Annual/Continuing Approval Checklist and Form

To prevent a lapse in approval, an application for renewal must be received electronically by the JREB office at least two weeks prior to the current JREB approval expiry date.

Checklist:

Yes	N/A	Items
☐	☐	Continuing Approval Application – Signed
☐	☐	Current Approved Protocol/Study Proposal
☐	☐	Current Approved Consent Form – Main
☐	☐	Current Approved Consent Form(s) – Other
☐	☐	Other – please indicate:
☐	☐	Have you included the applicable **Annual/Continuing Review JREB Review Fee** (Non-refundable) for Industry Sponsored Trials? (see JREB review fee policy)

Annual/Continuing Approval Form

Date of Application (yyyy/mmm/dd):

Section I: Study Identification and Contact Information:

1. Previous Approval Date (yyyy-Mmm-dd):

2. Expiry Date of current JREB approval (yyyy-Mmm-dd):

3. Study Title:

4. JREB #: Sponsor Name: Protocol #

5. Principal Investigator Name: Department:

6. Contact Information: Phone E-mail

Section II: Study Information:

1. Is this study open to enrollment? Yes ☐ No ☐
2.
3. If yes, what is the study activation date (yyyy-Mmm-dd)

   If no, please provide a reason:

4. If the study is open are participants enrolled? Yes ☐ No ☐

5. Is the study closed to enrollment but participants remain on treatment or follow-up?
   Yes ☐ No ☐

6. Is this study on hold? Yes ☐ No ☐

   If yes, please explain:

5. Please provide a summary of the progress of the study to date:

6. Number of participants in the study at Ontario Shores Centre for Mental Health Sciences:

	Original # of study subject planned
	# provided consent
	# incompetent to consent

	After screening # declined consent
	Total # completed the study
	# Prematurely withdrawn
	# included in a retrospective chart review (only applicable to retrospective chart review studies)

Number of participants in the study at the Abilities Centre:

	Original # of study subject planned
	# provided consent
	# incompetent to consent
	After screening # declined consent
	Total # completed the study
	# Prematurely withdrawn
	# included in a retrospective chart review (only applicable to retrospective chart review studies)

7. If participants have withdrawn or withdrew consent, please provide details:

8. Were there any problems/complaints in the study that affected the participants or others?

9. Please provide a brief summary of unanticipated events and the actions taken (i.e. unexpected SAEs, Safety Concerns, Protocol Deviations)

10. If applicable, has a Health Canada Inspection or FDA or Sponsor audit been conducted since the last annual/continuing approval? Yes ☐ No ☐

    If yes, please describe outcomes (issues, concerns, findings):

11. Have any relationships with the investigator and the sponsor or other party been developed that might be a conflict of interest (contractual or consultative)?

Yes ☐ No ☐

If yes, please explain:

12. Name of person completing this form:

Contact information: Phone: E-mail:

Section III: Signature of Principal Investigator (PI):
I confirm that all the above information is correct to the best of my knowledge.

Signature of Principal Investigator:	Date (yyyy-Mmm-dd):