

Ethical Considerations for the Use and Secondary Use of Human Biological Materials and Human Information for Research Purposes



1. What are human biological materials?

- ✓ Human biological materials, as defined by the [TCPS 2 2018](#), includes tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells (including pluripotent stem cells), hair, nail clippings, urine, saliva, other body fluids, embryos, fetuses, fetal tissue, and reproductive materials from a living or deceased human. Please see [Glossary of Terms](#) for additional definitions.

2. When is Research Ethics Board (REB) review required for the collection and use of human information and/or biological materials?

- ✓ All research involving collection and use of human information or biological materials requires REB review. [TCPS 2 2018 Chapter 2](#) outlines very specific situations that do not require REB review including:
 - ❖ Research that relies exclusively on publicly available information does not require REB review when:
 - (a) the information is legally accessible to the public and appropriately protected by law; or
 - (b) the information is publicly accessible and there is no reasonable expectation of privacy.
 - ❖ Research involving the 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 that relies exclusively on **secondary use of Anonymous human information or biological materials**, and so long as the process of data linkage or recording or dissemination of results **does not generate identifiable information**.
 - ❖ Non-research activities such as 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. These do not constitute research for the purposes of the TCPS 2 2018 and do not fall within the scope of REB review.

3. What about secondary use of human information or biological materials?

- ✓ Research involving secondary use of information or biological materials **does require** REB review. Depending on the circumstance, it **may not require consent** of the participant, but justification will need to be provided to the REB.
 - ❖ TCPS 2 2018 [Article 5.3](#) (Information) and [Article 12.3A](#) (Biologicals) provides a list of conditions that researchers must meet for secondary use of **identifiable human information/biological materials without having to seek consent from participants for secondary use**:
 - identifiable information is essential to the research;
 - the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
 - the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
 - the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
 - it is impossible or impracticable ([see Glossary](#)) to seek consent from individuals to whom the information relates; and
 - the researchers have obtained any other necessary permission for secondary use of information for research purposes.

4. TCPS 2 2018 [Article 5.5B](#) (Information) and [Article 12.3B](#) (Biologicals) indicates that researchers shall seek REB review, but are **not required to seek participant consent**, for research that relies exclusively on the secondary use of **non-identifiable human information or biological materials**. (e.g., the use of coded human biological materials where the researcher never had access to the coding key). What about research involving human biological materials related to human reproduction and pluripotent stem cells?
- ✓ Research involving human biological materials related to human reproduction and pluripotent stem cells requires REB review; however, there are additional guidelines and requirements that must be considered:
 - ❖ [TCPS 2 2018 Article 12.6-12.9](#) outlines research involving materials related to human reproduction. The TCPS 2 2018 recommends that researchers, in addition to TCPS 2 2018, also be aware of the detailed requirements and prohibitions set out in the [Assisted Human Reproduction Act](#) (i.e. research on embryos requires the consent of the gamete donors. The REB may not waive the requirement for such consent).
 - ❖ [TCPS 2 2018 Article 12.10-12.20](#) outlines research involving human pluripotent stem cells. In recognition of the complex ethical issues associated with pluripotent stem cells, a **Stem Cell Oversight Committee (SCOC)** was created. **The SCOC reviews research involving human pluripotent stem cells that have been derived from an embryonic source; and/or will be transferred into humans or non-human animals.** Applications that receive SCOC approval should then be submitted to local REBs for ethics review. Please see the [SCOC website](#) for additional information and application instructions.
5. **Is REB review of research involving the use of non-identifiable, ethically-sourced human cells necessary?**
- ✓ The TCPS 2 2018 [Article 12.3B](#) (Biologicals) indicates that researchers must seek REB review, but are **not required to seek participant consent**, for research that relies exclusively on the secondary use of **non-identifiable human information or biological materials**.
 - ✓ The Panel on Research Ethics (PRE) [consulted the public](#) regarding providing an exemption for REB review when cells or cell lines are non-identifiable and have ethical provenance from October 2017 to January 2018. The public supported simplifying the review process, but expressed concerns about the ethical and practical basis for the proposed exemption. PRE therefore decided to reassess the proposed exemption and consider alternate approaches to ensuring the ethical acceptability of research involving human cells. [Response from PRE September 2018](#).
 - ✓ The HSREB does acknowledge there is currently no exemption from REB review when using cells or cell lines that are non-identifiable and have ethical provenance per the TCPS 2 2018. However, until PRE finishes their investigation into alternate approaches for ensuring the ethically acceptability of this type of research, the HSREB **will not mandate ethics review** for research solely involving cells or cell lines that are non-identifiable and have ethical provenance.
 - ✓ For additional guidance on the use of human cells or cell lines in research please see the publication '[Guidelines for the use of cells lines in biomedical research](#)' (Geraghty R.J. et al., 2014). While this guidance is based upon the United Kingdom laws, regulations & guidelines, this publication includes principles of good practice for research using human cells and cell lines that are applicable in Canada.
6. **What is the difference between 'anonymous' and 'non-identifiable' information as defined in TCPS 2 2018?**
- ✓ PRE has stated that 'Anonymous information' and 'non-identifiable information' have different definitions for the purposes of the TCPS 2 2018. Anonymous information is "information [that] never had identifiers associated with it ... and the risk of identification of individuals is low or very low" ([Section A, Chapter 5](#)). TCPS 2 2018 defines information as non-identifiable "if it does not identify an individual, for all practical purposes, when used alone or combined with other available information ... An important distinction between the two definitions is that 'anonymous' is a type of information that does not change relative to a specific research project, while the assessment of whether information is 'non-identifiable' may differ depending on the context of a specific research project. In general, research that relies exclusively on secondary use of anonymous information is exempt from REB review ([Article 2.4](#)). Research that relies exclusively on secondary use of non-identifiable information generally requires REB review. However, consent is not required for this type of research ([Article 5.5B](#)).

