

### Research Ethics Board OPG Building,700 University Ave. Suite 8-600, Toronto, Ontario, M5G 1Z5 t:: (416) 586-4875 f: (416) 586-4715 www.mtsinai.on.ca/EthicsBoard

# Research Ethics Board Change in Study Personnel Amendment Form

Submit typed, hard copy of this form with "Original Signature" to the REB office for review: See the <u>Guidelines for Submitting Amendment and/or Administrative Change</u> for more information.

Date Submitted (dd/mmm/yyyy):

## **SECTION 1: Study Identification**

MSH REB Number:	
Sponsor:	
Study Title:	

Principal Investigator: Expiry Date:

Name of Person Competing the Form: Telephone Number: Email Address:

Fax Number:

### **SECTION 2: Change of Study Personnel**

Add	Drop	Personnel Name	Credentials	Role in Study

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

### **SECTION 3: Documents**

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

Consent Form(s)
Wallet Card(s)
Other:

### **SECTION 4: Questions**

Is the outgoing PI leaving MSH?	∐ Yes	🗌 No	∐ N/A
Does this change affect any other REB files? If yes, submit a separate form for each study.	☐ Yes	🗌 No	□ N/A
Has Contracts been notified of this change?	🗌 Yes	🗌 No	🗌 N/A
Will subjects be notified of this change?	🗌 Yes	🗌 No	🗌 N/A



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# SECTION 5: Updated 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?
   □ Yes □ No □ N/A
- (16D) Will new study personnel be obtaining consent?
   Yes No NA
   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.
  - E 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
- (22H) Will new personnel have access to the personal health information?  $\hfill Yes \hfill No \hfill N/A$

### **SECTION 6: Signatures**

## 6. a) Signatures for Change of Principal Investigator

#### **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.

Signature

Date (dd/mmm/yyyy)

### **Incoming Principal Investigator**

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: Ethics Conduct for Research Involving Human Subjects and any other relevant regulations or guidelines. 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 (dd/mmm/yyyy)



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# 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 (dd/mmm/yyyy)

6. b) Signature for Change in Co-Investigator					
<b>Incoming Co-Investigator</b> 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: Ethical Conduct for Research Involving Human Subjects and any other relevant regulations or guidelines.					
Print Name	Signature	Date (dd/mmm/yyyy)			
6. c) Signature of Principal Investigator for Staff Changes					
<b>Current Principal Investigator</b> 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 (dd/mmm/yyyy)			

## Section 7: Contact Information of Incoming Study Personnel

Incoming Principal Investigator: Department/Division/Program: Telephone Number: Email Address:	Fax Number:
Incoming Co-Investigator: Department/Division/Program: Telephone Number: Email Address:	Fax Number:
Incoming Study Coordinator: Department/Division/Program: Telephone Number: Email Address:	Fax Number: