**RESEARCH ETHICS BOARD**

**ETHICS SUBMISSION FORM FOR ARCHIVAL / SECONDARY USE OF DATA**

**(CHART ABSTRACTION)**

**REB Checklist:**

* **The Principal Investigator should complete this checklist to inform the REB of available documents and to confirm that all sections of the application are complete and ready for REB review. Completed and signed checklists must be submitted with the application.**

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| **FORM SECTIONS** | | **COMPLETED** | **NOTES FROM RESEARCHER(S)** |
| **A – General Information** | 1. Title 2. Principal Investigator 3. Principal WRH or Local Site Investigator 4. WRH Affiliation or WRH Contact Person 5. Faculty Advisor 6. Co-Investigators 7. Research Team Members 8. Main Project Contact |  |  |
| **B – Project Overview** | 1. Protocol 2. Project Start & End Dates 3. Project Funding 4. Additional REB Approvals 5. Departmental Impact 6. Conflict of Interest |  |  |
| **C – Summary of Proposed Research** | 1. Background & Rationale 2. Objectives 3. Methods |  |  |
| **D – Data Collection Information** | 1. Data Source 2. Data Collection Process 3. Data Analysis 4. Informed Consent Process 5. Waiver of Consent |  |  |
| **E – Safeguards For Protecting Data** | 1. Confidentiality/Anonymity 2. Identifiable Information 3. Data Management |  |  |
| **F – Signatures** | Signatures from PI and CO-Is (and Faculty Advisor if applicable) |  |  |

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| **STUDY/SUPPORTING DOCUMENTS** | | **ATTACHED** | **NOTES FROM RESEARCHER(S)** |
| **STUDY DOCUMENTS INCLUDED** | * Protocol, if available * Consent Form (where applicable) * Data collection tools, e.g. CRFs, data collection forms (where applicable) * Approvals/clearance letters from other REBs * Approvals/permissions from original data custodian (where applicable) * Proof of award of funds (for grant funded research), budget, and contract included (where applicable) |  | List all documents submitted: |
| **TRAINING & REGULATORY** | * [TCPS2: CORE 2022 certificates](https://tcps2core.ca/welcome) for all members of the research team * Submit certificates here: <https://redcap.link/WRH_researchtraining> |  |  |
| * [WRH REB Privacy Tutorial for Researchers](https://redcap.link/wrhreb_privacytutorial)  completed by all research team members (do not submit certificate) |  |  |
| * WRH Researcher Privacy Agreement completed for PI (or WRH PI for multi-centre studies) |  |  |
| * WRH Research Associate Privacy Agreements completed for Co-I’s and research team members |  |  |
| * CV for Principal Investigator (not required to resubmit if previously submitted within 5 years) |  |  |
| **WRH APPROVALS** | * Departmental Impact Form(s) |  |  |
| * Office of Research Notice of No Objection Letter |  |  |

**I certify that I have read all of the above, that this application is complete and coherent, and I understand that all applications that are not may not be reviewed by the REB and could be returned to the applicant(s) with a request for more information.**

**Optional: I consent to my project title and broad project overview to be shared on the WE-SPARK and WRH website should REB approval be granted. If I agree, I will be provided the opportunity to approve the content to be posted.**

**Signature of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Please email completed REB packages to the Research Ethics Office:**

research.ethics@wrh.on.ca

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| **SECTION A – GENERAL INFORMATION** |

1. **TITLE OF RESEARCH PROJECT:**

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1. **PRINCIPAL INVESTIGATOR:**

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| --- | --- | --- | --- |
| Title: | Name: | | |
| Department: | | Institution/Agency/Organization: | |
| Mailing Address: | | | |
| Telephone: | | | Email: |

1. **PRINCIPAL WRH SITE INVESTIGATOR:** (Complete if this is multi-centre research where a WRH PI oversight is required)

|  |  |  |  |
| --- | --- | --- | --- |
| Title: | Name: | | |
| Department: | | Institution/Agency/Organization: | |
| Mailing Address: | | | |
| Telephone: | | | Email: |

1. **PRINCIPAL INVESTIGATOR’S WRH AFFILIATION or WRH CONTACT PERSON:** (Complete if the project does not require oversight by a WRH PI but requires a WRH collaboration)

|  |  |  |  |
| --- | --- | --- | --- |
| Title: | Name: | | |
| Department: | | Institution/Agency/Organization: | |
| Mailing Address: | | | |
| Telephone: | | | Email: |

