
**Proportionate Approach to
Research Ethics Review in the TCPS:
Towards a Revised Definition of Research in the TCPS**

Prepared by the

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January 2008



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1. Purpose of this Document

In response to the identified need to address the definition of research in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS), ProGroup¹, a working committee of the Interagency Advisory Panel on Research Ethics (PRE), undertook a public consultation² (Dec 05 to March 06) on a discussion paper that included the specific area. The intent of the December 2005 discussion paper had not been to provide an actual revised definition of research but to introduce optional definitions for consideration of the research ethics community. While the feedback received in response to the first consultation was valuable, it suggested that another round of consultation would be needed and that as part of this, proposed wording of alternate definitions would be needed. Moreover, concerns were expressed about how wording changes might subsequently be interpreted and used. Historically, other groups have debated this issue for over two decades. The results of the ProGroup consultation has proven that establishing a definition of research that is inclusive of all disciplines is a complicated issue that requires time and reflection. This paper offers an alternative definition of research taking into consideration the feedback received from the 2005-06 public consultation, and subsequent discussions with PRE and its working committees.

2. Introduction

The December 2005 discussion paper addressed a number of issues relating to proportionate ethics review including the definition of research, risk, vulnerability and delegated ethics review. The discussion paper proposed an expansion of the definition of research, from sole reliance on “accepted scientific methods” and “generalizable” to more inclusive statements that would include the following elements:

- traditional or emergent techniques and research methodologies 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.

The paper also recognized the need to supplement the definition of research by providing supporting commentary and guidance in the TCPS that is discipline-specific.

The public consultation elicited responses from a wide spectrum of TCPS stakeholders including universities, hospitals, government, industry, granting agencies, researchers, research ethics boards, special interest groups and individuals. The following paper incorporates feedback on, and recommendations for wording changes to, the definition of research from the initial consultation.

¹ ProGroup was created by PRE in 2003 to provide advice about priorities, methods and mechanisms for identifying gaps and procedural and definitional issues within the TCPS, and to coordinate a response to those issues.

² http://www.pre.ethics.gc.ca/english/workgroups/progroup/Consultation_instructions.cfm

3. Revising the TCPS Definition of Research Based on Feedback

Most contemporary definitions of research include two key components;

- information is collected by means of systematic investigation, and
- information collected will develop or contribute to generalizable knowledge.

The current TCPS definition of research is consistent with this and provides a definition of research as:

“an undertaking which involves a systematic investigation to establish facts, principles, or generalizable knowledge.”

However, rather than clarify what is meant by “research,” these elements provide additional challenges. The term “*systematic investigation*” is both limited and limiting, because it suggests a lack of recognition of other research methods and of new and emergent techniques. The absence of recognition of other methods risks the marginalization of disciplines that utilize those methods by REBs that believe they must rely on and adhere to rigid and historic definitions of research.

Similarly, the terms “*generalizability*” and “*generalizable*” more often have utility and meaning in research that is hypothesis-driven and uses a traditional statistical perspective. These terms may not be sufficiently flexible when transferred to a broader context that includes humanities and social sciences activities in which research does not necessarily rely on hypothesis testing. Moreover, the terms may not be a good fit for activities and methods that use the data collected to inform or direct changes in policy or professional practice (for example, program evaluation, participatory action research), or to test a hypothesis or procedure that may eventually lead to further research that may answer a specific question related to an existing body of knowledge (for example, pilot research).

While the comments from the consultation raised valuable considerations and useful suggestions, some contradicted each other. This is likely dependent on the context in which the definition of research is being used by respondents, and the level of comfort with introducing changes to the TCPS. Most respondents indicated that they favoured a change to include/address both, new elements in the definition of research, and the addition of complementary commentary. They also offered a number of suggestions for alternate wording or processes.

Those supportive of the recommendations for wording changes felt the proposals:

- Added diversity and were more inclusive of all disciplines and methodologies.
- Recognized the difference between definition of research and what requires REB review.
- Maintained a needed distinction between research and quality assurance.
- Opened the door to consideration of a broader focus and more inclusive language.
- Felt that complementary in-depth commentaries were a good way to clarify some of the issue.
- Agreed that consideration of context and intended purpose were important in determining what constitutes research.

Feedback from others indicated they favoured the current definition of research in the TCPS which includes the terms “systematic” and “generalizability”. Their rationale is that a) all research follows a plan although there is a recognition that this may be more structured and formal in certain disciplines than in others (e.g. those that rely on emergent and qualitative

research), and b) the process of being systematic adds to the potential for “generalizability”. Others expressed the opinion that removing “generalizability” from the definition of research may add to the ambiguity of requiring REB review for activities that currently do not require such review (e.g. public health surveillance and quality assurance).

Those favouring a less specific definition feel that the requirement for “systematic” impinges on the ability to be flexible in responding to unique or emerging opportunities, and does not recognize or respect the differences in approaches used across disciplines.

We contend that this is not so. Systematic does not necessarily mean that there is a rigid “must be followed” protocol to get from one phase of the research to another. Rather, it recognizes that all research has an inherent level of planning or focus though it may be at a very broad level.

