

Principles to Determine Exemptions from Research Ethics Review

Preamble

According to the Tri-Council Policy Statement (TCPS), the mandate of a Research Ethics Board (REB) is to provide **Research Ethics Review (RER)** for all **research involving human subjects**, as defined in Article 1.1. It is not within the mandate of the REB to review research activities outside of this definition. Items c) and d) of this article give some guidance as to the types of activities which may be **exempt**: research based on publicly available data or individuals in the public arena, research-like activities that fall into the areas of quality assurance or performance reviews and non-research activities such as testing within normal educational requirements.

Even with these instructions, in many instances it is still difficult to determine which activities do not constitute **research involving human subjects**, and therefore do not require RER. Therefore, the purpose of this document is to provide guidance to facilitate the determination of whether an activity, possessing qualities of research, requires RER or may be exempt. Both principles must be taken into consideration when making this determination.

Principles

1. Intention/purpose of the activity and how the data shall be used

The current definition of research, according to TCPS is the involvement of a “systematic investigation to establish facts, principles or generalizable knowledge”. Many researchers and reviewers alike disagree with this narrow definition, preferring to expand the definition of research to include more encompassing statements:

- Traditional or emergent methodologies and techniques that are accepted as characteristic of the specific discipline; and
- Contribution or addition to a body of knowledge, or obtaining or confirming knowledge, which includes the expectation that the knowledge will be disseminated. (ProGroup 2005)

From either definition, some activities can quickly be ruled out as not involving research. However, for many others, making a firm determination is somewhat unrealistic, as the activities possess attributes common with research. They may:

- Employ or include research tools, methods and data collections practices.
- Be funded by the same agencies as research, and undertaken by persons or organizations that are primarily concerned with research.

In such situations, it may be more useful to evaluate the **intention or purpose** of the activity, and how data will be used in order to determine whether or not it requires RER. Although not perfect, the following **exemption categories** may be useful:

Quality Assurance, Performance Review: Activities that are inherent in the mandate of an organization or are required by law. The primary intent of conducting these types of activities is to assess how the organization/department/program's is doing, to better serve its clients/students. Typically, final reports remain internal to the organization. However, findings may be relevant to other stakeholders (e.g. similar organizations, departments or programs).

Reflective Practice / Professional Development: Reflective Practice has been defined as “Examining one’s situation, behavior, practices, effectiveness, and accomplishments by asking: What am I doing and why? The self-evaluation that follows involves active, persistent, and careful consideration, speculation, and contemplation of the practitioner's beliefs and knowledge and leads to professional development, growth, and greater understanding of self and the profession.”¹ Reflective Practice / Professional development may involve research-like activities where others (e.g. students, colleagues and supervisors) are engaged in order to solicit information that can be used for self-evaluation and growth, provided no information about these other individuals is made public or identifiable.

Standard Professional Practice*: Research-like activities that take place within acceptable standard practice of the respective profession. Typically, professional ethics codes cover these activities. An example of such an activity is evaluating the benefits of a change in teaching method in the professional setting, where the change is recognized within standard practice. The testing of activities that are novel, or used differently than is accepted as part of standard professional practice, or is conducted outside of the professional setting is research.

(*Not including those defined as research)

2. Does it Involve Human Subjects?

In many cases, this question is easy to answer: a literature review obviously does not involve human subjects, a clinical trial does. However, in other situations, human beings may be engaged with a research project, but their role may not be that of a research participant or subject, and therefore the research may not require RER. They may serve as collaborators, or members of the research team or steering committee. Human data may be used for secondary analysis, which is aggregated and anonymous. Students in a class may be asked for feedback to enable their teacher to reflect on his/her professional practice.

Determining whether or not the type of relationship is that of researcher – subject/participant is key to understanding whether the research does involve human subjects, and thereby requires RER. Professional courtesy and professional ethics should not be confused with the requirement for RER.

¹ Valverde, L (1982). The self-evolving supervisor. In T. Sergiovanni (Ed) Supervision of teaching (p 81 - 89). Alexandria: Association for Supervision and Curriculum Development.

Process

1. Development of Divisional Guidelines

The Delegated Ethics Review Committees (DERC) and departments/divisions should work together with the Ethics Review Office to develop *a priori* guidelines for activities that may be exempt from RER. Such guidelines will assist researchers in differentiating between activities that require REB review and those that do not. Guidelines will facilitate consistency and reduce *ad hoc* decision-making on the part of the REBs.

2. Evaluation of Exemption Requests

The ERO will develop an evaluation form to determine whether an activity may be **exempt** from RER. If the determination is that indeed the activity is exempt from RER, this form should be submitted to the respective DERC or the ERO (for departments not affiliated with a DERC). It is within the jurisdiction of the DERC or ERO to further investigate if the evaluation seems erroneous. If RER is required, a protocol should be submitted as per normal procedure.

In its Annual Report, the DERC will report to the ERO the number and types of research-like activities that were exempted over the course of the year.

Although an activity may be exempt from RER, it is expected that it is conducted ethically and professionally. This may require oversight by the department and/or consultation with ethics codes or experts.