**Research Ethics Board**

**Change in Study Personnel/Study Coordinator/Co-investigator Amendment Form**

Submit typed electronic and a hard copy of this form with "Original Signatures" to the REB office for review. Please include TCPS 2 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**

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Person Competing the Form: | |  | | |
| Telephone Number: |  | | Fax Number: |  |
| Email Address: |  | | | |

**SECTION 2: Change of Study Personnel/Study Co-Ordinator/Co-Investigator**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Add | Drop | Personnel Name | Credentials | TCPS 2/Chart Review Tutorial Certificates | Role in Study |
|  |  |  |  | Yes  No |  |
|  |  |  |  | Yes  No |  |
|  |  |  |  | Yes  No |  |
|  |  |  |  | Yes  No |  |
|  |  |  |  | Yes  No |  |

**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: | |  | | |
| 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 TAHSN Application Form for REB Review**

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 personnel be obtaining consent?  Yes  No  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.  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?  Yes  No  N/A |

**SECTION 6: Signatures**

**6a) Signature incoming Co-Investigator/Study Coordinator:**

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 (2014): 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 Staff 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)

**6c) Signature of Manager, Research & Academic Operations for Research Impact Analysis:**

I confirm that this application for change in Study Personnel/Study Co-Ordinator/Co-investigator meets institutional requirements of research impact analysis.

Print Name Signature Date (yyyy/mmm/dd)

**SUBMIT COMPLETED FORM TO:**

Glenn A. Robitaille, M.Div., D.Min., RP

Chair, Research Ethics Board

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