**WATERLOO-WELLINGTON RESEARCH ETHICS BOARD (WWREB)**

**Formerly known as Tri-Hospital Research Ethics Board (THREB)**

**CHANGE IN STUDY PERSONNEL AMENDMENT FORM**

**INSTRUCTIONS**

1. Please email completed form with original signature of local PI and all applicable revised documents (clean and tracked changes) to: WWREB Administrative Coordinator, wwreb@grhosp.on.ca.
2. Handwritten applications will not be accepted; please submit as a MS Word document.
3. Indicate the number associated with your submission (if this is the first, second, third, etc. change in study personnel amendment associated with this study).
4. Personnel should only be added to WWREB applications if they are affiliated with one of the institutions under the WWREB’s jurisdiction. The addition of non-affiliated staff to WWREB research ethics applications should be rare. If you have questions about the addition of an external research team member, please contact the WWREB at wwreb@grhosp.on.ca.
5. When **ADDING** study personnel please confirm that they have completed all training required for their role.

**Change in Study Personnel (CISP) Amendment Number (CISP 1, 2, 3, etc.**) \_\_\_\_

**SECTION 1: Study Information**

Study Title:

WWREB #:

Expiry Date of WWREB Approval:

Local Principal Investigator:

Sponsor/Funder:

**SECTION 2: Contact Information**

Name of Person Completing the Form:

Email:

Telephone:

**SECTION 3: Change of Study Personnel**

Detail the study personnel additions and/or removal in the table below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Add (A)****Drop****(D)** | **Personnel Name, qualifications (i.e. BSc, MSc, PhD, MD)**  | **Role in Study****(i.e. Assistant, Coordinator, Manager, Co-Investigator)** | **Access to PHI?****Yes/No****If yes, indicate why this is necessary** | **Obtaining Consent? Yes/No****If yes, indicate if there is relationship with participants and steps to avoid undue influence** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Have they completed all training required for their role on this study? [ ]  Yes [ ]  No

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

**SECTION 4: Documents Affected by Change in Study Personnel**

*Submit any documents affected by this change.*

[ ]  Consent Form(s) Specify Version date: Click or tap here to enter text.

[ ]  Recruitment Material(s) Specify Version date: Click or tap here to enter text.

[ ]  Other: Click or tap here to enter text. Specify Version date: Click or tap here to enter text.

**SECTION 5: Change in Local Principal Investigator**

[ ]  N/A

[ ]  Yes**:** please provide a brief explanation for the change in local Principal Investigator

 Click or tap here to enter text.

 Does this change affect any other WWREB files? [ ]  Yes [ ]  No

 If yes, submit a separate CISP for each study.

 Will participants be notified of this change? [ ]  Yes [ ]  No

**SECTION 6: Conflict of Interest Declaration**

[ ]  Not applicable - None of the added study personnel or their immediate family members have a Conflict of Interest to disclose

Conflicts of Interest do not imply wrongdoing. It is the responsibility of the hospital local PI to determine if any of the conflicts listed below apply to any persons listed above in the research study or any member of their immediate family. It is also the responsibility of the local PI to identify any conflicts of interest that may apply to their own role on a study. 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. NOTE: This disclosure does not replace any institutional guidelines and requirements for declaration and management of Conflicts of Interest.

|  |
| --- |
| **Explain how the Identified conflict will be managed:** |
| **Identify the nature of the Conflicts:** |
| [ ]  | Function as an advisor, employee, officer, director or consultant for the study sponsor |
| [ ]  | Have direct or indirect interest in the drug, device or technology employed in this research study (including inventorship, patents or stocks) |
| [ ]  | Receive an honorarium or other personal benefits from the sponsor (apart from fees for service) |
| [ ]  | Using services of a family member or a company in which you or a family member has a direct interest. |
| [ ]  | Receive direct or indirect financial benefit from the disclosure of personal health information |
| [ ]  | Competing interest (situations in which the researcher may be influenced to draw conclusions against the interest of the sponsor or another interested party to the study because the researcher or a family member has an opposing interest related to the research, including a legal suit against a company or sponsor or a financial interest in a competing company or product) |
| [ ]  | Other; describe: |

**SECTION 7: Signatures**

**7a) Signatures for Change of local Principal Investigator**

**Outgoing local Principal Investigator Statement**

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name Signature Date (dd/mmm/yyyy)

**Incoming local Principal Investigator**

I assume full responsibility for the scientific and ethical conduct of the study as approved by the WWREB and submitted protocol 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. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified and have completed appropriate training to fulfill their role in this project.

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Print Name Signature Date (dd/mmm/yyyy)

**b) Signature of Local Principal Investigator for Staff Changes**

**Local Principal Investigator**

This signature attests that the Principal Investigator is requesting the change(s) to study personnel as described in this form.

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Print Name Signature Date (dd/mmm/yyyy)