

REQUEST FOR ANNUAL APPROVAL

TO: PEI Research Ethics Board **DATE:** _____

FROM: _____ **Contact Nos.** _____
(Principal Investigator or Designate)

ADDRESS: _____

Study Number: _____ **Sponsor:** _____

Study Title: _____

In keeping with ethical and regulatory requirements, the following summary of activity is required with a request that continued approval be granted for the upcoming year:

1. This study was granted FULL APPROVAL on: _____ (Anniversary Date)
2. This request for continued annual approval is for the period/year _____ to _____
3. Has the study started? ___No ___Yes If yes, please give the start date: _____
4. **Study Statistics:**
Number of subjects **expected** for recruitment at this site? _____ How many subjects have been **screened**? _____
Of those screened, how many **enrolled/randomized**? _____ How many subjects remain **active**? _____
How many subjects are on **follow-up**? _____ How many subjects have **completed** the study? _____
5. Have any subjects withdrawn? ___ If yes, why? _____
6. If recruitment numbers are less than expected, what is the likely reason? _____

7. Have all serious adverse events been reported to the REB? ___No ___Yes ___N/A
8. Have important side effects been observed? ___No ___Yes *If yes, please specify as an Appendix to this form.*
9. Is there a Data Safety Monitoring Board (DSMB)? ___N/A ___No ___Yes *If yes, please submit the reports.*
10. Have there been any changes to the protocol in the last year? ___No ___Yes
11. What is the current version and date of the protocol? _____
12. Have there been any changes to the consent form in the last year? ___No ___Yes
13. What is the current version and date of the consent form? _____
14. Have there been any changes to the Investigator's Brochure/Product Monograph ___No ___Yes ___N/A
15. What is the current version and date of the IB/Product Monograph? _____
16. When is the recruitment phase expected to be completed? _____
17. When is the anticipated closure date? _____
18. During the past year, has there been any literature that may be relevant to the risks of the research? ___No ___Yes *If yes, please specify as an Appendix to this form.*

Signature of Principal Investigator or Designate

Printed Name of PI or Designate

Date (yyyy/mm/dd)