June 2018

FOR ALL REB RENEWAL AND AMENDMENT APPLICATIONS

Applications to renew an Research Ethics Board (REB) permit should be submitted a minimum of three (3) weeks prior to the current approval end date to allow sufficient time for review of the application.

UPEI researchers who conduct research that involves patients, staff, resources or data under the auspices of the Health PEI and the Department of Health and Wellness must obtain certification approval from the UPEI REB and from the Health PEI REB before the research begins. UPEI researchers must use the 'UPEI Ethics Review Protocol Submission Form' when submitting new protocols for review and approval. A copy of this form is on the UPEI website.

UPEI researchers who wish to renew or amend existing REB protocols must complete the 'UPEI Research Ethics Board Annual Renewal and Amendment Form for Approved Studies' (below). If the existing protocol was approved by the Health PEI REB then the Health PEI REB study number must be included on the application.

UPEI researchers are no longer required to submit a separate renewal application or amendment application to the Health PEI REB. However, researchers must use the following submission process for review of these files:

1. Submit one e-copy and one hard copy of the following documents to reb@upei.ca, UPEI Research Services, 200 Kelley Memorial Building:

- UPEI REB Annual Renewal and Amendment Form for Approved Studies;
- Revised recruitment advertisement (if applicable);
- Revised Participant Letter of Information (if applicable);
- Revised Participant Consent Form (if applicable);
- Description of important side effects that were observed (if applicable)
- Report/s from the Data Safety Monitoring Board (DSMB) (if applicable);
- Changes to the Investigator's Brochure/Product Monograph (if applicable);
- Updated literature that may be relevant to the risks of the research (if applicable).

2. The UPEI REB will review the submitted application form and associated documents for completeness and to ensure that the proposed renewal and/or amendment application is in compliance with the UPEI REB policy. Complete renewal/amendment applications will be forwarded by the UPEI REB to the Health PEI REB for review.

Please note that UPEI researchers must send their applications and associated documents directly to the UPEI REB – not to Health PEI REB.

3. The Health PEI REB will write to inform the UPEI researcher and the UPEI REB of their decision.

UPEI REB will accept the decision of the Health PEI REB.

RESEARCH ETHICS BOARD

ANNUAL RENEWAL AND AMENDMENT FORM FOR APPROVED STUDIES

Use this form for renewals or amendments of existing protocols. Projects require full ethics review every three years. Submission of new protocols for REB review should be submitted to the UPEI REB using the form 'Ethics Review Protocol Submission Form'. Submissions are regarded by the REB as strictly confidential.

Applications must be typed. Handwritten submissions will not be accepted. Submit one e-copy to reb@upei.ca and two signed hard copies to Research Services, 200 Kelley Memorial

Principal Investigator (PI) name: _____

PI telephone #: _____ PI email: _____

UPEI REB file #: _____ Health PEI REB Study # *(if applicable):* _____

Sponsor *(if applicable):* _____

Study Title: _____

_____

Original protocol Full Approval date *(yyyy/mm/dd):* _____

What type of approval permit is requested? Check all that are applicable:

1st annual renewal ☐ 2nd annual renewal ☐

1st amendment ☐ 2nd amendment ☐ 3rd amendment ☐

Current status of data collection: Complete ☐ Continuing ☐ Abandoned ☐

If data collection has been abandoned, please explain why:

1. Study statistics:
   Total number of participants required for the study: _____
   Number of participants **expected** for recruitment at this site (locally): _____
   How many participants have been **screened**? _____
   Of those screened, how many **enrolled/randomized**? _____
   How many participants remain **active**? _____
   How many participants are on **follow-up**? _____
   How many participants have **completed** the study? _____

2. Have any participants withdrawn? NA ☐ Yes ☐ No ☐
   If yes, why?

3. If recruitment numbers are less than expected, what is the likely reason?

4. When is the recruitment phase expected to be completed? *(yyyy/mm/dd)*: _____

5. Have there been any previously unidentified risks or benefits noted? NA ☐ Yes ☐ No ☐
   If yes, please explain:

6. How are adverse events monitored?

7. Have all serious adverse events been reported to the REB? NA ☐ Yes ☐ No ☐
   If 'no', then please attach information about previously unreported SAEs to this form.

8. Have there been any changes to the protocol (ie study design, changes in method of participant recruitment, funding status, etc) in the last year? Yes ☐ No ☐
   If yes, please explain:

9. What is the current version and date of the protocol? _____

10. What is the current version and date of the Participant Consent Form? _____

11. Do you consider the approved recruitment advertisement/Participant Letter of Information/Participant Consent form to still be appropriate? NA ☐ Yes ☐ No ☐
    If 'No' then please submit a copy of the original form/s as well as a copy of the new form/s with the proposed changes. Proposed changes should be highlighted or marked using 'track changes'.

12. What is the anticipated study closure date? _____

13. Have important side effects been observed? NA ☐ Yes ☐ No ☐
    If yes, please explain: *(attach additional page if necessary)*

14. During the past year, has there been any literature that may be relevant to the risks of the research?
    ☐ No ☐ Yes *(attach new, relevant literature)*

15. Is there a Data Safety Monitoring Board (DSMB)?
    ☐ NA ☐ No ☐ Yes *(attach report/s)*

16. Have there been any changes to the Investigator's Brochure/Product Monograph?
    ☐ NA ☐ No ☐ Yes

17. If applicable, what is the current version and date of the IB/Product Monograph?

Signature of PI: _____
Printed name of PI: _____
Date (yyyy/mm/dd): _____