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**Annual/Continuing Approval Checklist and Form**

**To prevent a lapse in approval, application for re-approval must be received in the REB office at least two weeks prior to the current REB approval expiry date.**

**It is highly encouraged that an electronic copy of the submission be provided in addition to the submission of the original in paper format.**

**Checklist:**

|  |  |  |
| --- | --- | --- |
| **Yes** | **N/A** | **Items** |
| [ ]  | [ ]  | Cover Letter to include,* Date, Study Title, PI Name, REB #
* Amendment # and Version Date.
 |
| [ ]  | [ ]  | Continuing Approval Application – signed |
| [ ]  | [ ]  | Current Approved Protocol/Study Proposal |
| [ ]  | [ ]  | Current Approved Consent Form – Main |
| [ ]  | [ ]  | Current Approved Consent Form(s) – Other |
| [ ]  | [ ]  | Other – please indicate:       |

**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 REB approval (yyyy-Mmm-dd):

3. Study Title:

4. REB #:       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. If yes, what is the study activation date (yyyy-Mmm-dd)

If no, please provide a reason:

1. If the study is open are participants enrolled? Yes [ ]  No [ ]
2. Is the study closed to enrollment but participants remain on treatment or follow-up?

 Yes [ ]  No [ ]

1. Is this study on hold? Yes [ ]  No [ ]

If yes, please explain:

1. Please provide a summary of the progress of the study to date:
2. Number of Participants in the study at Waypoint.

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|       | # Prematurely withdrawn |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

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 If participants have withdrawn or withdrew consent, please provide details:

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

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

1. 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):

1. 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:

1. 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): |

**SUBMIT COMPLETED FORM TO:**

Glenn A. Robitaille, M.Div., D.Min., RP

Chair, Research Ethics Board

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