1. **FACULTY ADVISOR**:(Complete if student is PI on research)

|  |  |  |  |
| --- | --- | --- | --- |
| Title: | Name: | | |
| Department: | | Institution/Agency/Organization: | |
| Mailing Address: | | | |
| Telephone: | | | Email: |

1. **CO-INVESTIGATORS** (Insert as many co-investigator tables as necessary)

***\*****Co-investigators refers to key investigators involved in the study who do not have the overall responsibility and authority of the PI, but make significant contributions and are expected to ensure the project is conducted in compliance with applicable laws, regulations, and institutional policy governing the conduct of the research.*

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| Title: | Name: | | |
| Department: | | Institution/Agency/Organization: | |
| Mailing Address: | | | |
| Telephone: | | | Email: |

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| Title: | Name: | | |
| Department: | | Institution/Agency/Organization: | |
| Mailing Address: | | | |
| Telephone: | | | Email: |

1. **RESEARCH TEAM MEMBERS** (Insert as many research team member tables as necessary)

***\*****Research team member roles include research coordinators/associates, research assistants, statisticians, volunteers, etc.*

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| Title: | Name: | | |
| Department: | | Institution/Agency/Organization: | |
| Mailing Address: | | | |
| Telephone: | | | Email: |
| Study Role Title: | | | Study Responsibilities: |

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| Title: | Name: | | |
| Department: | | Institution/Agency/Organization: | |
| Mailing Address: | | | |
| Telephone: | | | Email: |
| Study Role Title: | | | Study Responsibilities: |

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| Study Role Title: | | | Study Responsibilities: |

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| Title: | Name: | | |
| Department: | | Institution/Agency/Organization: | |
| Mailing Address: | | | |
| Telephone: | | | Email: |
| Study Role Title: | | | Study Responsibilities: |

1. Of the individuals listed above, indicate who the main contact person(s) will be for this project:

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| **SECTION B – RESEARCH PROJECT OVERVIEW** |

1. **PROTOCOL**
   1. Is there a protocol for this study?  Yes  No

If ‘Yes’:

* + 1. Version Number:
    2. Version Date:
  1. Is this an industry sponsored study?  Yes  No

If ‘Yes’, provide the complete contact information for REB fee invoicing:

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| --- | --- | --- |
| Title: | Name: | |
| Institution/Agency/Organization: | | |
| Street Address: | | |
| City: | | Province/State: |
| Postal Code: | | Country: |
| Telephone: | | Email: |

1. **PROJECT START & END DATES**

***\*Study procedures including data collection SHALL NOT begin until REB clearance is granted. Progress reports must be submitted annually if the end date for this project exceeds more than 12 months.***

1. Estimated start date for data project:
2. Estimated completion date for data collection:
3. Estimated completion date for this project:
4. **PROJECT FUNDING**

Has funding been received to conduct the research?

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| --- | --- |
| Funded | Agency: |
| Title of project associated with the funding: |
| Funding dates: |
| Does the funding agency prohibit publication? If yes, explain any restrictions: |
| Applied for Funding | Agency: |
| Title of project associated with the funding: |
| Submission date: |
| Does the funding agency prohibit publication? If yes, explain any restrictions: |
| Un-funded |  |

1. **ADDITIONAL REB APPROVALS**

**\* *Attach any other REB approvals to this application***

* 1. Do any of the other non-WRH institutions/sites require administrative approval or REB approval from their own board for the research to be conducted?

Yes  No  N/A

* 1. Has the protocol received approval by another Ethics Review Committee?

Yes  No

If ‘Yes’,from which REB(s):

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If ‘No’:Will any other REB be asked for approval?

Yes No

1. **DEPARTMENTAL IMPACT**

***\* Departmental Impact Forms for each department impacted by the study must be reviewed by the Office of Research and signed by departmental Director or delegate and must be approved prior to submission to REB.***

Are hospital resources/facilities required for this project (i.e. labs, imaging, Decision Support report, staff/professional staff time, space usage, clinic time etc.)?

Yes  No

If ‘Yes’, indicate what departments will be impacted and attach signed Departmental Impact Form(s):

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1. **CONFLICT OF INTEREST** 
   1. Will the researcher(s), members of the research team, and/or their partners or immediate family members receive any personal benefits (e.g. financial benefit such as remuneration above and beyond the direct costs of conducting the research, intellectual property rights, royalty income, rights of employment, consultancies, board membership, share ownership, stock options, etc.) as a result of or in connection to this study?

Yes  No

If ‘Yes’, please describe the benefits (do not include benefits such as conference and travel expense coverage):

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* 1. Describe any restrictions regarding access to or disclosure of information (during or at the end of the study) that has been placed on the investigator(s). These include controls placed by sponsors, funding sources, advisory or steering committees. Indicate ‘N/A’ if none.

