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

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

**APPLICATION FOR PROJECT REVIEW FORM: PART 2**

**INSTRUCTIONS**

1. Please email completed form with original signature of the Local Principal Investigator to: WWREB Administrative Coordinator, wwreb@grhosp.on.ca
2. Handwritten applications will not be accepted; please submit as a MS Word document
3. All applicable requested information must be provided within the application form itself.
4. If a question is considered “not applicable” to the study, state that.
5. Incomplete applications will be returned.

|  |
| --- |
| *For WWREB Office Use Only***DATE Received: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ WWREB # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

1. **FULL TITLE OF RESEARCH PROJECT (Include Version #, Study Code and Protocol date if applicable)**

Click here to enter text.

**2. RESEARCH TEAM**

1. **Local Responsible Investigator**

**Name:** Click here to enter text.

**Hospital Program:** Click here to enter text.

**University Affiliation & Dept:** Click here to enter text.

**Email:** Click here to enter text.

**Telephone:** Click here to enter text.

**Fax:** Click here to enter text.

1. **Principle Investigator if other than above**

**Name:** Click here to enter text.

**Hospital or Institution Affiliation:** Click here to enter text.

**University Affiliation & Dept:** Click here to enter text.

**Corporate Affiliation:** Click here to enter text.

**Email:** Click here to enter text.

**Telephone:** Click here to enter text.

**Fax:** Click here to enter text.

1. **Co-Investigator(s)**

**Name:** Click here to enter text.

**Hospital or Institution Affiliation:** Click here to enter text.

**University Affiliation & Dept:** Click here to enter text.

**Corporate Affiliation:** Click here to enter text.

**Email:** Click here to enter text.

**Telephone:** Click here to enter text.

**Fax:** Click here to enter text.

**Name:** Click here to enter text.

**Hospital or Institution Affiliation:** Click here to enter text.

**University Affiliation & Dept:** Click here to enter text.

**Corporate Affiliation:** Click here to enter text.

**Email:** Click here to enter text.

**Telephone:** Click here to enter text.

**Fax:** Click here to enter text.

1. **Study Coordinator**

**Name:** Click here to enter text.

**Hospital Affiliation:** Click here to enter text.

**University Affiliation & Dept:** Click here to enter text.

**Corporate Affiliation:** Click here to enter text.

**Email:** Click here to enter text.

**Telephone:** Click here to enter text.

**Fax:** Click here to enter text.

 **e. Approval letter to be sent to the following person and address:**

Click here to enter text.

**3**. **WHERE WILL THE STUDY BE CONDUCTED**? Identify specific hospital site.

*GRH – KWHC* [ ] yes [ ] no Service area: Click here to enter text.

*GRH – Freeport* [ ] yes [ ] no Service area: Click here to enter text.

*GRH – GRRCC* [ ] yes [ ] no Service area: Click here to enter text.

*SMGH* [ ] yes [ ] no Service area: Click here to enter text.

*CMH* [ ] yes [ ] no Service area: Click here to enter text.

*Other* Click here to enter text.

**4. IS THIS A CHART REVIEW STUDY ONLY?** [ ] **Yes** [ ] **No**

If YES, please use the other application form: “Application for Retrospective Review of Health Records”

**5. IS THIS STUDY PART OF A STUDENT PROJECT OR THESIS?** [ ] **Yes** [ ] **No**

**6. FUNDING**

**(a) Status of Funding**

[ ] Industry Sponsored (private, for-profit organizations)

[ ] Applied - Date submitted (yyyy-mm-dd): Click here to enter a date.

 [ ] Funded - Date of decision (yyyy-mm-dd): Click here to enter a date.

 [ ] None

 [ ] In-Kind support (drugs, equip, devices)

Specify contribution: Click here to enter text.

**(b) Name(s) of Research Sponsor/Funding Agency/Industry Partner (state full name):**

Click here to enter text.

**(c) Budget (attach budget summary)**

 **Global $** Click here to enter text.

 **Local $** Click here to enter text.

**(d) Will there be a signed contract/agreement with a study-related funding source?**

[ ] **Yes** [ ] **No**

**(e) Will the institution be named in the contract/agreement with the study-related funding source?** [ ] **Yes** [ ] **No**

**7.** **Expected start date** (yyyy-mm-dd) **:** Click here to enter a date.

 **Expected completion date** (yyyy-mm-dd) **:** Click here to enter a date.

**8a. Does this research involve institutions other than WWREB sites?** [ ] **Yes** [ ] **No**

**NOTE:** Research involving investigators from other universities or hospitals will need also to have been submitted for review to those organizations. For research at WWREB sites involving investigators from the University of Waterloo, research ethics review will be done through the [co-ordinated review process](https://uwaterloo.ca/research/office-research-ethics/research-human-participants/application-process/waterloo-and-threb-co-ordinated-ethics-review-process).

