

**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 living and deceased individuals

*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:

* **Secondary use** of **identifiable** and **anonymized** data and human biological material.
* **Data linkage** (TCPS Art. 2.4, 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
* **Data linkage** where there is a reasonable prospect that this could generate identifiable information.
* **Qualitative research** (TCPS Art. 10.1)

*Secondary use:* use for a purpose other than the current research purpose

***Anonymized*:** data was initially collected with identifiers and has since been irrevocably stripped of said direct identifiers.

**General Rule**

**When in doubt, please always flag ethics as a requirement and we’ll clarify with the researcher.**

# Exceptions and 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 if (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

**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.

**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*.*

**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.