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WHAT RESEARCH REQUIRES ETHICS REVIEW?

BASIC PRINCIPLE

All research involving human participants requires ethics review, including (TCPS¹ Art. 2.1):

- **Living human participants**
- **Human biological materials**, including materials obtained from living and deceased individuals

Research: an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation

*Disciplined inquiry*²: 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

Human participant: those individuals whose data or responses to interventions, stimuli or questions by the researcher or biological materials are relevant to answering the research question

Biological materials: includes tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva, and other bodily fluids. Also includes: materials related to human reproduction, including embryos, fetuses, fetal tissues, and human reproductive materials, as well as stem cells

SPECIFIC INCLUSIONS

The following require ethics review:

- **Data linkage** (TCPS Art. 5.7): The merging or analysis of two or more separate data sets (e.g. health information and education information about the same individuals) for research purposes (TCPS Glossary).
- **Secondary use** of identifiable information (TCPS Art. 5.5), and of and human biological material identifiable as originating from **Aboriginal communities or peoples** (TCPS Art. 9.20)
- **Data linkage** where there is a reasonable prospect that this could generate information identifiable as originating from a specific **Aboriginal community or a segment of the Aboriginal community at large** (TCPS Art. 9.22)

Secondary use: The use in research of information or human biological materials originally collected for a purpose other than the current research purpose (TCPS Glossary)

¹ Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010. See www.pre.ethics.gc.ca.

² <http://pre.ethics.gc.ca/eng/policy-politique/interpretations/scope-portee/>

EXCEPTIONS / EXEMPTIONS

Individuals who are **authorized to release information** or data in the ordinary course of their employment about organizations, policies, procedures, professional practices or statistical reports are not considered to be participants (TCPS Art. 2.1).

Research based on exclusively on **publicly available material** does not require ethics review if the information is (TCPS Art.2.2):

- Legally accessible to the public and appropriately protected by law; or
- Publicly accessible and there is no reasonable expectation of privacy

Research involving **observation of people in public places**, does not require ethics review if there is (TCPS Art. 2.3):

- No intervention staged by the researcher or direct interaction
- No reasonable expectation of privacy, and
- No potential for identification of specific individuals when the research results are disseminated

Research that relies on secondary use of **anonymous information** does not require ethics review so long as it does not generate identifiable information (TCPS Art. 2.4).

Anonymous information: information that never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low (TCPS Glossary).

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 require ethics review (TCPS Art. 2.5).

Creative practices activities do not require ethics review. However,

- Research that uses creative practice to elicit responses from participants and answer a research question does require ethics review.

Creative practice: a process through which an artist makes or interprets a work or works of art (TCPS Art. 2.6).

The initial exploratory phase of qualitative research (often involving contact with individuals or communities) intended to discuss the feasibility of the research, establish research partnerships, or the design of a research proposal does not require ethics review (TCPS Art. 10.1).

ADDITIONAL NOTES

- The requirement to obtain ethics approval should not be confounded with the requirement to seek informed consent.
- Please consult with the Ethics Unit if you have any doubts about whether your research requires review.