WAYPOINT CENTRE FOR MENTAL HEALTH CARE

WAYPOINT Research Ethics Board
Clinical Record Review Application Form Guidelines

The request for clinical records information for research purposes can arise as a retrospective study of information previously collected, as part of an ongoing prospective clinical trial, or as part of an audit function carried out by study sponsors or regulatory agencies related to a clinical trial.

In accordance with the Tri-Council Policy Statement, research studies requiring access to information with identifying information must be reviewed and approved by the Research Ethics Board (REB) at WAYPOINT.

This type of REB application is often expedited or delegated (i.e., reviewed by REB Chair and designees only or dealt with without a face-to-face meeting of the REB) yet is occasionally referred to the REB for a full review. Once approved, an REB approval letter and study number will be issued. The turn-around time for a record review application at a regular REB meeting can take a minimum of three weeks.

The REB approval for access to clinical records only entitles investigators (or sponsors and regulators accompanied by WAYPOINT investigators) access to clinical records under the normal security conditions imposed by Clinical Information Services. Costs for photocopying may be charged to investigators. No identifying information may be photocopied and details regarding how copies will be disposed of will be required.

Investigators must sign the application form. In signing the application form, the investigator agrees to comply with the WAYPOINT Confidentiality Policy and acknowledges that the person who will be gaining direct access to the clinical information (e.g., research coordinator, fellow, student, research assistant, monitor) is acting as an agent or delegate of the Investigator. The Investigator accepts full responsibility for the protection of the information.

The Investigator is responsible for contacting the Clinical Information Services Director for further procedures and requirements for accessing the clinical record.

Instructions:

1) Please type your responses. Submit one copy of the Clinical Record Review Application Form to Alison Townsend/ REB Coordinator. You may fax or e-mail the application but **original signatures must be submitted** prior to the start of data collection. If you have questions please contact Alison Townsend/ REB Coordinator].

2) Forms that are incomplete will be returned to the investigator.
3) The WAYPOINT Clinical Information Services will request verification of REB approval (copy of REB approval letter), the Clinical Record Review Application Form, and individual identification prior to granting access to records.

Note: Costs associated with record retrieval may be charged for outside investigators. Contact Alison Townsend, REB Coordinator at WAYPOINT for further information.