

## Determining Whether a Study is Research or Qualifies for Exemption under TCPS2

### BACKGROUND & DEFINITIONS:

The purpose of this Checklist is to aid researchers, physicians, staff and students to help determine if their study is research or would qualify for exemption under TCPS2. Studies at Bruyère Health/Bruyère Health Research Institute that qualify as research must be reviewed and approved by the Bruyère Health REB. However, TCPS2 specifically exempts studies that meet the criteria for exemption as defined below. For these types of studies, an exemption application must be submitted via Cayuse Human Ethics.

**Please note:** The Bruyère Health REB has the final authority to determine whether a study qualifies for exemption under TCPS2.

**Research Definition (TCPS2 Article 2):** An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. The term “disciplined inquiry” refers to an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community.

#### **Exempt from REB Review (TCPS2 Article 2):**

- Quality assurance and quality improvement studies [QA and QI, program evaluation [PE] activities and performance reviews, or testing within normal educational requirements [curriculum development or evaluation], when used exclusively for assessment, management or improvement purposes.
- Observation of people in public places where:
  - a) it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
  - b) individuals or groups targeted for observation have no reasonable expectation of privacy; and
  - c) any dissemination of research results does not allow identification of specific individuals.
- Research relies exclusively on information that is:
  - a) publicly available through a mechanism set out by legislation or regulation and that is protected by law; or
  - b) in the public domain and the individuals to whom the information refers have no reasonable expectation of privacy.
- Research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.
- Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

**TCPS2 CHARACTERISTICS OF RESEARCH AND QI/QA/PE STUDIES**

|                                      | <b>Research</b>   | <b>QI/QA/PE</b>   |
|--------------------------------------|---|---|
| <b>Intent of Study</b>               | To answer a question or test a hypothesis with the intention of contributing to generalizable knowledge.  | Intent of study is to improve a practice or process within a particular institution, or specified group of institutions, or ensure it conforms to expected norms.   |
| <b>Design</b>                        | Designed to develop or contribute to generalizable knowledge; may involve randomization of individuals to different treatments, regimens, or processes; or novel research ideas supported by literature search.   | Not designed primarily to develop or contribute to generalizable knowledge; generally does not involve randomization to different practices or processes.   |
| <b>Mandate</b>                       | Activities generally not specifically mandated by the institution or program.   | Activities mandated by the institution or clinic as part of its operations.   |
| <b>Population</b>                    | Usually involves a subset of individuals and specific sample size. Universal participation is not expected; generally, statistical justification for sample size is used to ensure significant endpoints can be met.  | Information on all or most receiving a particular treatment or undergoing a particular practice or process expected to be included; exclusion of information from some individuals may significantly affect conclusions.  |
| <b>Effect on Program or Practice</b> | Findings of the study are generally not expected to directly or immediately affect institutional or programmatic practice.  | Findings of the study are expected to directly affect institutional practice and identify corrective action(s) needed.  |
| <b>Benefits</b>                      | Participants may or may not benefit directly. A benefit, if any, to individuals may be incidental or delayed.   | Participants continuing to use tested services are expected to benefit directly from changes or refinements to the services.  |
| <b>Adoption of Results</b>           | Dissemination of results may require more time.   | Dissemination of results may occur rapidly and are intended to be adopted into institutional program(s).  |
| <b>End Point</b>                     | Answer a research question, and/or invite critical appraisal of that conclusion by peers through presentation.  | Improve a program, process, or service; implement, monitor and sustain program improvement.   |
| <b>Publication/Presentation</b>      | Intent to publish or present is generally presumed at the outset of study as part of professional expectations, and/or obligations; and usually occurs in research/scientific publications, grant proposals, or other research/scientific forum. Results are expected to contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies. | Intent to publish or present generally not presumed at the outset of the study; dissemination of information often does not occur beyond the institution evaluated, but may occur in quality improvement publications/forums. When published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge. |

**PART 1 – “Yes” answers tend to indicate Research and not QI/QA/PE or other conditions for exemption**

|  |                                     |                                    |
|--|-------------------------------------|------------------------------------|
| 1. Is the study being presented to the public, colleagues, the institution, your department or others (including students) as a “research” study: that is, do you consider the study research? | <b>Yes</b> <input type="checkbox"/> | <b>No</b> <input type="checkbox"/> |
|--|-------------------------------------|------------------------------------|

|   |                              |                             |
|---|------------------------------|-----------------------------|
| 2. Is the study funded by (or being submitted to) a grant/award competition from a funding agency that <u>requires</u> research ethics review?  | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3. Does the study involve randomization to compare interventions with participants, or use other sampling techniques to divide participants into different groups?  | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 4. Does it involve a control group for whom the procedure or therapy or study intervention is withheld to allow an assessment of its efficacy?  | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 5. Does the study intend either to test a novel intervention, drug, device, treatment or program, or test hypotheses about issues that are of broad interest, or beyond the knowledge of current science? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 6. Does the study involve a prospective evaluation of drug, procedure or device not currently approved by Health Canada?  | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 7. Is the study exploring a previously unknown phenomenon with a marketed or approved product (i.e. off-label use of a drug/device)?  | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 8. Is the study design and methodology rigorous enough to support statistical generalizations beyond the particular population that will participate in the study?  | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 9. Will your study be blinding caregivers to any element of care?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 10. Is there a national or provincial registry/database from which a hypothesis will be tested?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 11. Is the study designed to support generalizations that go beyond the particular population the sample is being drawn from?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 12. Is the <b>primary</b> purpose of the study to produce the kind of results that could be published in a <u>research</u> journal?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

**PART 2 – “No” Answers tend to indicate Research and not QI/QA/PE**

|  |                              |                             |
|--|------------------------------|-----------------------------|
| 1. Is the study intended <b>primarily</b> to develop a better practice within your organization and/or affiliated organizations? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. Is the current study part of a continuous process of gathering or monitoring data within an organization?                     | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3. Would this study still be done at your site even if the results might not be applicable anywhere else?                        | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

**Still have questions?**

**Please contact the REB office:**

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