**8b. HAS THIS STUDY BEEN OR WILL IT BE REVIEWED BY ANOTHER RESEARCH ETHICS BOARD OR INSTITUTION?** [ ] **YES** [ ] **NO**

If YES, indicate [ **x** ] which of the following:

 [ ] University of Waterloo: [ ] Attached [ ] To follow [ ] Co-ordinated Review

[ ] Wilfrid Laurier University [ ] Attached [ ] To follow

 [ ] McMaster University (HIREB) [ ] Attached [ ] To follow

 [ ] Guelph University [ ] Attached [ ] To follow

 [ ] London Health Sciences [ ] Attached [ ] To follow

 [ ] University Health Network (UHN) [ ] Attached [ ] To follow

 [ ] Sunnybrook [ ] Attached [ ] To follow

 [ ] Other Click here to enter text. [ ] Attached [ ] To follow

**9. CONFLICT OF INTEREST:**

**Does the principal investigator(s) or any co-investigators involved in this research study:**

1. Function as an advisor, employee, officer, director or consultant for the sponsor? [ ] YES [ ] NO
2. Have direct or indirect financial interest in the drug, device or technology employed (including patents or stocks) in this research study? [ ] YES [ ] NO
3. Receive an honorarium or other benefits from the sponsor (apart from fees for service)? [ ] YES [ ] NO
4. If the answer is YES to any of the above, please describe and explain how that conflict is being managed to ensure that participant rights and welfare are not affected.

Click here to enter text.

**10. IS THIS STUDY A CLINICAL TRIAL?** [ ] YES [ ] NO

If yes, give the clinical trial registry number: Click here to enter text.

Name of the Registry used (e.g. clinicaltrials.gov): Click here to enter text.

Is there a Health Canada No Objection Letter (NOL) [ ] Attached [ ]  No [ ] To follow

**Note:** Clinical trials must be registered before beginning. For clinical trials requiring Health Canada review, a copy of the Health Canada NOL must be submitted before final approval is given.

A clinical trial as defined by the WHO is: "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects of health outcomes." Further information on clinical trials may be obtained at numerous sites including [University of Waterloo](https://uwaterloo.ca/research/office-research-ethics/research-human-participants/application-process/clinical-trials-or-studies-involving-drug-medical-device-or) or [McMaster University](http://fhs.mcmaster.ca/healthresearch/research_agreement_ct.html)

**SUMMARY OF PROPOSED RESEARCH**

**11.** **PURPOSE AND/OR RATIONALE:**  Summarize (**10 lines maximum):**

a) the main research question, b) what is being studied, and c) why the research is important.

Click here to enter text.

**12. HYPOTHESES/OBJECTIVES**: (must be filled out in entirety)

Click here to enter text.

**13**. **STUDY PARTICIPANTS** (describe the sample in terms of number, sex, age range, diagnostic criterion, and any special circumstances – must be filled out in entirety)

Click here to enter text.

**14**. **RECRUITMENT OF PARTICIPANTS:** How, and from where/what source will participants be recruited? How will participants be identified and contacted? (Attach copies of any advertisements or letters used for recruitment)

Advertisements to recruit participants should be limited to:

* The name and address of the clinical investigator;
* The purpose of the research, and in summary form, the eligibility criteria that will be used to admit participants into the study;
* A straightforward and truthful description of the benefits (such as payments or free treatments) to the participant for participation in the study;
* The location of the research and the person to contact for further information.

Click here to enter text.

**15**. **HOW MUCH TIME WILL BE REQUIRED FROM PARTICIPANTS AND/OR THEIR FAMILIES, HOSPITAL STAFF AND/OR CLINICIANS?**

Click here to enter text.

**16. WHO WILL BE CONDUCTING THE STUDY (**clearly identify investigators and/or assistants who will have direct contact with participants, families, hospital staff/clinicians)

Click here to enter text.

**17. EXPERIMENTAL PROCEDURES** (Outline and provide brief justification for the procedures in which participants will be involved, e.g., physical manipulation, doses, and methods of administration of drugs, physiological tests, paper and pencil tasks, interviews, questionnaires, time requirements, etc.) A separate research protocol must be submitted with this application form.

A copy of any questionnaires or test instruments to be used in the research must be appended to this application *unless they have been previously published in a peer reviewed journal.*

Click here to enter text.

