Boxes will expand as needed and headers rows will repeat if boxes break between pages. If you have difficulty completing this form contact SJCG\_REO@tbh.net.

|  |
| --- |
| **Section A: Research Project/Protocol Title**  |
| Study Title:      |

|  |
| --- |
| **Section B: Research Team**  |
| **Principal Investigator:** The **Principal Investigator (PI)**is the individual responsible for the research.The PI must also submit their Tri-Council Policy Statement CORE (Course on Research Ethics) Tutorial certificate with the application. |
| Name:       | Department and Institution:       | Position:       |
| Address:       |
| Phone:       | Fax:       | Email:       |
|  |  |  |
| Best Contact Person for Project:  |  [ ]  same as PI  |
| Name:       | Department and Institution:      | Position:      |
| Address:      |
| Phone:      | Fax:      | Email:      |

| **Section B: Research Team** (continued) |
| --- |
| Research Team: Each team member must complete a Declaration of Conflict of Interest Form and append to the application. All team members must also submit their Tri-Council Policy Statement CORE (Course on Research Ethics) Tutorial certificate. |
| Name:      | Department and Institution:      | Email:      |
| Name:      | Department and Institution:      | Email:      |
| Name:      | Department and Institution:      | Email:      |
| Name:      | Department and Institution:      | Email:      |
| Name:      | Department and Institution:      | Email:      |
| Name:      | Department and Institution:      | Email:      |
| Name:      | Department and Institution:      | Email:      |
| Name:      | Department and Institution:      | Email:      |
| Name:      | Department and Institution:      | Email:      |
| Name:      | Department and Institution:      | Email:      |

|  **Section C: Overall Description of Research Project/Protocol** |
| --- |
| Research Question:In one sentence, state in question format. |
|       |
| Research Summary:In 300 words or less describe the goals of the overall research project in clear and simple language. Do not use technical language, jargon or acronyms. |
|       |

| **Section D: Application Overview**  |
| --- |
| If you require assistance in responding to these questions, please consult the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html).  |
|  | **Yes** | **No** | Provide details: |
| a. | Does this research project involve organizations in addition to SJCG?  |[ ] [ ]  List additional organizations:      |
| b. | Does this research project require research ethics review elsewhere?  |[ ] [ ]  Organization & status of application      |
| c. | Has this research proposal/clinical protocol been peer-reviewed for scientific merit (e.g. CIHR, OMHF)? |[ ] [ ]       [ ]  Copy attached |
| d. | Do you consider this research project to be minimal risk as defined by the [TCPS 2](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html)? |[ ] [ ]        |
| e. | Does this research involve recruitment of individuals vulnerable in the context of research as defined by the [TCPS 2](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter4-chapitre4.html#7)?  |[ ] [ ]  Identify group(s):      |
| f. | Is this research in partial fulfillment of academic requirements, e.g., undergraduate, graduate, or postgraduate training. If “Yes”, provide details. |[ ] [ ]  Program, Supervisor & Institution:      |
| g. | Has this project received the support for resources required to complete this project at SJCG?  |[ ] [ ]  Attached: [ ]  Signed SJCG Organizational Impact Form |
| h. | Does this research project require Joint Pharmacy & Therapeutics (P&T) approval? |[ ] [ ]  Status (e.g., approved, submitted):      |
| i. | Is there research funding associated with this project? |[ ] [ ]  Specify:      |
|  | If yes, will SJCG administer any portion of the funding for this project (e.g., sign a contract or researchers agreement, required financial reporting) | [ ]  Copy of contract/agreement attached  |
| j. | Is this an industry-sponsored research initiative?**Note:** A $3,000 review fee is charged for industry-sponsored protocols at the time of application.  |[ ] [ ]  Specify company:      |

|  |
| --- |
| **Section E: Research Project/Protocol Design and Methodology** |
|  | Information obtained at SJCG | Information obtained at other sites |
| Qualitative Methods |[ ] [ ]
| Quantitative Methods |[ ] [ ]
| Chart Review |[ ] [ ]
| Clinical Trial/Medical Device |[ ] [ ]
| Describe the specific methodology:      |

