**Guidance Notes**

**For the SHA Research Ethics Board Application for Exemption Determination**

The following Guidance Notes (GNs) are intended to provide assistance in completing the ***Application for Exemption Determination***. The information in this GN complies with the Tri-Council Policy Statement 2022 (TCPS2) and will link to specific Articles when relevant.

**Background:**

The TCPS2 requires ethics review and approval by a Research Ethics Board (REB) for any studies involving living human participants, their data, or human biological materials. However, not all research activities, or activities that seem like research, require approval by the REB. Such activities are exempt from REB review, and individuals are free to conduct exempt activities without input or clearance from the REB. However, it can be difficult to make this determination and it is not uncommon for investigators to assume incorrectly that their project is exempt.

In order to help, the REB will provide a formal determination of whether a project is exempt from requiring REB approval. The *Application for Exemption Determination* is designed to elicit the specific information that the REB requires to make an informed determination. If the REB determines that the project is exempt, the applicant will receive a formal Letter of Exemption, stating that the REB has deemed the project exempt and why. Otherwise, the applicant will be informed why the REB has determined that the project requires REB approval and will request the submission of the appropriate form.

**Who should use this form?**

This application is for staff within the SHA who would normally submit an ethics application to the SHA REB.

The REB does not require that a study team submit this application, if they are certain that their study is exempt. Rather, if a study team is unsure whether their study requires REB approval, they can submit this form to receive a formal determination from the REB.

Some organizations may require evidence that the study team received formal clearance from their institution’s REB. For example, the SHA’s Operational Approval process requires that quality improvement studies include a Letter of Exemption with their application. Study teams can submit this application in order to receive the Letter of Exemption as evidence of formal clearance by the SHA REB.

Before completing the application or undertaking your project, please note the following:

1. The [TCPS2](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html#1) states that the REB “makes the final decision on exemption from research ethics review.” Although you may strongly believe that your project is exempt, the final determination is the REB’s.
2. The SHA REB will not perform a retrospective review of projects currently in progress to determine whether it was exempt. If you are at all unsure, please submit the *Application for Exemption Determination* before you start your project.
3. While there is no issue with conducting an exempt activity without a formal determination, journals may require evidence of consultation with the REB, which the REB will not provide retrospectively. So, if you intend to (or even may want to) publish your findings, it may be prudent to submit the *Application for Exemption Determination* in order to secure a Letter of Exemption.
4. Even if the project is exempt from REB approval, you will still need to seek SHA [Operational Approval](https://www.saskhealthauthority.ca/our-organization/our-direction/research/getting-approval-conduct-research-sha/operational-approval).
5. The expectation is that investigators will conduct their activities ethically and professionally, even if exempt from REB approval. It may be beneficial to apply the TCPS2 principles and guidelines, to an exempt project. You can also consult with the REB for advice on the ethical conduct of exempt studies, if you wish.

**How to Use the Guidance Notes with the Application Form:**

The GNs are numbered and correspond to the same numbered box in the Application Form. It is the responsibility of the applicant(s) to ensure that the information contained in each GN is applied in a manner appropriate to each individual project for both the Application Form and any accompanying documentation.**The REB requires a complete response to each question in the Application Form.**

**General Guidance**

Evaluating projects for whether they are exempt requires specific information different to the information required for the review of research. Primarily the REB needs clear information about the intent and scope of the project, as opposed to detailed information about recruitment, consent, and data collection, since this is a determination of exemption, not an evaluation of the project. When filling out the application, please consider these points in particular and write your responses using simple, easy to understand language.

Please also consult **Articles 2.1 to 2.6** of the [TCPS2](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html) for more information and guidance, since the REB will rely on these Articles to inform its determination. These articles are especially important for determining whether a project is exempt, since they identify and discuss the most common types of exempt projects. The [Interpretations – Scope](https://ethics.gc.ca/eng/policy-politique_interpretations_scope-portee.html) provided by the Panel on Research Ethics may also provide helpful guidance and context regarding exemptions. You can also contact the Research Ethics Office (REO) for advice regarding exemptions and completing the application.

Please also note that sometimes a project initially deemed to be exempt may nevertheless result in research outcomes, leading to the creation of new knowledge. If this occurs, please contact the REO for a re-evaluation of the exemption of the project.

**PART 1: IDENTIFICATION**

**GUIDANCE NOTE 1.1:****PROJECT TITLE**

The title of the project should accurately reflect the nature of the project.

**GUIDANCE NOTE 1.2: PRINCIPAL INVESTIGATOR**

The Principal Investigator (PI) is the individual who is ultimately responsible for the actions of those acting with delegated authority. They are the person responsible for the conduct of the project at a site or the responsible leader of the team. This means that students and residents should not be identified as the PI. Rather, it should be their supervisor.

Unless noted otherwise in Section 1.4, the REB will send all correspondence to the address provided for the PI.

**GUIDANCE NOTE 1.3: THESIS/PROJECT SUPERVISOR**

Include the name of the student’s or resident’s supervisor. The supervisor takes responsibility for ensuring that the student or resident researcher conducts the project ethically and professionally.**GUIDANCE NOTE 1.3:PROJECT PERSONNEL**Include the names of all persons assuming a formal role within the project that are to be listed on the Letter of Exemption. This may include, but is not limited to, co-principal investigators, co-investigators, residents, students, supervisors, and faculty advisors.  **GUIDANCE NOTE 1.4: PRIMARY CONTACT PERSON**If another contact besides the PI will be handling all paperwork and correspondence related to this file, please indicate here.
**GUIDANCE NOTE 1.5: LOCATIONS WHERE THE PROJECT WILL BE CARRIED OUT**

Enter the names of all locations/institutions/sites where the project will be carried out. If the study will be conducted online (e.g., an online survey), indicate the locations/institutions/sites where the participants will be located.

