A Project Categorization Decision Tree
(QA/QI/PE vs. Research)

1. Will the project involve testing an experimental drug, device (including medical software or assays) or biologic?
   - NO
   - YES: REB review is required to address Health Canada requirements. Submit application via IRISS

2. Has the project received funding to be conducted as a human participants research study?
   - NO
   - YES: REB review is required. Submit application via IRISS

3. Is this a multi-site project (e.g., there is a coordinating or lead center, more than one site participating, and/or a study-wide protocol)?
   - NO
   - YES: REB review is required. Submit application via IRISS

4. Will the project occur regardless of whether individuals conducting it may benefit professionally from it?
   - NO
   - YES: The project is most likely research. Contact the CHREB’s Office for guidance.

5. Will the results of the project be published, presented or disseminated outside of the institution conducting it?
   - NO
   - YES: REB review is required. Submit application via IRISS. Access the CHREB’s website for guidance.

6. Is this a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g., testing a hypothesis; randomization of participants; comparison of case vs. control; observational research; comparative effectiveness research; or comparable criteria in alternative research paradigms)?
   - NO
   - YES: The project is most likely research. Contact the CHREB’s Office for guidance.

7. Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program?
   - NO
   - YES: This project appears to constitute QI and/or Program Evaluation and doesn’t fit the TCPS2 definition of research. REB review likely not required, please confirm exemption status with the CHREB. Ensure that all those associated with the project are aware that it is ongoing.

   - NO
   - YES: This project appears to constitute QI and/or Program Evaluation and doesn’t fit the federal definition of research. REB review likely not required, please confirm exemption status with the CHREB. Ensure that all those associated with the project are aware that it is ongoing.

   - NO
   - YES: In future publications/presentations, it is recommended you refer to this as QI/program evaluation and not as research.

Note: If you feel your project meets the definition of a QI and/or Program Evaluation program, please confirm it is exempt from CHREB review prior to starting your project. CHREB approval cannot be granted retrospectively.