| **Section F: Implementation of Research Project/Protocol Including Timelines** |
| --- |
| In clear and simple language: * Describe what aspects of the overall project are to be accomplished at SJCG.
* Outline in detail the all steps required to accomplish the project.
 |
|  | Start Date:      (month day, year)  | End Date:       (month day, year) |
| Provide details:      |

| **Section G: Recruitment of Participants Involved in the Research Project/Protocol** |
| --- |
|  | **Yes** | **No** |
| Does this research project involve direct participation of human participants?  |[ ] [ ]
| Does this research project involve the review of health records (i.e., electronic and/or paper charts)?  |[ ] [ ]
| **Recruitment numbers** |  |  |
| a. | The number of participants to be recruited at SJCG  |  |
| b. | The number of individuals meeting eligibility criteria for study at SJCG |  |
| c. | The number of charts to be reviewed at SJCG  |  |
| d. | Total number of participants to be recruited at **all** sites (i.e., SJCG and other sites) |  |
| e.  | Total number of charts to be reviewed at **all** sites (i.e., SJCG and other sites) |  |
| Recruitment of participants and/or their information requires clear and locally appropriate strategies. Describe in detail, the plans for recruitment and/or data collection. What incentives are offered to participants, if any? |
|       |

| **Section H: Informed Consent** |
| --- |
| Please provide a copy of all documentation to be used in the recruitment process (e.g., information letter, consent form, promotional flyers, emails). |
| **Consent Process**  | **Yes** | **No** |
| a. | Will informed consent be obtained from all participants directly?  |[ ] [ ]
| b. | Are allparticipants capable of providing full and informed consent themselves?  |[ ] [ ]
| c. | Do participants have the right to withdraw at any time during the research project?  |[ ] [ ]
| Describe in detail the consent process.  |
|       |
| Describe in detail how participants will be informed of their right to withdraw from the study. Consider withdrawal at all phases of the study.  |
|       |

| **Section I: Potential Benefits** | **Yes** | **No** |
| --- | --- | --- |
| a. | Are there potential benefits to participants? |[ ] [ ]
| b. | Are there potential benefits to the control group? [ ]  no control group |[ ] [ ]
| c. | Are there potential benefits to the scientific community? |[ ] [ ]
| d. | Are there potential benefits to society? |[ ] [ ]
| Describe the proposed benefits to the participants, the scientific community and/or society that would justify asking participants to participate.  |
|       |

| **Section J: Potential Risks** | **Yes** | **No** |
| --- | --- | --- |
| a. | Are there any physical risks? |[ ] [ ]
| b. | Are there any psychological risks (e.g., embarrassed, worried or upset)? |[ ] [ ]
| c. | Are there any social risks (e.g., loss of status, privacy, and/or reputation)? |[ ] [ ]
| d. | Are there any financial risks? |[ ] [ ]
| e. | Will the participants be deceived in any way?  |[ ] [ ]
|  | * If “Yes”, will participants be debriefed? Debriefing is when a participant is informed they were deceived and why. Provide details in the box below.
 |  |  |
| If the answer is“Yes” to any of the above questions in Section I, please justify the methodology proposed indicating why alternative approaches involving less risk cannot be used.  |
|       |

| **Section K: Confidentiality** |
| --- |
| Describe the steps that will be taken to ensure confidentiality of the data. If confidentiality cannot be maintained, explain why not. Consult the guidelines for questions to consider.  |
|       |

| **Section L: Personal Health Information** |
| --- |
| NOTE: Principal Investigators are to ensure request for personal health information 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) |
| Access to personal health information is being requested from:  | SJCG | Other sources |
| Human Participants |[ ] [ ]
|  Health Records  |[ ] [ ]
| Other: Please specify      |
| Provide a description of the personal health information required and the anticipated sources from which this information will be accessed. Attach surveys and/or data abstraction forms.  |
|       |
| Describe the process to ensure confidentiality/anonymity of health information. Include who will have access to the personal health information collected in the study, including position titles and credentials of this/these individual(s). Indicate if the access will be to identifiable or non-identifiable information (use definitions as described in [TCPS 2: Chapter 5](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter5-chapitre5.html)). |
|       |