The project cannot begin until you receive Operational Approval from the appropriate authorities that oversee access to these locations/institutions/sites. It is the PI’s responsibility to obtain necessary approvals from these sites.

**GUIDANCE NOTE 1.6:****STUDIES BEING SUBMITTED FOR REB APPROVAL AT OTHER SITES**

Indicate whether this project is under review or has received approval from another REB in Saskatchewan and/or a REB outside of Saskatchewan.

REB approval at another institution may suggest that the project is not exempt, but is not solely determinative.

**GUIDANCE NOTE 1.7:****FUNDING INFORMATION**

Indicate by name the source of funds and whether or not the funds have been awarded. The provision of funds by some funders, such as CIHR, may suggest (or even require) that the project is research.

**PART 2: BRIEF OVERVIEW OF PROJECT**

**GUIDANCE NOTE 2.1: DESCRIPTION OF THE PROJECT**

Provide a short summary of the project written in lay language and suitable for non-scientific REB members. It should include a brief description of your objectives and/or purpose.

**GUIDANCE NOTE 2.2: DATA COLLECTION METHODS**

List the methods you intend to use to collect your information (e.g., interviews, surveys, secondary use of health data). Please include a copy of the data collection tool, if available.

**GUIDANCE NOTE 2.3: WHY THE PROJECT IS EXEMPT**

Please identify the Article under which you think your project is exempt and discuss why. Please only choose **one** Article that you feel best demonstrates why your project is exempt.

Please see below for advice specific to each Article. Please also ensure that you read the applicable Article in the TCPS2 carefully.

[2.1 (not research)](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html#1): Please state why you believe that your project does not meet the definition of research in the TCPS2.

2.1 (not research – case studies): Please indicate the total number of health records you intend to access/extract, noting that three or more constitutes research.

[2.1 (institutional information):](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html#1) The TCPS2 states “In some cases, research may involve interaction with individuals who are not themselves the focus of the research, in order to obtain information. For example, one may collect information from authorized personnel to release information or data in the ordinary course of their employment about organizations, policies, procedures, professional practices or statistical reports.” For a project to meet this criterion, the data collection cannot ask participants to share their personal feelings or opinions regarding the topic (e.g., “What do you think, How do you feel about) and instead should focus solely on factual information about the organization. Please be sure to include a copy of the data collection tool, such as interview questions, to help the REB make its determination.

[2.2 (publicly available):](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html#2) As described in this Article, this exemption also covers data that has been made public by law or regulation, even if it is not readily available to the public. Please include in your application a description of where the data you intend to access is located and an identification of the data’s steward.

[2.2 (public domain with no expectation of privacy](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html#2)): Please include in your application a description of where the data you intend to access is located and an identification of the data’s steward. Please also include a discussion of whether there is a reasonable expectation of privacy associated with the data.

2.3 (non-participant observational research): Please discuss how your project meets the three criteria identified in this article (a. the project does not include an intervention or direct interaction with participants; b. those being observed have no reasonable expectation of privacy; and c. the dissemination of the results will not allow individuals to be identified).

2.4 (secondary use of [anonymous information](https://ethics.gc.ca/eng/tcps2-eptc2_2022_glossary-glossaire.html#i) or human biological [materials](https://ethics.gc.ca/eng/tcps2-eptc2_2022_glossary-glossaire.html#h)): Please include whether the data/materials include any direct or indirect identifiers when originally collected. Please also include whether you intend to [link](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html#e) the information or [materials](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter12-chapitre12.html) to other datasets/materials and whether this process, collection, and/or dissemination may generate identifiable information or result in the identification of individual participants.

[2.5 (quality assurance/improvement, program evaluation)](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html#5): Please include in the application a clear statement of purpose and, if available, a copy of the data collection tool. This statement should include whether this is a new or ongoing effort to manage internal processes. The data collection tool should reflect the stated purpose, which should be to evaluate and/or improve a program, service, or resource, not generate new and generalizable knowledge. Please also include a description of the applicants’ and sponsor’s (if applicable) relationship with the program, service, or resource being evaluated, since the ability to effect change is a key indicator of QI. Projects that are mandated by the institution or a specific program or department are more likely to be QI than research. Projects that have a dual purpose of QI and research will require REB approval.

[2.6 (creative practice)](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html#6): Please describe the creative activity you intend to undertake (i.e., the creation or interpretation of art), including a copy of any data collection tools, if available.

**PART 3: RECRUITMENT**

**GUIDANCE NOTE 3.1: INCLUSION CRITERIA**

Provide a brief description of the criteria for inclusion.

**GUIDANCE NOTE 3.2: METHOD OF RECRUITMENT**

Provide a brief description of the planned method(s) of recruitment, including how eligible individuals will be identified, who will contact them, and the manner in which it will be done.

**SECTION 5: DOCUMENTS**

The REB normally does not require documents, such as consent forms and data collection tools, in order to determine whether a project is exempt. However, they can help inform the REB’s determination. If you have any of the following documents ready, even if drafts, it may be helpful to include them with your application. If the REB feels that it requires documents to make an informed determination, the REB will request them in a Notice of Review.

1. Memorandum of Understanding
2. Research Agreement
3. Protocol
4. Data Collection Tools (e.g., variables for extraction, interview guide, survey questions).
5. Recruitment Materials
6. Consent Forms