by completing the brief web-based program at** <https://tcps2core.ca/welcome>.  **Upon successful completion of the tutorial, print a certificate for your own record, provide a copy to the REB and enter the certificate number in the appropriate place on the Application.**

**5.** Submit the Application form, together with supporting documentation to Laura Snow ([lsnow@waypointcentre.ca](mailto:lsnow@waypointcentre.ca)). Secondary Data applications normally undergo a delegated review process. The Principal Investigator is responsible for providing the data custodian with the REB approval letter.

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| SECTION 1A: Principal Investigator Information (Must be Waypoint Staff Member) | | | |
| Name: |  | Telephone #: |  |
| Title |  | Fax # |  |
| Department:  Wing/Floor/Room: |  | Email |  |
| Address Including Postal Code |  | Privacy Tutorial Certificate  Number |  |

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| **SECTION 1B: Co-Investigator(s) Information *(Attach additional pages if required)*** | | | |
| Names(s) | 1.  2. | Telephone # | 1.  2. |
| Title | 1.  2. | Fax # | 1.  2. |
| Department & Wing/Floor/Room | 1.  2. | Email | 1.  2. |
| Address Including Postal Code | 1.  2. | Privacy Tutorial Certificate Number | 1.  2. |

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| **SECTION 1C: Data Extractor(s) Information (*Attach additional pages if required*)** | | | |
| Same as Principal Investigator  Same as Co-Investigator(s) | | | |
| Name(s) | 1.  2. | Title | 1.  2. |
| Institution | 1.  2. | Telephone # | 1.  2. |
| Department/  Division | 1.  2. | Email | 1.  2. |
| Address | 1.  2. | Privacy Tutorial Certificate Number | 1.  2. |

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| SECTION 2: Data Base Being Accessed: | | |
| Name of Data Base: | Electronic Databases  Specify: | State of Data (anonymous, de-identified, identifiable)  Specify: |
| Number of Records/Participants | When/where data was collected. | Other  Specify: |

**IMPORTANT:** Please include a copy of the user/site access agreement for the specific database being accessed (if applicable).

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| SECTION 3: Project Summary | | | | | | | |
| Project Title |  | | | | | | |
| **State the rationale, objectives and the question(s) this study will answer?** |  | | | | | | |
| **Provide study summary**  **and outline analyses**  ***(maximum 250 words)***  \*Attach detailed protocol separately |  | | | | | | |
| **Risks and benefits of the proposed study and how will you manage the risks?** |  | | | | | | |
| **Specify the variables that will be included in the analysis** |  | | | | | | |
| **Proposed start date of project** | /     /  (DD/MM/YYYY) | | | **Proposed termination date** | | /     /  (DD/MM/YYYY) | |
| How will this be funded? | | Grant  Specify funding source: | Industry  Sponsor: | | Internal  Specify funding source: | | No Funding Required |

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| **Please address the following ethical concerns regarding secondary use of data. The response to these issues should be sufficiently detailed and complete to allow the REB to determine the merit of the investigation and that sufficient protection is in place to protect the confidentiality and security of the information. Incomplete applications will be returned. All Study Personnel must sign the confidentiality agreement below.** | |
| SECTION 4: Information Protection - Patient Identifying Data | |
| **Will any identifying information be used in this research?** | Yes  No  **If yes, please justify the necessity for its collection:** |
| **Please indicate the type of patient identifying data *(check all that apply)*** | Full Name  Address  Telephone Number  Provincial Health Card Number  Social Insurance Number  Medical Record Number  Full Date of Birth  Age or Year of Birth  Month and Year of Birth  Gender  Discharge date  Email addresses  Healthcare Provider e.g. Family Physician, VON Etc.)    Other (Specify) |
| **Why is it necessary to use identifiable data for this research??** | Using identifiable data  Not using identifiable data  **If you are using identifiable data, please justify the necessity for its use:** |
| **If you are proposing to use identifiable data without consent from participants for this new use of their data, explain how the criteria for secondary use without consent are met (TCPS 5.5A).** | Is the use of this data essential for the research? Explain.   1. Is the use of identifiable information unlikely to adversely affect the welfare of participants? Explain. 2. How will you protect participants’ privacy and safeguard identifiable information? 3. How will you ensure that you do not include information about individuals who would not have wanted their data used in this way? 4. Is it impossible or impracticable\* to seek consent from participants for the use of their data? 5. Have you received necessary permissions for secondary use of data from the data owners?   \*Impracticable means causing undue hardship or onus that jeopardizes the conduct of the research. It does not mean a mere inconvenience. |
| **Will individual identifiers be removed and data anonymised or de-identified once the relevant data is collected?** | Yes  No  **If no, please justify**: |
| **Will this data be transferred external to Waypoint?** | Yes  No  **Is a Data Sharing Agreement with the outside institution in place?**  Yes  No  Pending  **How will the confidentiality be protected?** |

