**RESEARCH ETHICS BOARD**

**ETHICS SUBMISSION FORM FOR RESEARCH INVOLVING HUMANS**

**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.**

|  |  |  |
| --- | --- | --- |
| **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 Approvals
5. Departmental Impact
6. Additional Details
7. Conflict of Interest
 |[ ]   |
| **C – Summary of Proposed Research** | 1. Background & Rationale
2. Methods
3. Participant Recruitment
4. Compensation/Incentive/Reimbursement
5. Experience
 |[ ]   |
| **D – Risks and Benefits** | 1. Possible Risks
2. Possible Benefits
 |[ ]   |
| **E – Informed Consent Process** | 1. Waiver of Consent
2. Informed Consent Process
3. Consent by an Authorized 3rd Party
4. Participant Withdrawal
5. Post-Study Information/Feedback
 |[ ]   |
| **F – Safeguards for Protecting Participants & Data** | 1. Confidentiality/Anonymity
2. Identifiable Information
3. Data Management
 |[ ]   |
| **G – 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 (required for all submissions)
* Consent Form(s)/Assent Form(s)
* Recruitment Materials (Posters, social media posts, e-mail or verbal scripts, etc.)
* Study Instruments (questionnaires, surveys, interview guides, etc.)
* Permissions/Approvals (e.g. other REB clearance letters)
* Proof of award of funds (for grant funded research), budget, and contract included (where applicable)
* Health Canada NOL (if applicable)
* Other (list document name(s) in notes)
 |[ ]  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
 |[ ]   |
|  | * 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)
 |[ ]   |
| **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:**

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

1. **PRINCIPAL WRH or LOCAL 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 the PI on the project)

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| --- | --- |
| 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.*

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

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| Department:       | Institution/Agency/Organization:       |
| Mailing Address:       |
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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.*

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

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

|  |  |
| --- | --- |
| 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:       |

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. Version Number:
	2. Version Date:
	3. This is project a clinical trial? [ ]  Yes [ ]  No
	4. Trial Phase (if applicable):
	5. Is this an industry sponsored study? [ ]  Yes [ ]  No

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

|  |  |
| --- | --- |
| 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?

|  |  |
| --- | --- |
| [ ]  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. **ADDITIONAL DETAILS**
	1. For clinical trials, has Health Canada approval been obtained for this protocol?

[ ]  Yes - Attach NOL [ ]  No [ ]  N/A

* 1. Is an Investigator Brochure available? If ‘Yes’, please attach to submission documents.

[ ]  Yes - Attach IB [ ]  No [ ]  N/A

* 1. Has this study been registered on a clinical trial registry?

**\* *All clinical trials must be registered before recruitment of the first trial participant.***

[ ]  Yes [ ]  No [ ]  N/A - not a clinical trial

If ‘Yes’:

Registry Name:

Registration Number:

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, and the hypotheses or research questions to be examined in this study. 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. **METHODS**
	1. Please indicate all the research methods that will be utilized on this project:

[ ] Descriptive study design

[ ] Case-series study design

[ ] Survey research design

[ ] Correlational (ecological) study design

[ ] Cross-sectional (prevalence) study design

[ ] Case-control study design

[ ] Retrospective cohort study design

[ ] Prospective cohort study design

[ ] Randomized Clinical Trial

[ ] Qualitative Research - Please specify methodology

[ ]  Other, please specify

* 1. Will the research make use of human biological materials or tissues from Windsor Regional Hospital?

[ ]  Yes [ ]  No

***\* If ‘Yes’, complete questions (i)-(iii) below.***

* + 1. Please check the source(s) from where the biological materials or tissues are coming:

|  |  |
| --- | --- |
| [ ]  Archived Fixed Tissue[ ]  Frozen Tumor Bank[ ]  Autopsy[ ]  Fresh Tissue obtained from a Surgical Specimen[ ]  Fresh Tissue obtained from Excess Bodily Fluid (e.g., urine, saliva, etc.) [ ]  Fresh Tissue obtained from Excess Blood Sample (e.g., blood, plasma or serum) | [ ]  Human DNA/RNA/proteins [ ] Material related to Human Reproduction (e.g., embryos, fetuses, fetal tissue, cord blood)[ ]  Other (e.g., skin, hair, finger/toenails, bones, etc.) please specify:       |