| **Section M: Data Management and Storage**  |
| --- |
| Describe data management, storage and security regarding information collected.  |
|       |

| **Section N: Funding Sources**  |
| --- |
| Please acknowledge all sources of funding/support to complete the project. Indicate the name of the organization that will administer the funding. Append a copy of the project budget with the application.  |
|       |

| **Section O: Declaration of Conflict of Interest for Principal Investigator** |
| --- |
|  | **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 and 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. | Are you or any member of your immediate family representatives on the sponsor’s Board of Directors (or comparable body)?  |[ ] [ ]
| If the answer is“Yes” to any of the questions in Section N above, please describe the arrangement and the implications of the potential conflict of interest, including the additional protections which have been put into place to protect study participants and/or information accessed.  |
|       |

| **Section P: Clinical Trial/Medical Devices Studies** [ ]   **This study is NOT a Clinical Trial: Skip Section P** [ ]   **This study is a Clinical Trial: complete Section P**  |
| --- |
| REB review for this Clinical Trial is required to follow... | Yes | No | Details |
| a. | OHRP regulations? |[ ] [ ]        |
| b. | FDA regulations? |[ ] [ ]        |
| Provide status of required Clinical Trial documentation. | Completed | In progress | Not applicable | Details or attach documentation |
| c. | Registered with clinicaltrials.gov (provide #) |[ ] [ ] [ ]        |
| d. | Registered with another trial registry |[ ] [ ] [ ]        |
| e. | Health Canada No Objection Letter |[ ] [ ] [ ]        |
| f. | Health Canada Investigational Testing Authorization |[ ] [ ] [ ]        |
| g. | Any other regulatory documentation (list) |[ ] [ ] [ ]        |
| h. | Research team local credentials to conduct project  |[ ] [ ] [ ]        |
| i. | Data Safety Monitoring Board established |[ ] [ ] [ ]        |
| j. | Is interim analysis planned for this study  |[ ] [ ] [ ]        |
|  | Provide details       |

| **Section Q: List of Documentation for this application.**  |
| --- |
| This list will be referenced in the approval letter, therefore be clear to identify all documents by title, appendix reference, version number and/or version date, as appropriate.  |
| Document title | Title/Appendix Reference | version #  | version date (month day, year) |
| REB application form  |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

|  |
| --- |
| **Section R: Research Ethics Agreement** |
| As the Principal Investigator:* I agree to assume full responsibility for this study.
* I understand that any approval granted by the REB is limited to the information, activities and conditions as outlined within this application including all supporting documents (e.g., Information letters, consent forms). Any amendments and re-approval requirements will be submitted for approval by the REB prior to implementation.
* I agree to ensure compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, [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, if applicable, the related funding agreement/contract.
* I have read and will conduct my research in accordance with the research policies and procedures specific for each organization to which I am applying, including all required notifications and renewals.
* I am aware of my responsibility to be familiar with and adhere to the standards outlined by my professional College and academic institution.
* I agree that all information received or exchanged as approved in the REB application will be held in strict confidence. Information disclosed will not be linked to other sources unless specified and approved by the REB.
* I will ensure all co-investigators and research personnel are provided training and demonstrate adequate understanding in the above referenced guidelines and regulations. I will ensure all co-investigators and research personnel have reviewed and demonstrate an understanding of the protocol and are in agreement with the implementation of the protocol at SJCG as submitted to this Research Ethics Board.
* I agree to provide access to all required documents for the purpose of monitoring and auditing by the REB, the sponsor and/or other appropriate regulatory authorities.
* I will not initiate research activities within SJCG as outlined in this research ethics application until formal notification of approval has been received from all required REBs and, if required, related financial agreements/contracts.
 |
| The undersigned hereby agrees to these terms: |
| Principal Investigator’s Signature:(sign final hard copy after printing) |  |
| Print Name:  |       |
| Date: (month day, year)  |       |
|  |  |  |
| Please check the proper box for the following statement:I agree to allow SJCG to post my name, the full research title and the effective dates of the active study on their internal website for communication purposes. If you indicate “No”, consult the Research Ethics Board at time of application. | Yes | No |
|  |[ ] [ ]