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| Is this a Multisite Study? | Yes  No  **If yes, identify all participating sites, along with the REB approval status**:    **Please identify the coordinating site**: |
| **Is the linkage of collected data with other data expected?** | Yes  No  **If yes, please provide details regarding the handling of the linked data** : |
| **Will the data be reported publicly?**  **(e.g. publication, seminar, conference etc.,)** | Yes  No  **Please specify:** |
| **Will the data being collected be used now or in the future for Commercial purposes? Describe any Conflict of Interest (such as financial benefits, share ownership stock options etc.) by members of the research / team/institution/ sponsor** | Yes  No  N/A  **If yes, please provide details:** |
| **How will security and confidentiality of the data be protected, maintained and retained?** |  |
| **When will the cut of data be destroyed? How?** |  |

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| ***Confidentiality and Data Use Agreement:***  THE FOLLOWING REPRESENTS THE TERMS AND CONDITIONS UNDER WHICH THE HANDLING OF CONFIDENTIAL INFORMATION FOR THE PROJECT SHALL PROCEED. THESE TERMS AND CONDITIONS HAVE BEEN DRAFTED IN COMPLIANCE WITH THE *PERSONAL HEALTH INFORMATION PROTECTION ACT* AND OTHER PRIVACY LEGISLATIONS.   1. All information received or exchanged will be held in strict confidence. 2. Information will not be used for any purpose other than for the project for which it was provided. The information will be shared only with those individuals listed on this form, who are working directly on the project, except for authorized oversight of the study. Information use will comply with REB approved conditions, if any. 3. No attempt will be made to contact any individual, directly or indirectly, unless the health information custodian first obtains the individual’s consent to being contacted (see PHIPA (2004) s. 44(6)e) 4. Information will be kept in a location that is physically secure as per approved research protocol and to which access is given only to the individual(s) listed on this form. 5. All direct identifiers will be segregated / stripped from clinical data; a unique study identifier (i.e. a randomly generated or meaningless ID number) will be assigned to each patient record; the Master list linking the ID with identifiable material will be stored in a separate computer file and/or physical location; and the Master list will be locked and password protected. 6. No information will be stored on mobile devices without encryption. 7. No information will be released outside the province of Ontario. 8. Data sent or received electronically by the institution will require that the outside individuals/vendors enter into a confidentiality agreement before the data transfer takes place. The “Statement of Confidentiality” form must be signed, witnessed and returned to Clinical Information Services before providing access to any system/data. The “Statement of Confidentiality” form can be obtained from Clinical Information Services. 9. Policies and procedures on the secure retention and secure destruction of information must be in place by the party undertaking the project. 10. It is strongly recommended that members of the research team and any individual(s) listed below read the   ***Part IV, Sec 44(6)-“Compliance by Researcher” -*** [***http://www.e-laws.gov.on.ca/html/statutes/english/elaws\_statutes\_04p03\_e.h***](http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm)***tm***   1. Publication of confidential information requires adherence to the following principles: 2. The institution agrees to allow the publication of the information as it pertains to the project providing that the institution or its practices are not the main focus of the publication. 3. In cases where the publication focuses on the institution, the institution reserves the right to review and approve the use of this information prior to publication. 4. The institution will be acknowledged within any publication as providing the source information in the following fashion: “The authors kindly acknowledge and thank authorities of Waypoint Centre for Mental Health Care for providing source information on health data for use on this research for the year (XXXX) (specify year)”. 5. A copy of the publication will be given to the institution. 6. In the event of a potential/suspect/or actual breach of privacy (lost/stolen), the Privacy Officer will be contacted within 1 business day. In the event of an actual breach, the Privacy Officer will also be notified in writing (S44(6)). 7. A breach of institutional policy regarding access to information and protection of privacy may have serious consequences or be just cause for termination of my employment and/or affiliation with the institution. 8. Personal Health Information that can easily identify a patient should not be published.   NOTE: any mishandling or unauthorized use of study data will lead to cancellation of REB approval for the study.  The undersigned hereby agree to these terms and conditions governing the handling of confidential information, and commits him /her to these terms and conditions:  \*\* Insert extra terms around the use of data from the database\*\*  ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_*     /     /     \_*\_***  ***Signature of the Principal Investigator Date* (DD/MM/YYYY)**  ***Signatures of all Study Team members (Co-investigator(s)/Data Abstractors):***   |  |  |  | | --- | --- | --- | | ***Print Name*** | ***Signature*** | ***Date Signed***  **(DD/MM/YYYY)** | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |

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| SECTION 4: | | | | |
| **DIVISION/DEPARTMENT/PROGRAM MANAGER APPROVAL:**  I have reviewed this proposal and approve this request. | | | | |
| **Division/Department/Program Manager Signature:**  **Department:** | | **Print Name:** | | **Date:**  **/****/**  **(DD/MM/YYYY)** |
| SECTION 5: REB Office Use Only REB # | | | | |
| 🞏 Approved 🞏 Not Approved 🞏 Pending with revisions | | | | |
| Comments: | | | | |
| **Signature of REB Chair or Designate:** | **Print Name:** | | **Date:**  **/      /**  **(DD/MM/YYYY)** | |