* + 1. Please specify the type of human tissue sample or biological materials being requested:

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* + 1. How will the biological materials or tissues be collected (select all that apply):

[ ]  Prospectively collected for this study (i.e., not yet collected)

[ ] Previously acquired clinical specimens (i.e., leftover or archived specimens)

[ ] Other (Please specify):

* 1. **Data Collection Instrument(s)**

Indicate which of the following study instruments will be used in this study (select all that apply and attach copies of all study instruments to be used):

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| [ ]  Paper Survey(s)/ Questionnaire(s) |
| [ ]  Online Survey(s)/ Questionnaire(s) (i.e. REDCap, Qualtrics, SurveyMonkey, etc.)* Specify platform:
* Can all questions after consent be skipped by the participant?

[ ]  Yes [ ]  NoIf ‘No’: Specify which questions are not able to be skipped and provide justification:       |
| [ ] Interview Guide(s)If selected, will the interview be recorded in any way (e.g., audio recorded, video recorded, digitally recorded)? [ ]  Yes [ ]  NoIf ‘Yes’: Please describe the use of the recording in the project. Please indicate any specific recording devices to be used (e.g. digital recorder, video recorder, etc.) and/or any online platforms that will be used (e.g. Teams, Zoom, etc.). Indicate if the recording will be mandatory or optional to the participant:      |
| [ ] Other (e.g., case report forms, data abstraction database, other data collection forms)Describe “Other” instrument(s) and how they will be used in this project:       |
| [ ] None |

* 1. **Procedural Overview**

Clearly specify in a **step-by-step** outline all procedures that will occur between the point of first contact with participants until the completion of the study. **A separate outline is required for each methodology selected above.** Include the settings, study instruments, types of information to be involved, and team members involved.

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* 1. 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. **PARTICIPANT RECRUITMENT**
	1. **Sample Size**

Anticipated total number of participants to be recruited in the study:

Number to be recruited from Windsor Regional Hospital:

* 1. What is your participant source (select all that apply):

[ ] WRHIn-patients

[ ] WRH Out-patients

[ ] Patient families

[ ] WRH Staff, Professional Staff, or Volunteers

[ ] Students. Specify:

[ ]  Other. Specify:

* 1. Will patients/non-patients be selected from a department other than your department of affiliation?

 [ ]  Yes [ ]  No

If yes, list the other department(s) from which patients/non-patients will be selected:

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* 1. **Recruitment Procedure**

***\*Attach copies of any posters, flyers, letters, telephone scripts, etc. to be used for recruitment.***

* + 1. Where there is formal recruitment, please describe from where the participants will be recruited. If participant observation is to be used, please explain the form of “insertion of the researcher into the setting” that will be used (e.g. living in a community, visiting on a bi-weekly basis, attending organized functions). If applicable, attach letter(s) of permission from other organizations where research is to take place.

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* + 1. **Inclusion/Exclusion Criteria**

What are the study inclusion and exclusion criteria?

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* + 1. Will participants be excluded based on culture, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, sex, age group, etc.?

[ ]  Yes [ ]  No

If ‘Yes’: Describe who is being excluded and provide justification:

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1. **COMPENSATION/INCENTIVE/REIMBURSEMENT**
	1. Will participants receive any of the following? (Select all that apply)

[ ] Compensation for participation

[ ] Incentives for participation

[ ] Reimbursement for expenses that participants will accrue

[ ] Other. Specify:

[ ] No compensation/incentive/reimbursement

* 1. If compensation, incentives, or reimbursement will be provided:
		1. Provide details and justify the proposed amount:

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* + 1. If using an Online/internet method, describe how participant data and compensation, incentive, and/or reimbursement data will be managed:

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* + 1. Where there is a withdrawal clause in the research procedure and a participant chooses to withdraw, how will compensation, incentive, and/or reimbursement be handled?

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1. **EXPERIENCE**

Please provide a brief description of the researcher’s/research team’s experience **with each type of applicable research**. Include all members of the team. How will requisite research skills be obtained for research team members new to this type of research? (Note: please *describe* experience relevant to this proposal; this requires providing more than citations or professional qualifications.)