**18.** **WHAT METHODS WERE USED TO CALCULATE SAMPLE SIZE?** (must be filled out in entirety)

Click here to enter text.

**19.** **DESCRIBE HOW THE DATA WILL BE ANALYZED (Statistically, or by whatever other means** (must be filled out in entirety)

Click here to enter text.

**20. INFORMED CONSENT:**  **IS THERE A CONSENT FORM?**

a. Will the study consent process use a written consent form? [ ] **Yes** [ ] **No**

If **YES**, attach a copy of the Consent Form(s) to be provided to participants. Make sure the form follows the requirements set out in Application Part 1.

b. If NO written consent, what kind of consent process will be use?

[ ] Verbal consent only

[ ] Implied consent (e.g. as in an anonymous survey)

[ ] No consent need be sought

For any of the above, justify the use of such an option.

Click here to enter text.

**21.** **BRIEFLY OUTLINE THE POTENTIAL BENEFITS OF YOUR RESEARCH:** Participants, hospital and/or broader community)

Click here to enter text.

**22.** **POTENTIAL RISKS FROM THE STUDY:**  Outline in adequate detail any potential risks to participants in this study. Potential risks can be of a physical or psychological nature. Indicate whether the anticipated level of risk is considered to be low, moderate, or high – if high, explain why alternate approaches involving less risk cannot be used.

Click here to enter text.

**23a.** **COMPENSATION OF PARTICIPANTS:**

**Will participants receive remuneration?** [ ] **Yes** [ ] **No**

If Yes, Indicate and give details if participants will be compensated financially. (Does not include reimbursement for expenses)

Click here to enter text.

**23b. REIMBURSEMENT TO PARTICIPANTS:**

**Will participants be reimbursed for expenses?** [ ] **Yes** [ ] **No**

If Yes, Indicate and give details if participants will be compensated for expenses

Click here to enter text.

**24.** **DECEPTION:**  **Is deception of participants involved in the study?** [ ] **Yes** [ ] **No**

If any deception is involved in the design of the study, please describe it, and justify its use. How will the use of deception be explained to participants in your debriefing procedure?

Click here to enter text.

**25. REPORT- BACK TO PARTICIPANTS:** How will participants be informed of the results of the study? Written feedback about the study should be provided to the participants ensuring that their participation minimally becomes an educational experience. Any use of deception should be described.

Click here to enter text.

**PROTECTION OF PERSONAL INFORMATION AND PERSONAL HEALTH INFORMATION**

Investigators must comply with the duties set out for researchers in the Ontario Personal Health Information Protection Act, 2004 (PHIPA).

**26. PERSONAL INFOMRATION AND/OR PERSONAL HEALTH INFORMATION:** List all personal information and personal health information, personal identifiers (e.g. name, DOB) required to be collected, and identify all potential sources of this information. For all non-clinical trials, attach data collection forms.

***NOTE:*** *Under Ontario privacy legislation, personal health information (PHI) includes identifying information about the health and health-related treatment of an individual. Identifying information can be both direct and indirect, meaning that it includes information that either identifies an individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual. (For example, a coded data collection form is PHI as long as a key linking the coded data to an identified individual exists.)*

**a) Personal Information and Personal Health Information (identifiers)? (Please check all applicable):**

**Direct Identifiers: Indirect Identifiers:**

[ ] Full Name [ ] Initials

[ ] Address [ ] Full Date of Birth (day/month/year

[ ] Telephone Number [ ] Age at time of data collection or year of birth

[ ] Email [ ] Full Postal Code

[ ] OHIP# [ ] Partial Postal Code

[ ] Social Insurance Number [ ] Healthcare Provider

[ ] Medical Record Number [ ] Discharge Date

[ ] Full Face Photography [ ] Other Date (e.g. date of service)

[ ] Other Direct or Indirect Identifiers (please specify)

 Click here to enter text.

Investigators should plan to collect personal data at the lowest level of identifiability necessary to achieve the study objectives. Even a dataset without direct identifiers may present a risk of indirectly identifying data subjects if the dataset contains sufficient information about the individuals concerned. For advice, consult the CIHR Best Practice Guidelines for Protecting Privacy and Confidentiality: <http://www.cihr-irsc.gc.ca/e/29072.html>

**b) If you are collecting any of the above identifiers, justify why they are required:**

Click or tap here to enter text.

 **c) What information source are you accessing?**

[ ] **Health Records/Clinic/Office Files? (Specify which)** Click here to enter text.

