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| **NEW STUDY APPLICATION TO THE JOINT GROUP HEALTH CENTRE (GHC) /****SAULT AREA HOSPITAL (SAH) RESEARCH ETHICS BOARD (REB)** |

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| ***N. B. Investigators must make a brief oral presentation to the REB at the meeting in which their study proposal will be discussed. REB staff will provide Investigators with an appointment day/time for their oral presentation.*** |

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| For REB Office Use Only: |  | **Section A – Description of Research Team** |
| Date Received by REB Office: |  | **Principal Investigator:** The individual responsible for the research |
|  |  | Name: |
|  |  |  |
|  |  | Position: |
|  |  |  |
|  |  | Signature: **The REB will not issue approval letters without the original signature of the PI** |
| REB Project Number: |  |  |  |
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| ***N. B. All investigators and co-investigators must submit copies of their*** [***TCPS 2***](https://tcps2core.ca/welcome) ***or*** [***GCP***](https://crt.nihtraining.com/login.php) ***training completion certificates prior to receiving REB approval for the research project*** |
| **Research Team:** list all co-investigators; append a list, if necessary | **TCPS2 Certificate Appended?** |
| Name: | Role: |  |
|  |  |[ ]
| Name: | Role: |[ ]
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| Name: | Role: |[ ]
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| **SIGNED Declaration of Conflict of Interest form(s) attached for each investigator (pages 6 & 7):**  |[ ]  **Yes** |
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| **Best Contact Person for Project:** | [ ]  same as PI | **Is This A Student Project?** |[ ]  **Yes** |
| Name: | Phone Number: |
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| Position: | Email: |
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| Mailing Address (should be a professional office, educational institution, hospital, clinic, etc., and not a private residence): |
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| **Section B – Research Project/Protocol Title** |
| Full Study/Project Title: |
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| Short Study/Project Title (if applicable): |
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| **Research Question:** (In one sentence, state in question format) |
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| **Research Summary:** (Describe the goals of the project in clear and simple language. Do not use jargon or acronyms.) **Please note: in addition to the REB submission form a full description of the study must be submitted (e.g. Protocol, research proposal, outline of the study etc. These documents must have a date and a version number; please list them in Section M.** |
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| **Section C: Application Overview** | **Yes** | **No** | **Provide Details (as applicable):** |
| a. | Does this research involve organizations in addition to GHC or SAH? |[ ] [ ]  List Additional Organization(s): |
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| b. | Does this research require ethics review elsewhere (other than GHC and SAH)? |[ ] [ ]  Organization & Status of Application: |
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| c. | Is this project low risk, as per [TCPS 2](http://www.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/)? |[ ] [ ]   |
| d. | Is this research being done for academic requirements (e.g. thesis or dissertation)? |[ ] [ ]  Name of Program, Supervisor, and Institution: |
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| e. | Is any funding associated with the project (i.e. sponsorship, academic grant, etc.)? |[ ] [ ]  Specify Source(s), Including Duration (append a list, if needed): |
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| f. | Does this research involve a vulnerable population, as defined by [TCPS 2](http://www.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/)?  |[ ] [ ]  Identify Group(s): |
|  |  |  |  |  |
| g. | Has this project received administrative approval from GHC and/or SAH? |[ ] [ ]  Approver Name and Department (append written approval): |
|  |  |  |  |  |
| h. | Does this project require the collection of Personal Health Information (PHI) from **paper** charts/records from SAH or GHC? (Please consult with Health Records and/or Analytics if unsure). |[ ] [ ]  If yes –please complete and attach the **Request for Departmental Approval Form – Health Records.** If no, and all charts to be viewed electronically – Health Records approval not required.Approver Name: |
|  | Have you consulted with the Analytics Department regarding your criteria? |[ ] [ ]  If required – please complete and attach the **Request for Department Approval Form – Feasibility & Analytics.**Approver Name: |
|  | Data Sharing Agreement Complete?  |[ ] [ ]  **Must be provided with Initial Submission – please attach** |
|  | Does this study involve the SSMIC/SSM AMA? |[ ] [ ]  **If yes –** please give a brief description of involvement (direct and/or indirect):  |