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* 1. Are there any other real, potential, or perceived conflict of interest to declare to the REB?

Yes  No

If ‘Yes’, please specify:

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* 1. Please describe the proposed management plan to mitigate any of the conflict(s) of interest listed above.

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| **SECTION C – SUMMARY OF PROPOSED RESEARCH** |

1. **BACKGROUND & RATIONALE**

Describe the purpose and rationale for the proposed project. This background should be succinct, but include all information that an educated layperson needs to understand the purpose of the proposed project. Include a brief scholarly background and relevant literature. References for any citations can be provided within this section or as an appendix.

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1. **OBJECTIVES**

List your research objectives/questions and aims.

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1. **METHODS**

Provide a detailed summary of the study design. Attached a study protocol if available.

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| **SECTION D – DATA COLLECTION INFORMATION** |

1. **DATA SOURCE**
   1. Total number of records in the study:
   2. When and where was the original data collected?
   3. Who is the custodian of the original data?
   4. If the custodian is not WRH (i.e. for patient charts), has permission been granted by the custodian for use of the data as outlined in this application?  Yes  No

If ‘Yes’, please attach any approval/permission documentation from custodian.

* 1. Please describe the purpose for which original data/records were collected.

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1. **DATA COLLECTION PROCESS**
   1. Describe how and by whom the archival/secondary data will be accessed/extracted (i.e. provided to researcher by custodian in anonymized form; extracted directly from the original source; etc.).

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* 1. Please provide a list of all the data collection fields for this study. Attach a copy of the data collection tool if available.

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* 1. Does this project include any prospective data collection?  Yes No

If ‘yes’, describe how prospective data will be collected:

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1. **DATA ANALYSIS**

Provide a brief explanation of your plans for data analysis (e.g. software, statistical tests, location analysis will be conducted). Who will monitor and analyze the data?

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1. **INFORMED CONSENT PROCESS**
   1. Describe the process that was used to obtain consent in the original collection of the data.

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* 1. Do you have a copy of the consent form for the original collection of the data?  Yes  No

If ‘Yes’, please attach a copy or the consent form.

* 1. Did subjects provide express consent for subsequent use of their data?  Yes  No

1. **WAIVER OF CONSENT**

Is a waiver of the requirement to obtain informed consent being requested for any aspect of this study?  Yes  No

* 1. **If ‘Yes’**: Specify for what type of data the consent waiver is being requested and complete all of the associated questions:

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| Waiver for secondary use of identifiable information | **In accordance with Tri-Council Policy Statement 2, Article 5.5A, all of the following conditions must apply for approval to waive consent. By checking each box, you are confirming that the condition applies.**  Identifiable information is essential to the research  The use of identifiable information without the participants’ consent is unlikely to adversely affect the welfare of individuals to whom the information relates  The researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information  The researchers will comply with any known preferences previously expressed by individuals about any use of their information  It is impossible or impracticable to seek consent from individuals to whom the information relates  The researchers have obtained any other necessary permission for secondary use of information for research purposes |
| Explain why not obtaining consent is unlikely to adversely affect the welfare of individuals to whom the information relates: |
| Explain why it is impossible or impracticable to obtain consent: |
| Waiver for secondary use of non-identifiable information | **In accordance with Tri-Council Policy Statement 2, Article 5.5B,** please describe how, in the context of the proposed research, the information to be used can be considered non-identifiable for all practical purposes: |

* 1. If no waiver of consent is being requested, describe the process that the investigator(s) will be using to obtain informed consent. Description should include when participants will be contacted for recruitment, who will be conducting consent discussions with potential participants, when/how participants will receive the Letter of Information/Informed Consent Form, and how long they will have to decide whether to consent to participate. Describe plans to obtain permission to contact the participants if recruiters are not part of circle of care. If there will be no written consent form, please explain how consent will be *documented*. Please note it is the quality of the consent, not the format that is important.

*\*Please attach a copy of the Information Letter/Consent Form and any other materials that will be used in the informed consent process.*

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| **SECTION E – SAFEGUARDS FOR PROTECTING DATA** |

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| **Anonymity**: Participants cannot be identified by the researchers, research team, or anyone in the research project at any point over the course of the study.  **Confidentiality**: The protection of the identity of participants or information from unauthorized access, use, disclosure, modification, loss or theft.  **De-identified:** Any process by which identifiable information is rendered unidentifiable.  Please refer to the [TCPS2](https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf) for information on distinguishing anonymity and confidentiality. |

1. **CONFIDENTIALITY / ANONYMITY**
   1. Will the data be treated as confidential?

