**Does this project require REB review?**

This document is presented, recognizing that there are no watertight definitions that can be provided for Healthcare Providers (HCP), researchers and Research Ethics Board (REB) reviewers: judgement, on occasion, will be needed in defining the proposed project. Any of the following examples may also be used as criteria in consideration for publication or reporting purposes. If there are queries or concerns the REB will always be pleased to review and work with the HCP and researcher to provide guidance.

**Guidance:**

1. **TCPS 2 — 2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans**

 ***Article 2.5***
Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.

 ***Application***
[Article 2.5](http://www.ger.ethique.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#ch2_en_a2.5) refers to assessments of the performance of an organization or its employees or students, within the mandate of the organization, or according to the terms and conditions of employment or training. Those activities are normally administered in the ordinary course of the operation of an organization where participation is required, for example, as a condition of employment in the case of staff performance reviews, or an evaluation in the course of academic or professional training. Other examples include student course evaluations, or data collection for internal or external organizational reports. Such activities do not normally follow the consent procedures outlined in this Policy.

 If data are collected for the purposes of such activities but later proposed for research purposes, it would be considered secondary use of information not originally intended for research, and at that time may require REB review in accordance with this Policy. Refer to [Section D](http://www.ger.ethique.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/#toc05-1d) of [Chapter 5](http://www.ger.ethique.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/ch5_en) for guidance concerning secondary use of identifiable information for research purposes.

1. Additional online resource: [ARECCI Ethics Screening Tool](http://www.aihealthsolutions.ca/arecci/screening/25997/676ffa74aa5604c03daf5523a7152e14) - to determine a project's "primary purpose" (i.e., research or not), "category of risk" and "associated review action".

**Screening Tool Instructions:**

Select the appropriate boxes in the table below, contact the Manager of Research & Innovation if your project falls under category 2 or 3. Provide a brief summary of your project (approximately 250 words or more if needed) including a title by completing the form below. Submit an **electronic copy** and the **mandatory research certifications** to the contact information listed below. If your project falls under category 1 do not complete this form; please complete the appropriate TAHSN application.

|  |  |  |
| --- | --- | --- |
| **Category 1:****RESEARCH** | **Category 2:****CLINICAL AUDIT** | **Category 3:****SERVICE EVALUATION** |
| [ ]  Designed and conducted to generate new knowledge | [ ]  Designed and conducted to provide new knowledge to provide best care | [ ]  Designed and conducted to define current care |
| [ ]  Quantitative research - hypothesis based[ ]  Qualitative research - explores themes following established methodology | [ ]  Designed to answer the question: “Does this service reach a predetermined standard?” | [ ]  Designed to answer the question: “What standard does this service achieve?” |
|  | [ ]  Measures against a standard | [ ]  Measures current service without reference to a standard |
| [ ]  May involve a new treatment and/or intention to change practice | [ ]  Doesn’t involve a new treatment | [ ]  Doesn’t involve a new treatment |
| [ ]  May involve additional therapies, samples or investigations / focus groups, surveys, interview | [ ]  Involves no more than administration of questionnaire or record analysis | [ ]  Involves no more than administration of simple interview, questionnaire or record analysis |
| [ ]  May involve allocation to treatment groups NOT chosen by HCP or patient | [ ]  Does not involve allocation to treatment groups: the HCP and patients choose treatment | [ ]  Does not involve allocation to treatment groups: the HCP and patients choose treatment |
| [ ]  May involve randomization | [ ]  Does NOT involve randomization | [ ]  Does NOT involve randomization |
| **ALTHOUGH ANY OF THESE THREE MAY RAISE ETHICAL ISSUES** |
| [ ]  RESEARCH REQUIRES REB REVIEW TAHSN Application Required | [ ]  CLINICAL AUDIT DOES NOT REQUIRE REB REVIEW | [ ]  SERVICE EVALUATION DOES NOT REQUIRE REB REVIEW |

**Demographics:**

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| **MGH Supervisor / MGH Principal Investigator:** *(Must be MGH affiliated; cannot be a resident or student)* |
| Title:       | Name:       | Role:       |
| Mailing Address:       |
| Email:       | Phone Number:       |
| **Co-Investigator(s):** *(If applicable)* |
| Name:       | Email:       |
| Name:       | Email:       |
| Name:       | Email:       |
| **Resident(s):** *(If applicable)* |
| Name:       | Email:       | Academic Institution:       | Program and Year:       |
| Name:       | Email:       | Academic Institution:       | Program and Year:       |
| **Student(s):** *(If applicable)* |
| Name:       | Email:       | Academic Institution:       | Program:       |
| Name:       | Email:       | Academic Institution:       | Program:       |
| **Other; please identify:** |
| Name:       | Email:       |
| Name:       | Email:       |

**Department Impact:** *(If applicable)*

|  |  |  |
| --- | --- | --- |
| **Department** | **Manager/Director** | **Signature** |
|       |       |  |
|       |       |  |
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**Project Information**

**Project Title:**

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|  |

**Project Summary:**

(*Please include enough detail for the REB to make an informed decision, approximately 250 words or more if needed)*

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|  |

**Please attach**:

[ ]  Survey

[ ]  Data collection forms

[ ]  Other, specify:

All documentation being used for this project should be included with this submission. If any of these items are still in development, please indicate this at the end of your project summary including the reason.

You are reminded that when sharing the results of this project, such as in a poster or publication, that you do so within the framework of, for example, quality improvement rather than research. That is, you must specify that any conclusions or learnings were not gained through research (for wide external application) but through a project carried out in the local context.

**Required Certifications:**

The following research certifications are **mandatory** for all team members:

|  |
| --- |
| [ ]  Tri-Council Policy Statement 2 (TCPS 2) Tutorial Certificate(s) **for each team member**[ ]  Privacy Training for Research Personnel Module Certificate(s) **for each team member** |

**Signature:**

As the **MGH Supervisor / MGH Principal Investigator** for this project, my signature testifies that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant hospital, provincial and national policies and regulations that govern research involving human participants. Any deviation from the project as originally approved will be submitted to the Research Ethics Board for approval prior to its implementation.

Supervisor/Principal Investigator: Date:

**Submission Instructions:**

Please submit a fully completed and **signed** electronic copy of this document including the **required research certifications** to the email address below. Please use the subject line "Clinical Audit" or "Service Evaluation" based on your category selections.

**Contact Information:**

Research Ethics Board – Email: ResearchEthicsBoard@tehn.ca