[ ] **Electronic Database (Specify which)** Click here to enter text.

[ ] **Outside Institution (Specify which)** Click here to enter text.

[ ] **Other (Specify which)** Click here to enter text.

**27. PARTICIPANT IDENTIFICATION:**

a) Will study participants will be identified on data collection forms and how (e.g. study number, initials).

Click here to enter text.

b) Will a study “key” be kept that links participant identity to the coded data collection forms? [ ] Yes [ ] No

c) If yes:

 Where will it be stored: Click or tap here to enter text.

 Who will have access: Click or tap here to enter text.

**28. DATA STORAGE:** How will data be stored?

[ ] Computerized files (specify): [ ] Server [ ] Desktop [ ] Laptop [ ] Other device (e.g. USB key)

[ ] Audio recordings

[ ] Hard copy

[ ] Videotape

[ ] Other (e.g. PDA): Click here to enter text.

[ ] If a portable device is to be used, justify: Click here to enter text.

**29. SECURITY:**

**a) Indicate the steps to be taken to ensure security of data with personal identifiers. Please check all that apply.**

Procedural:

* Access to identified data will be limited study team members identified within [ ] Yes [ ] No

Sections 2 and 30 of this application

* There will be an audit trail of access to electronic records [ ] Yes [ ] No

Physical

* Storage location for paper study documents: Click here to enter text.
* Storage location of study computers: Click here to enter text.
* Other: Click here to enter text.

Technical

* Electronic files will be backed-up and stored in a separate location [ ] Yes [ ] No
* Electronic files will be stored on a computer which is password protected [ ] Yes [ ] No
* Electronic files will be stored in a computer file which is password protected [ ] Yes [ ] No
* Electronic files will be encrypted with a minimum 128 bit encryption protocol [ ] Yes [ ] No
* Data will be stored on a computer system with virus protection [ ] Yes [ ] No
* Data will be stored on a computer system with uninterrupted power source [ ] Yes [ ] No

**b) What are the possible harms/risks to participants if personal health information was inappropriately released and how will you manage the risks? (Describe briefly)**

Click here to enter text.

**30. ACCESS:** Who other than those named in Item #2 will have access to the data?

Click here to enter text.

**31. TRANSFER OF INFORMATION:**

1. **Will any of the collected data be sent outside of the institution where it was collected?** [ ] YES [ ] NO

If “No”,go to Question 32.

1. **Why is it necessary to send data outside of the institution where it was collected?**

Click here to enter text.

1. **Where will data be sent?**

Click here to enter text.

1. **How will the data be sent?**

 [ ] Fax (Describe security at the receptor site) Click here to enter text.

 [ ] Private Courier (must be able to trace delivery)

 [ ] Canada Post – Xpresspost or Priority Courier (Regular mail may not be used.)

 [ ] Other (Please specify): Click here to enter text.

**e) Has a contract or Research Data Agreement or Data Transfer Agreement been approved by the “Data Custodian” (hospital)?**

 [ ] YES

 [ ] NOT REQUIRED

 [ ] IN PROCESS (**A finalized Agreement must be reached before research begins.)**

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**32. LINKAGE:** Do you plan to link the locally collected data [ ] **YES** [ ] **NO**

with any other data set(s) *(e.g. OHIP data, census tract data)*?

**If YES,** a) identify the data set, b) justify why the linkage is necessary, c) explain how it will occur and d) provide a list of data items used:

Click here to enter text.

**33. ONGOING USE:** Will this data be entered into an ongoing electronic[ ] **YES**[ ] **NO**

database for future use in another research study? *(Please note: Any*

*secondary analysis must be approved by the REB prior to implementation.)*

**If YES,** specify where it will be stored, who will be the custodian (i.e. the person responsible for data storage and integrity), who will have access to it, and security measures:

Click here to enter text.

**34. STORAGE TIME:**

**a) How long do you plan to keep the data?** *(Please note: You are required to destroy identifiers [or links] at the earliest possible time.)*

Click here to enter text.

**b) Will data be:**

[ ] destroyed

[ ]  irreversibly anonymized *(i.e. the key identifying the link between data and the individual’s identity is deleted)*?

 **c) When will the following be destroyed?**

**Consent forms** (yyyy-mm-dd)**:** Click or tap to enter a date.

**Study Key (should be destroyed at the earliest possible time)** (yyyy-mm-dd)**:** Click or tap to enter a date.

**Collected data: Anonymized** (yyyy-mm-dd)**:** Click or tap to enter a date.

**Destroyed** (yyyy-mm-dd)**:** Click or tap to enter a date.

 **d) Additional comments or explanations**

Click or tap here to enter text.