Yes  No

* 1. Will the participant be anonymous to the researcher or anyone associated with the research?

Yes  No

* 1. Describe the procedures to be used to ensure anonymity/confidentiality of participants or informants, where applicable, or the confidentiality of data during the conduct of research and dissemination of results (for instance, have identifiers of the participants been removed)?

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1. **IDENTIFIABLE INFORMATION**

Will identifying data be collected, such as names, contact information, other personal identifiers?

Yes  No

If ‘Yes’:

1. Identify all directly and indirectly identifiable information that will be collected for this study. (Select ALL that apply):

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| --- | --- |
| Name  Initials  Address  Postal Code  Telephone Number  Email Address  Date of Birth | IP Address  Audio Recording  Video Recording  Medical Record Number  Age  Sex/Gender  Other (specify): |

1. For each identifier selected above, please explain why the collection of that identifier is necessary for the project.

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1. **DATA MANAGEMENT**
   1. Describe how the data will be securely stored during data collection and analysis.

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* 1. Identify all research personnel who will be able to identify participants or who will have access to the data during the course of the study.

***\*Each person listed above must sign a*** [***WRH Privacy Agreement***](https://www.wrh.on.ca/ResearchEthics#accordion-6-2) ***and signed agreements must be attached to this application.***

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* 1. If you are sharing data amongst the research team or with others outside of the research team, please describe the procedures you will use to share the data. If this data includes identifiers, provide details on steps taken to ensure data security and privacy. If study data will be sent offsite or outside of the WRH network, please explain where the data will be sent, the name(s) and affiliation(s) of the persons to whom the data will be sent, and the mode(s) by which the data will be sent (e.g. online electronic data collection, secured fax, secure file transfer, encrypted email, private courier delivery, Canada Post registered mail – note that regular mail may not be used).

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* 1. Describe who will have custodianship of the data and corresponding documentation once the study is complete. Please indicate who will take responsibility for providing permission for the subsequent use of the data or archiving.

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* 1. How long will you keep the study data and what will you do with the study data after this period? If collecting data on-line, please describe the length of time the data will be kept on the server and the process of downloading, storage and disposal of identifying information or sensitive data.

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* 1. Will you link the locally collected data with any other datasets, databases or registries (e.g., health registries, Statistics Canada)?

Yes  No

If ‘Yes’:

* + 1. Identify the dataset, databases, or registries to which it will be linked:

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* + 1. Explain how the linkage will be done:

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* + 1. Describe the security measures that will be in place to protect the confidentiality of the data:

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* 1. Is the purpose of this study to establish a registry/database?

Yes  No

If ‘Yes’:

* + 1. Where will it be stored and who will be the custodian?

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* + 1. Who will have access to the registry/database?

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* 1. Do you anticipate depositing the data or archiving the data with a Tri-Council compatible academic data repository?

Yes  No

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| **SECTION F – SIGNATURES** |

Principal Investigator and all Co-Investigators (and Faculty Supervisor, if applicable) must sign below in order for this application to be processed and reviewed.

As the Principal Investigator on this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant, provincial, national and international policies and regulations that govern research involving human participants. Any deviation from the project as originally cleared will be submitted to the Research Ethics Board for clearance prior to its implementation.

I agree to comply with the Tri-Council Policy Statement and all policies and procedures, governing the protection of human participants in research including, but not limited to, ensuring that:

* the project is performed by qualified and appropriately trained personnel in accordance with REB protocol and relevant laws governing the collection and use of personal information in research;
* no changes to the project as outlined in this application (and in the REB cleared protocol or other submitted documents, if applicable) will be implemented without amendment application to the REB of the proposed changes and receipt of the subsequent REB clearance;
* significant data security breaches or events are promptly reported to the REB within 5 working days of occurrence; and
* at a minimum, a progress report is submitted annually or in accordance with the terms of certification.

Your signature below represents informed consent for the sole purpose of knowledge of the proposal moving forward as a research application to the REB for consideration and review. The signature of the Principal Investigator confirms that all co-investigators have reviewed the protocol contents and are in agreement with the contents as submitted.

All Signatures as applicable (add additional rows as necessary):

| **Signatory Name** | **Signature** | **Date** |
| --- | --- | --- |
| Principal Investigator (or WRH PI for multi-centre studies): |  | Date: |
| Co-Investigator: |  | Date: |
| Co-Investigator: |  | Date: |
| Co-Investigator: |  | Date: |
| Co-Investigator: |  | Date: |
| Faculty Supervisor/Advisor (if applicable): |  | Date: |