

**Joint Research Ethics Board
Change in Study Personnel/Study Coordinator/Co-Investigator/Research
Assistant/Volunteer Amendment Form**

Submit copy of this form with original signatures to the JREB office for review. Please include an updated CV, as well as TCPS2 and Chart Review Tutorial Certificates of all the new study personnel with the amendment application.

Date of Application (yyyy/mmm/dd):

SECTION 1: Study Identification

JREB Number:		Principal Investigator(PI):	
Sponsor (if any):		Study Expiry Date(yyyy/mmm/dd):	
Study Title:			
PI Contact Information	Telephone	E-mail	

Name of Person Completing the Form:			
Telephone Number:		Fax Number:	
Email Address:			

SECTION 2: Change of Study Personnel/Study Coordinator/Co-Investigator/Research Assistant/Volunteer

Add	Drop	Personnel Name	Credentials	TCPS 2/Chart Review Tutorial Certificates/CV	Role in Study
<input type="checkbox"/>	<input type="checkbox"/>			Yes <input type="checkbox"/> No <input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>			Yes <input type="checkbox"/> No <input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>			Yes <input type="checkbox"/> No <input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>			Yes <input type="checkbox"/> No <input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>			Yes <input type="checkbox"/> No <input type="checkbox"/>	

Effective Date of Change (yyyy/mmm/dd):

Section 3: Contact Information

Incoming Co-Investigator:

Department/Division/Program:			
Telephone Number:		Fax Number:	
Email Address:			

Incoming Study Coordinator:

Department/Division/Program:			
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Telephone Number:		Fax Number:	
Email Address:			

Incoming Research Assistant:

Department/Division/Program:			
Telephone Number:		Fax Number:	
Email Address:			

Incoming Volunteer:

Department/Division/Program:			
Telephone Number:		Fax Number:	
Email Address:			

SECTION 4: Documents

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

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

Other:

SECTION 5: Updates to the Toronto Academic Health Science Network (TAHSN) Initial Application

Numbers in brackets reference the question number in the TAHSN application.

(16B)	Will new personnel be reviewing health records/identifying information for recruitment purpose? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
(16D)	Will new personnel be obtaining consent? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If Yes, please indicate if there is any relationship with the subjects and describe what steps will be taken to avoid the perception of undue influence
(20)	Do any of the conflicts listed below apply to any of the new personnel involved in the research study or any member of their immediate family? If Yes, indicate which conflicts apply and append a letter to the Chair of the REB 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. <input type="checkbox"/> Function as an advisor, employee, officer, director or consultant to sponsor <input type="checkbox"/> Have direct or indirect financial interest in the drug, device, or technology <input type="checkbox"/> Receive an honorarium <input type="checkbox"/> Receive direct or indirect financial benefit from disclosure of personal health information <input type="checkbox"/> Other: <input type="checkbox"/> None of the above
(22H)	Will new personnel have access to the personal health information? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

SECTION 6: Signatures

6a) Signature of Incoming Co-Investigator/Study Coordinator/Research Assistant/Volunteer:

I agree to participate in this study as approved by the REB and agree to conduct this study in compliance with the Tri-Council Policy Statement 2 (2018): Ethical Conduct for Research Involving Human Subjects; 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.

Print Name

Signature

Date (yyyy/mmm/dd)

6b) Signature of Principal Investigator for Study Personnel Changes

Current Principal Investigator

This signature attests that the Principal Investigator has assessed the safety implications of this amendment, its impact on study procedures and is prepared to take any necessary steps to implement the change(s). Further, the Principal Investigator will not implement any changes to, or deviations from the protocol without Research Ethics Board approval except to eliminate an immediate hazard to study subjects or when changes involve only logistical or administrative aspects of the study.

Print Name

Signature

Date (yyyy/mmm/dd)

(This form adapted from Mount Sinai Hospital, Toronto Research Ethics Board)