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| **SECTION D – RISKS AND BENEFITS OF THE PROPOSED RESEARCH** |

1. **POSSIBLE RISKS**

Discuss the risks and benefits of the proposed research to all parties, specifying the particular risks associated with each procedure, test, interview, or other aspect of the protocol. (Note: Ensure correlation with study protocol and/or Investigator Brochure). Please indicate potential risks that the participants as individuals or as part of an identifiable group or community might experience by being part of this research project. **\* Add additional risk matrices for methods as needed**

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| **Method #1:**       |
| **Risk Type** | **Low** | **Medium** | **High** |
| Physical risks (including any bodily contact or administration of any substance)? |[ ] [ ] [ ]
| Psychological/emotional risks (feeling uncomfortable, embarrassed, anxious or upset)? |[ ] [ ] [ ]
| Social risks (including possible loss of status, privacy and/or reputation)? |[ ] [ ] [ ]
| Economic risks (including possible costs, loss of job, money, fees)? |[ ] [ ] [ ]
| Dual/multiple relationship with study participants? |[ ] [ ] [ ]
| Data security (i.e., risk to participant from data exposure)? |[ ] [ ] [ ]
| Tied to deception involved in the study? |[ ] [ ] [ ]

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| --- |
| **Method #2 (if applicable**):       |
| **Risk Type** | **Low** | **Medium** | **High** |
| Physical risks (including any bodily contact or administration of any substance)? |[ ] [ ] [ ]
| Psychological/emotional risks (feeling uncomfortable, embarrassed, anxious or upset)? |[ ] [ ] [ ]
| Social risks (including possible loss of status, privacy and/or reputation)? |[ ] [ ] [ ]
| Economic risks (including possible costs, loss of job, money, fees)? |[ ] [ ] [ ]
| Dual/multiple relationship with study participants? |[ ] [ ] [ ]
| Data security (i.e., risk to participant from data exposure)? |[ ] [ ] [ ]
| Tied to deception involved in the study? |[ ] [ ] [ ]

* 1. Briefly describe each risk identified above associated with the methods used in this research. Address any actual known risks associated with the research, and any risks that might be reasonably perceived.

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* 1. Briefly describe how each of the potential risks described above will be managed/minimized.

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1. **POSSIBLE BENEFITS**

Discuss any potential direct benefits to the participants from their involvement in the project; these might include education about research methods, useful knowledge gained about self, etc. Comment on the (potential) benefits to the scientific/scholarly community or society that would justify involvement of participants in this study.

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| **SECTION E – INFORMED CONSENT PROCESS** |

1. **WAIVER OF CONSENT**

Is a waiver of the requirement to obtain informed consent being requested for any aspect of this study? (i.e. waiver of consent to access medical records to identify potential participants prior to full consent; or a portion of your study will include secondary data not linked to prospective participants). **\* If you are obtaining consent for part of the study and requesting a waiver for another aspect of the study select both Yes AND No.**

[ ]  Yes I am requesting a waiver of consent

[ ]  No I am not requesting a waiver of consent

If ‘Yes’: In accordance with Tri-Council Policy Statement 2, Article 3.7A, confirm that ALL of the following conditions apply:

• The research involves no more than minimal risk to the participants.

• The waiver of consent is unlikely to adversely affect the welfare of participants.

• It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required.

[ ]  **I CONFIRM**

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:

|  |
| --- |
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1. **INFORMED CONSENT PROCESS**

Describe the procedure for informing participants or informants about the research, including the information imparted to them. Please submit any information pamphlets, etc., that will be distributed to participants.

* 1. **Participants Capacity to Provide Informed Consent:**

 Indicate and check the box(s) which best apply to your participants (select all that apply):

| **Competent** | **Non-Competent** |
| --- | --- |
| [ ] Competent Adult [ ]  Vulnerable Population (See TCPS2 criteria) | [ ]  Non-Competent Adult[ ]  Consent from authorized party will be obtained[ ]  Assent from the participant will be obtained |
| [ ]  Competent Youth[ ]  Consent of both youth & parent/guardian required[ ]  Consent of youth required & parent/guardian informed[ ]  Consent of youth required & parent/guardian **not** informed | [ ]  Non-Competent Youth[ ]  Consent from parent/guardian[ ]  Assent from the youth will be obtained |
| [ ]  Competent Children[ ]  Consent of parent and child[ ]  Other:       | [ ]  Non-Competent Children[ ]  Consent from parent/guardian[ ]  Assent from the child will be obtained |

* 1. Indicate if there is a preceding, current, or anticipated relationship between participants and any of the following (including clinical or supervision relationship):
* Person obtaining consent: [ ]  Yes [ ]  No
* Investigator(s): [ ]  Yes [ ]  No
* Any other research team members: [ ]  Yes [ ]  No

If ‘Yes’ to any: What steps will be taken to avoid the perception of undue influence?