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| **Section D: Research Design & Methodology - check the appropriate box(es) by location, then provide details** |
| Design | **GHC** | **SAH** | **Other Sites** |
| Qualitative Methods |[ ] [ ] [ ]
| Quantitative Methods |[ ] [ ] [ ]
| Clinical Trial/Medical Devices |[ ] [ ] [ ]
| **Methodology & Implementation** (Describe how the project will be conducted at GHC and/or SAH, including start and end dates): |
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| **Section E: Informed Consent – All consents must include a date and version number; please list them in Section M** |
| Provide a copy of **all** documents to be used for recruitment (e.g. letters, consent forms, pamphlets, posters, etc.): |
| **Consent Process** | **Yes** | **No** |
| a. | Will informed consent be obtained from **all** potential participants? |[ ] [ ]
| b. | Are **all** participants capable of providing full and informed consent themselves? |[ ] [ ]
| c. | Can participants withdraw **at any time** during the research project without penalty? |[ ] [ ]
| Describe the consent process and how participants will be informed of their right to withdraw from the study.  |
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| Indicate whether the following are incorporated into the consent form (check all that apply): |
| Invitation for subjects to participate in the study |[ ]  Notice that study participation is voluntary |[ ]
| Resources for mitigating potential risks |[ ]  Signature of the person obtaining consent |[ ]
| Subjects’ responsibilities for study participation  |[ ]  Notice that participation does not waive legal rights  |[ ]
| Contact information for the Joint Group Health Centre/Sault Area Hospital REB Chair: Dr. Brian Mitchell (phone: 705-759-5560) | [ ]  |
| **Section F: Recruitment of Participants Involved in the Research** | **Human Subjects** | **Health Records** |
| Does the study involve direct participation of human subjects or review of health records?  |[ ] [ ]
| Total number of participants and/or charts at **all** sites (locally + nationally + internationally): |  |
| **Local Recruitment Numbers** | **GHC** | **SAH** |
| Maximum number of participants and/or charts to be recruited/reviewed **locally** |  |  |
| List the plans for local recruitment and/or data collection, and describe any incentives for study participation. |
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| **Section G: Potential Risks** | **Yes** | **No** |
| a. | Are there any physical risks associated with participation in the study? |[ ] [ ]
| b. | Are there any psycho-social risks (e.g. embarrassment, stress, loss of privacy or status)? |[ ] [ ]
| c. | Are there any financial risks? |[ ] [ ]
| d. | Will the participants be deceived in any way? |[ ] [ ]
|  |   | **If “Yes,”** will participants be informed that they were deceived? (Explain below.) |[ ] [ ]
| If the answer is “**Yes**” **to any of the above questions**, describe the risk and why an alternate process cannot be used. |
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| **Section H: Potential Benefits** | **Yes** | **No** |
| a. | Are there potential benefits to participants? |[ ] [ ]
| b. | Are there potential benefits to the scientific community? |[ ] [ ]
| c. | Are there potential benefits to society? |[ ] [ ]
| Describe any proposed benefits to the participants and/or the scientific community that justify participation. |
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| **Section I: Confidentiality & Personal Health Information** |
| NOTE: Principal Investigators are to ensure that requests for personal health information are in accordance with the [Personal Health Information Privacy Act (2004)](http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm) and [Personal Information Protection and Electronic Documents Act](http://laws-lois.justice.gc.ca/eng/acts/P-8.6/). |
| Access to **personal health information** is being requested from: | **GHC** | **SAH** | **Other** |
| Human Participants |[ ] [ ] [ ]
| Health Records (electronic or paper) |[ ] [ ] [ ]
| Indicate what measures will be/have been taken to protect the data, as per [TCPS: Chapter 5](http://www.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/) (check all that apply). |
| Data will be encrypted |[ ]  Data will be password-protected |[ ]
| Paper records will be kept in locked cabinet/room  |[ ]  Data will be stored on secure institutional network |[ ]
| Only study team can access records and data |[ ]  All identifiers to be removed once data is collected |[ ]
| Master list linking data with identifiers will be stored separately from the data |[ ]  Data will be destroyed after: (enter number of months/years) |

