Retrospective Chart Review Application

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)

If NO, then please complete this form, Retrospective Chart Review Application.

You must provide justification for a waiver of consent. Note: The REB may waive the requirement for subject consent and authorization if these criteria are met (***see also PHIPA (2004) s. 44(3)***): a) the research purposes cannot be achieved without the information; b) it is impracticable to obtain consent; c) the information is used in a manner that will ensure its confidentiality; and d) the public interest in conducting the research exceeds the public interest in protecting the privacy of the individuals.

Submit the Application form, together with supporting documentation to Laura Snow, lsnow@waypointcentre.ca. Applications normally undergo a delegated review process. Once the submission is approved, the REB will notify the Principal Investigator (PI) and Health Information Management (HIM) by email. The PI is responsible for providing HIM with the REB approval letter, REB approved Study proposal and the Retrospective Chart Review Application.

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

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.		

SECTION 1C: Data Abstractor(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.		

SECTION 2A: Type of Data Request		
☐ Diagnosis	☐ Demographic Information	☐ Aggregate
☐ Other		
SECTION 2B:Data to be extracted from Note: If data collected from Health Records, this form **MUST** be signed by the Manager, Health Information Management		
☐ Health Records/Clinic/Office Files Specify:	☐ Electronic Databases Specify:	☐ Outside Institutions Specify:
☐Other Specify:		

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 data to be collected (attach data collection form)				
Proposed number of Patients/Charts				
Proposed start date of project	/ / (DD/MM/YYYY)	**Proposed termination date**	/ / (DD/MM/YYYY)	
Date range of requested data under review (e.g. 22/01/1999 to 22/07/1999)	**Start date** / / (DD/MM/YYYY)		**End date** / / (DD/MM/YYYY)	
How will this be funded?	☐ Grant Specify funding source:	☐ Industry Sponsor:	☐ Internal Specify funding source:	☐ No Funding Required

Please address the following ethical concerns regarding access to confidential health information. 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	
If personal health information is collected, used or disclosed, without consent from individuals to whom the information relates, explain why obtaining explicit consent would be impractical.	☐ Yes ☐ No
How will relevant patient charts be identified?	
Have you already developed a list of specific patients?	☐ Yes ☐ No **If yes, please indicate how patients were identified:**
Will any identifying information be recorded?	☐ 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)
Will individual identifiers be removed and data anonymised 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 in place with the outside institution?** ☐ YES ☐ NO ☐ Pending **How will the confidentiality be protected?**

Is this a Multicentre Study?	☐ Yes ☐ No **If yes, identify the coordinating site and the other sites and indicate the REB approval status**:
Any anticipated linkage of the data with other existing data?	☐ Yes ☐ No **If yes, please provide details and how will the linkage information be treated** :
Will the data be reported publicly? **(e.g. publication, seminar, conference etc.,)**	☐ Yes ☐ No **Please specify:**
Will the data 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?	

Confidentiality 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 ***Personal Health Information Protection Act. Part IV, Sec 44(6)-"Compliance by Researcher" - http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm***

11. Publication of confidential information requires adherence to the following principles:

- 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.
- 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.
- 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)".
- A copy of the publication will be given to the institution.

11. In the event of a potential/suspect/or actual breach of privacy (lost/stolen), the Manager, HIM, Privacy and Risk Management (MHP&RM) will be contacted within 1 business day. In the event of an actual breach, the MHP&RM will also be notified in writing (S44(6)).

12. 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.

13. 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:

_____ __ / / __

Signature of the Principal Investigator ***Date* (DD/MM/YYYY)**

Signatures of <u>all</u> Study Team members (Co-investigator(s)/Data Abstractors):

Print Name	***Signature***	***Date Signed*** **(DD/MM/YYYY)**

SECTION 6:		
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 7: REB Office Use Only REB #		
☐ Approved ☐ Not Approved ☐ Pending with revisions		
Comments:		
Signature of REB Chair or Designate:	**Print Name:**	**Date:** / / **(DD/MM/YYYY)**
SECTION 8: Health Information Management (HIM) Office Use Only		
☐ Approved ☐ Not Approved		
Comments:		
Signature of Manager, HIM, Privacy and Risk Management	**Print Name:**	**Date:** / / **(DD/MM/YYYY)**