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* 1. Which of the following types of consent/assent will be collected? (select all that apply):

[ ]  Written consent/assent (this is the default option recommended by TCPS II; it provides clear documentation of consent/assent)

[ ]  Verbal consent/assent (e.g., for a telephone interview)

[ ]  Implied consent/assent (e.g., submitting/accessing a survey with consent preamble, etc.)

* 1. 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. If the research involves extraction or collection of personal information from a data participant, please describe how consent from the individuals or authorization from the custodian will be obtained and documented.

*\*Please attach a copy of the Information Letter/Consent Form, Audio/Video Recording Consent Form (if separate), the content of any telephone scripts, letters of administrative consent or authorization and/or any other material that will be used in the informed consent process.*

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* 1. **This question is applicable to Human Biological Material and/or Tissues ONLY:**

Is consent to collect human biological material/tissues being obtained?

[ ]  Yes [ ]  No

**If ‘No’,**

* + 1. Has the donor given consent for the tissue to be used in original research?

[ ]  Yes [ ]  No

* + 1. Has the donor given consent for tissue to be used in subsequent research?

[ ]  Yes [ ]  No

1. **CONSENT BY AN AUTHORIZED 3rd PARTY:**

***\*Please attach a copy of any permission/information letters to be provided to the person(s) providing the alternate consent as well as the assent process for the actual participants.***

* 1. If the participants are children, or are not competent to consent, describe the proposed alternate source of consent.

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* 1. If the research is taking place within a recognized community or an organization that requires that formal consent be sought prior to the involvement of individual participants, explain whether consent from that community/organization will be sought. Describe this consent process and attach any relevant documentation. If consent will not be sought, please provide a justification and describe any alternative forms of consultation that may take place.

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1. **PARTICIPANT WITHDRAWAL**
	1. Where applicable, please describe how the participants will be informed of their right to withdraw from the project. Outline the procedures which will be followed to allow them to exercise this right.

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* 1. Indicate what will be done with the participant’s data and any consequences which withdrawal may have on the participant.

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* 1. If participants will not have the right to withdraw from the project at all, or beyond a certain point, please explain.

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* 1. Are there limits to the ability of participants to withdraw their data?

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1. **POST-STUDY INFORMATION/FEEDBACK**
	1. Will participants receive any information either during or immediately after they have completed their involvement in data collection, such as at the end of an interview or survey completion? (e.g. resource list, links to further information, more information about the study, etc.).

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* 1. How will participants be informed of study results?

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| **SECTION F – SAFEGUARDS FOR PROTECTING PARTICIPANTS & 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 procedures to be used to ensure confidentiality of data during the conduct of research and dissemination of results.

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* 1. Describe any limitations to protecting the confidentiality of participants whether due to the law, the methods used, the nature of the sample population, or other reasons (e.g., duty to report, contract obligations, etc.)

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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 below 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 outside of the research team, 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 has 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. 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. Describe the security measures that will be in place to protect the confidentiality of the data:

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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

* 1. **These questions are applicable to Human Biological Material and/or Tissues ONLY:**
		1. Will the researchers collect additional personal health information or data directly from the patient charts?

[ ]  Yes [ ]  No

If **‘Yes’**, please specify the data to be collected:

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* + 1. Is the donor of the sample still identifiable or is the tissue de-identified with a unique study code identifier or anonymized with no code identifier? Please explain:

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* + 1. Could there be any leftover tissue or biological material upon completion of the research?

[ ]  Yes [ ]  No

**If ‘Yes’**, please describe the plan for the leftover tissue or its destruction:

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| **SECTION G – 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 consent form/statement, or other submitted documents) will be implemented without a formal amendment application to the REB of the proposed changes and receipt of the subsequent REB clearance;
* significant adverse effects 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** |
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| 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:       |