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| 1. Describe the personal health information required and **who will have access**; indicate whether access will be to identifiable or non-identifiable information. Explain how confidentiality will be protected, or why it will not be.
2. Please identify if study files (hardcopy/paper) will be stored in a location other than SAH/GHC (if yes, please identify where).
3. Will remote/VPN access be requested to conduct the study from a location other than SAH/GHC? (If yes, please include details of where research will be conducted). **If study will be conducted remotely/through VPN access, please ensure that only the Principal Investigator and authorized Research Team staff will have access to study data/study information, and that the terms of the DSA/Attestation is adhered to throughout the course of the study.**
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| **Section J: Clinical Trial/Medical Devices Studies ONLY (if not a clinical trial, skip to Section K)** |
| Provide status of required Clinical Trial documentation. | **Yes** | **Pending** | **N/A** | **Details or Attach Documentation** |
| a. | Registered at [clinicaltrials.gov](http://www.clinicaltrials.gov) or other registry (list #) |[ ] [ ] [ ]   |
| b. | Health Canada No Objection Letter |[ ] [ ] [ ]   |
| c. | Local research team has credentials to conduct project |[ ] [ ] [ ]   |
| d. | Independent Data Safety Monitoring Board (DSMB)  |[ ] [ ] [ ]   |
| e. | Is interim analysis planned for this study? |[ ] [ ] [ ]   |
|  | Provide Details: |
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| **Section K: Declaration of Conflict of Interest & Research Ethics Agreement for Principal Investigator**  |
| **Please note:** Each additional project investigator is required to complete and sign a separate [Declaration of Conflict of Interest Form](#ConflictInterest) to append to this application. | **Yes** | **No** |
| Do you or any of your immediate family members:* have any proprietary interests in the product under study or the outcome of the research, including patents, trademarks, copyrights, or licensing?
* have equity interest in the sponsoring company?
* receive payments of any kind from this sponsor (e.g. grants, compensation in the form of supplies or equipment, retainers for ongoing consultation, or honoraria)?
* serve as representatives on the sponsor’s Board of Directors (or comparable body)?
 |[ ] [ ]
| If the answer is “**Yes**”, describe the arrangement(s) of the potential conflict of interest, including additional protections put into place to safeguard study participants and/or information accessed. |
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| *As Principal Investigator, I,* |  | , *assume full responsibility for this study and affirm that:* |
|  | *print name* |  |

* The information reported herein is accurate;
* I understand that any approval granted by the Joint Group Health Centre/Sault Area Hospital Research Ethics Board (REB) is limited to the information and activities outlined herein, including all supporting documents. Any amendments and re-approval requirements shall be submitted for approval by the REB prior to implementation;
* I will comply with the [Tri-Council Policy Statement 2: (TCPS 2)](http://www.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), the [Personal Health Information Privacy Act (2004)](http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm), and any other regulations required by this specific protocol, and that I have submitted [ICH Good Clinical Practice](http://ichgcp.net/) or [TCPS 2](http://www.ethics.gc.ca/eng/education/tutorial-didacticiel/) training certificate(s);
* I will conduct my research in accordance with the research policies specific for each organization to which I am applying, including all required notifications and renewals;
* I am aware of my responsibility to adhere to the standards outlined by my professional College and institution;
* I will hold all information received or exchanged in this course of this project in strict confidence; information disclosed will not be linked to other sources unless specified and approved by the REB;
* I will ensure that all co-investigators and research personnel are provided with training and demonstrate adequate understanding in the above-referenced guidelines and regulations;
* I will ensure that all co-investigators and research personnel have reviewed and demonstrate an understanding of the protocol, and agree with the implementation of the protocol at GHC/SAH, as submitted to the REB;
* I will provide access to all required documents for auditing by the REB and/or other regulatory authorities;
* I will not initiate research activities within GHC/SAH as outlined in this application until formal notification of approval has been received from all required REBs and, if required, related financial agreements/contracts; *and*
* I will seek REB approval prior to the implementation of any changes/revisions to the project described herein.

**For Sault Area Hospital research studies only:**The Research Ethics Board decision will be shared with the Institution (SAH).

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| Signature: |  |  | Date:mm/dd/yy |  |
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**The REB will not issue approval letters without the original signature of the PI.**

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| **Section L: Additional Project Investigator Declaration of Conflict of Interest** |
|  NOTE: This form must be completed and **signed** by each additional investigator on this project. Copies of this form may be made for each investigator, but **original copies/signatures must be submitted to the REB**. Each completed and signed Declaration of Conflict of Interest form must be appended to this application. |
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| **Name of Additional Project Investigator:**  |  |
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| **Name of Project:**  |  |
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|  | **YES** | **NO** |
| a. | Do you or your immediate family have any proprietary interests in the product under study or the outcome of the research, including patents, trademarks, copyrights, or licensing agreements? |[ ] [ ]
| b. | Do you or your immediate family members receive any compensation which is linked to the outcome of this study? |[ ] [ ]
| c. | Do you or your immediate family members have equity interest in the sponsoring company? |[ ] [ ]
| d. | Do you or your immediate family members receive payments of any kind from this sponsor (e.g. grants, compensation in the form of equipment or supplies, retainers for ongoing consultation, or honoraria)? |[ ] [ ]
| e. | Do you or your immediate family members serve as representatives on the sponsor’s Board of Directors (or comparable body)? |[ ] [ ]
| If the answer is “**Yes**” **to any of the questions above**, please describe the arrangement(s) and the implication(s) of the potential conflict of interest, including the additional protections which have been put into place to protect study participants and/or information accessed. |
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| Signature: |  |  | Date:mm/dd/yy |  |
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**The REB will not issue approval letters without the original signature(s) of the Co-Investigator(s).**

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| **Section M: List of Appended Items (These documents must have a date and a version number)** |
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*\*If more space is needed, append a separate list*