

RESEARCH ETHICS BOARD

CHANGE IN PRINCIPAL INVESTIGATOR AMENDMENT APPLICATION FORM

Please use this form only for reporting a change in Principal Investigator (PI) of a REB approved study. For any other changes to the study personnel, please use “Change in the Study Personnel/Study Coordinator/Co-Investigator/Research Assistant/Volunteer” form. Please include an updated CV and TCPS2 (2018) and Chart Review Tutorial Certificates of the new PI with this amendment application.

SECTION 1: Study Identification

Date of Application (yyyy/mm/dd): REB File #:
 Sponsor (if any):
 Study Title:
 Study Expiry Date (yyyy/mmm/dd):
 Current PI: Phone: E-mail:
 Person Completing the Form: Phone: E-mail:

SECTION 2: Incoming Principal Investigator

First Name: Last Name: Credentials (MD, Ph.D., RN etc.):
 Department/Division/Program: Phone:
 E-mail: Effective Date of Change (yyyy/mmm/dd):

SECTION 3: Documents

Submit any documents affected by this change. Highlight the changes (both additions and deletions) in a tracked changes copy and also include a clean copy of the document.

- Consent Form(s) Wallet Card(s)
 Recruitment-Related Materials Specify:
 Participant-Directed Materials Specify:
 Other:

Section 4: Questions:

- 1) Is the outgoing PI leaving Ontario Shores or Abilities Centre? Yes No
- 2) If PI not leaving Ontario Shores or Abilities Centre, reason for requesting change in PI
- 3) Does this change affect any other REB files? Yes No
(If yes, submit a separate form for each study)
- 4) Has Contracts been notified of this change? Yes No
- 5) Will study participants be notified of this change? Yes No N/A (No current participants)

6) Do any of the conflicts listed below apply to the incoming PI or any member of his/her immediate family? Yes No

If Yes, indicate which conflicts apply and append a letter to the Chair of the JREB detailing these activities and how they will be managed. Disclose all contracts and any conflicts of interest (actual, apparent, perceived, or potential) relating to this project. Conflict of interest may also arise with regard to the disclosure of personal health information.

- Function as an advisor, employee, officer, director or consultant to sponsor
- Have direct or indirect financial interest in the drug, device, or technology
- Receive an honorarium
- Receive direct or indirect financial benefit from disclosure of personal health information
- Other:
- None of the above

Important Information:

- 1) If the study is governed by one or more research agreements or contracts, please inform Director of Research & Academics and Risk Management Departments at Ontario Shores, or the Senior Director of Programs & Services at Abilities Centre of the change in PI.
- 2) If the study involves research support services from other departments or programs of the hospital (such as Pharmacy, Laboratory Medicine, Data & Analytics, etc.) or the Abilities Centre (Information Technology department, etc.) please inform the affected departments or programs of the change in PI.

Section 5: Signatures for Change of Principal Investigator

A. Outgoing Principal Investigator Statement:

I will no longer assume the role of Principal Investigator for this study and hand over the responsibility of the study conduct to the person named below as the Incoming Principal Investigator.

Print Name

Signature

Date (yyyy/mmm/dd)

B. Incoming Principal Investigator Statement

I assume full responsibility for the scientific and ethical conduct of the study as approved by the REB and submitted protocol and agree to conduct this study in compliance with the Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans (2018); The International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified or will undergo appropriate training to fulfill their role in this project.

Print Name

Signature

Date (yyyy/mmm/dd)

C. Department/Division/Program Head for Incoming Principal Investigator

I am aware of this change in personnel. I consider it to be feasible and appropriate. I attest that the Principal Investigator responsible for the conduct of this study is qualified by education, training, and experience to perform his/her role in this study.

Print Name

Signature

Date (yyyy/mmm/dd)

(This form adapted from UHN Research Ethics Board)