**35. PRIVACY TUTORIAL:** Have all those who have access to personal health information completed a privacy tutorial acceptable to the hospitals/institutions?

**NOTE:** Those requiring access to personal health information must successfully complete a privacy tutorial acceptable to the institution(s) involved.

Grand River Privacy Tutorial: [ ] YES [ ] NO [ ] IN PROGRESS

McMaster tutorial: (<http://ethics.mcmaster.ca/chart/>) [ ] YES [ ] NO [ ] IN PROGRESS

Other: Click here to enter text. [ ] YES [ ] NO [ ] IN PROGRESS

**36.TCPS2 TUTORIAL:** **Each investigator is to indicate if they have completed the TCPS2 tutorial. If there are more than two investigators, please attach a page with the names of each additional investigator along with their TCPS2 tutorial completion information.**

**NOTE:** All UW faculty and staff listed as investigators must complete the tutorial for the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)](http://pre.ethics.gc.ca/eng/education/tutorial-didacticiel/) prior to submitting an ethics application. The tutorial takes at least three hours; it has start and stop features.

Name of Investigator/Supervisor: Click here to enter text.

Date (yyyy-mm-dd): Click here to enter a date.

Completed TCPS2 tutorial: [ ]  YES [ ]  NO [ ]  In progress

Name of Investigator/Supervisor: Click here to enter text.

Date (yyyy-mm-dd): Click here to enter a date.

Completed TCPS2 tutorial: [ ]  YES [ ]  NO [ ]  In progress

**Each student investigator is to indicate if they have completed the Tri-Council Policy Statement, 2nd Edition Tutorial. If there are more than two student investigators, please attach a page with the names of each additional student investigator along with their TCPS2 tutorial completion information.**

Name of Student: Click here to enter text.

Date (yyyy-mm-dd): Click here to enter a date.

Completed TCPS2 tutorial: [ ]  YES [ ]  NO [ ]  In progress

Name of Student: Click here to enter text.

Date (yyyy-mm-dd): Click here to enter a date.

Completed TCPS2 tutorial: [ ]  YES [ ]  NO [ ]  In progress

**37. For Clinical Trial investigators,** **each investigator is to indicate if they have completed Good Clinical Practice Training. If there are more than two investigators, please attach a page with the names of each additional investigator along with their Good Clinical Practice Training completion information.**

Name of Local Responsible Investigator/Supervisor: Click here to enter text.

Date (yyyy-mm-dd): Click here to enter a date.

Completed GCP Training: [ ]  YES [ ]  NO [ ]  In progress

Certificate Number (if available): Click here to enter text.

Name of Principal Investigator/Supervisor: Click here to enter text.

Date (yyyy-mm-dd): Click here to enter a date.

Completed GCP Training: [ ]  YES [ ]  NO [ ]  In progress

Certificate Number (if available): Click here to enter text.

**AGREEMENT**

I agree to abide by the ethical guidelines and procedures of the Waterloo-Wellington Research Ethics Board, of the *Tri-Council Policy Statement*, of my profession or discipline, as well as of the institution in which the research is undertaken. I am aware of my responsibility to be familiar with these standards.

Approval by the WWREB to conduct research at its affiliated sites is limited to the conditions and details outlined within this Application Form. Approval from the WWREB must be granted prior to any departures from this protocol. The local responsible investigator assumes full responsibility for this study as detailed and will notify the WWREB should any unexpected results, serious and unexpected adverse events, or complaints arise. Any new information learned about potential risks must also be communicated (i.e., information concerning risks learned from new publications or from other current research projects).

I understand that research at the affiliated sites requires administrative approval from the respective sites prior to review by the WWREB.

I understand that **for all research projects** both 1) approval by the WWREB and 2) separate approval by the Hospital Administration, along with their approval of any required Contract, Clinical Trial Agreement, Research Data Agreement or Data Sharing Agreement must be obtained before beginning the project.

I further agree to **notify the Waterloo-Wellington Research Ethics Board** of **each of the following, using the appropriate signed forms (available on the WWREB website):**

* Any amendment or change in the research project and to comply with requests made by WWREB during the life of this research;
* Any local unanticipated problem, SAE, or protocol violation
* An annual progress report requesting continued approval;
* A final study completion report within three months of study completion

|  |  |
| --- | --- |
|  | Click here to enter a date. |
| Signature of Local Responsible Investigator | Date |
|  |  |

E-Mail completed applications to: WWREB Administrative Coordinator

 wwreb@grhosp.on.ca