A consideration of the usual process of research may help in the discussion of establishing a new more inclusive definition of research:

- the stage at which the researcher begins to identify the issues and questions.
- the stage during which the researcher develops hypotheses or research questions.
- the stage during which the researcher gathers information.
- the stage during which the researcher analyzes and integrates information.
- the stage during which the researcher shares information from the research in a formalized way such as publications but may also be informal such as sharing the research findings with the research participants.

It should not be assumed that there is linearity across the process. In the case of research with humans, it is most likely that REB review will be required for the testing component. However, if the inductive component consists of data gathering involving humans, REB review may also be required for that component.

A proposed definition of research should not perpetuate the more traditional statistical perspective of the meaning of “generalizable” (for example, sufficient representation of a sample so that the results can be applied more broadly to a population). This paper presents a broader interpretation involving various paradigms that all seek to develop knowledge that informs humanity beyond the specific situation in which the work was conducted. For example, interviewing a group of first-time mothers about their experiences during a time of crisis can expand our understanding of what it is to be human.

It is generally accepted that research in the broadest terms involves purposeful action to extend knowledge. This discussion paper proposes a revised definition of research that is more encompassing through the inclusion of the following elements and wording:

- the act of extending knowledge by obtaining or confirming information,
- traditional or emergent techniques and methodologies that are relevant to the discipline(s), which are characterized as “inquiry”.

Therefore, the following revised definition of research is proposed:

“Research is an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.”

4. Deciding What Research Involving Humans Requires REB Review

At times there is disagreement between REBs and researchers, as well as among REBs, about which research involving humans should undergo research ethics review.

The TCPS provides some guidance on this matter:

- Article 1.1 (a) “All research that involves living human subjects”
- Article 1.1 (b) “Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses”
- Article 1.1 (c) “Research about a living individual involved in the public arena, or about an artist...if the subject is approached directly for interview or for access to private papers...”
- Article 2.3 “... research involving naturalistic observation...” with some exceptions outlined in the same article.
- Article 3.1 “...interviews a human subject to secure identifiable personal information...”
- Article 3.2 “...obtaining identifiable personal information about subject...”
- Article 3.3 “If identifying information is involved...secondary uses of data...”
- Article 3.6 “The implications of approved data linkage in which research subjects may be identifiable...”

However, the TCPS does not provide sufficient guidance on how to make effective and accurate determinations about which research activities should be reviewed by an REB.

The boundary between investigations or data-gathering activities with humans requiring research ethics review and those which do not is becoming increasingly difficult to distinguish because they both:

- may employ or include similar research tools, methods and data collection practices.
- may be funded by agencies that traditionally fund research.
- may be undertaken by persons or organizations primarily concerned with research.
- may be of interest to the broader community, and are published in journals or are presented at conferences.

However, it is impractical and unrealistic to expect that all investigative or data-gathering activities involving humans should be subject to review by an REB simply because they pose ethical issues and use methods that are similar to research activities whose purpose would dictate that REB review was required.

This report recommends that a determination of the intended **purpose** of the activity, as distinct from the use of potentially similar methods (for example, interviews or surveys) is the key for differentiating the activities that require review by an REB and those that do not.

A priori guidelines based on specific examples should be appended to the TCPS to assist REBs and researchers in differentiating between activities that require REB review and those that do not. This would begin to reduce ad hoc decision-making on the part of REBs. However, it must be recognized that no ‘list’ in the TCPS will ever cover all contingencies. For this reason, we recommend REBs and researchers work together to develop a consensus on what requirements for ethics review would apply to unique local situations.

The following are some examples of activities that would not require ethics review by an REB but may, nevertheless, raise ethical issues that would benefit from careful consideration outside of the REB. Such issues include, for example, the potential for real or perceived coercion in certain quality assurance activities and the potential for stigmatization of individuals or communities by unrestrained secondary use of data even when individual identities have been anonymized.

- Scholarship based on personal reflections and self-study where no one other than the researcher is involved in the research (e.g., autoethnography).
- Occasions when individuals other than the researcher provide information, but are not themselves the focus of the research e.g.,
 - data collection about organizations, policies, procedures, professional practices, statistical reports (e.g., individuals are asked to provide information about hospital policies).
 - consultation to frame or develop the research (e.g., a graduate student interviews an agency manager to determine if the data s/he is interested in, can be accessed and how. The information from the interview will inform planning decisions about the research).
- Program evaluation, quality assurance or the review and assessment of the program or service e.g.,
 - student course evaluations;
 - staff performance reviews;
 - website usability testing;
 - discussion with stakeholders and consultants;
 - data collection for internal or external organizational reports.
- Public health surveillance.
- Secondary use of previously collected data where identifying information is not included.
- Analysis or scrutiny of material in the public domain
 - studies of people's writings that appear in the public domain (e.g., letters to the editors of newspapers; postings to public websites);
 - studies of public figures (e.g., politicians; celebrities) e.g., based on material such as interviews with a journalist or broadcast on television; biographical profiles based on materials in a public archive.
- Student assignments, considered to be minimal risk which teach about the design, conduct and process of research and might involve 'practice' data collection from or about a few students within their class.