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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: | | |
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| 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** |
|  | | | | | | | |  | |
| **Best Contact Person for Project:** | | same as PI | | | | | **Is This A Student Project?** |  | **Yes** |
| Name: | | | | | | Phone Number: | | | |
|  | | | | | |  | | | |
| 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): | |
|  | |
| b. | Does this research require ethics review elsewhere (other than GHC and SAH)? |  |  | | Organization & Status of Application: | |
|  | |
| 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: | |
|  | |
| e. | Is any funding associated with the project (i.e. sponsorship, academic grant, etc.)? |  |  | | Specify Source(s), Including Duration (append a list, if needed): | |
|  | |
| 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) | | |  | | --- | |  | | | |  |
| 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).   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Signature: |  |  | Date:  mm/dd/yy |  | |  |  | |

**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 |  | |  |  |   **The REB will not issue approval letters without the original signature(s) of the Co-Investigator(s).**   |  |  | | --- | --- | | **Section M: List of Appended Items (These documents must have a date and a version number)** | | | 1. |  | | 2. |  | | 3. |  | | 4. |  | | 5. |  | | 6. |  | | 7. |  | | 8. |  | | 9. |  | | 10. |  | | 11. |  | | 12. |  | | 13. |  | | 14. |  | | 15. |  | | 16. |  | | 18. |  | | 19. |  | | 20. |  | | 21. |  | | 22. |  | | 23. |  | | 24. |  | | 25. |  | | 26. |  | | 27. |  | | 28. |  | | 29. |  | | 30. |  | | 31. |  | | 32. |  | | 33. |  | | 34. |  | | 35. |  | | 36. |  | | 37. |  | | 38. |  | | 39. |  | | 40. |  | | 41. |  | | 42. |  | | 43. |  | | 44. |  | | 45. |  | | | | | | | | | | | |

*\*If more space is needed, append a separate list*