7. What if the collection or use of the human information or biological materials is occurring at Kingston Health Sciences Centre or Providence Care Centre?

- ✓ All research that will be occurring in an affiliated hospital setting or using hospital resources requires that the Principal Investigator submit a [TRAQ DSS](#) to receive hospital approval. Please see [Hospital-Based Research Frequently Asked Questions](#) and [Tips for Completing the TRAQ DSS Form for Hospital-Based Research](#) for additional details and requirements.
- ✓ **Opt-out research policy:** The affiliated hospitals display a privacy poster in various areas of the hospital (e.g., outpatient clinic areas, emergency/urgent care areas) that informs patients they have a right to opt out of research. Patients must withdraw their consent in writing through the Opt-Out form (not retroactive). To verify consent for research purposes has not been withdrawn within PCS Clinical Desktop, researchers, research staff, students and trainees can follow the steps outlined in the research Roadmap titled, '[Accessing Patient Data for Research](#)'.
- ✓ **If a patient has opted out of research, this would also override the collection of discarded biological samples, as described in the KHSC pre-surgical consent form.** The surgery team must verify in the patient chart, prior to pre-surgical consent, if a patient has opted out of research. If the patient has opted out of research, the section within the pre-surgical consent form regarding consent to research should be struck out.

Additional Information

Please be aware that you will be required to follow all other applicable laws & regulations, Queen's University policies, as well as any involved Affiliated Hospital policies for research involving the collection, use and transfer of human information and biological materials. **When in doubt about the ethics requirement for a particular research project, the researcher should contact the [Office of Research Ethics Compliance](#).** The REB makes the final decision on exemption from research ethics review.

Additional Resources

[TCPS 2, 2018: Tri-Council Policy Statement for Ethical Conduct for Research Involving Human](#)

[Queen's University Biosafety](#)

[Kingston General Health Research Institute \(KGHRI\)](#)

[Assisted Human Reproduction Act](#)

[Stem Cell Oversight Committee \(SCOC\)](#)

Geraghty, R.J., Capes-Davis, A., Davis, J.M., Downward, J., Freshney, R.I., Knezevic, I., & ... Vias, M. (2014). [Guidelines for the use of cell lines in biomedical research](#). *British Journal of Cancer*, 111 (6), 1021-1046.

Glossary of Terms

- **Anonymized human information/biological materials:** the information/materials are irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
- **Anonymous human information/biological materials:** the information/materials never had identifiers attached to them and risk of identification of individuals is low or very low.
- **Coded human information/biological materials:** direct identifiers are removed from the information/materials and replaced with a code. Depending on access to the code, it may be possible to re-identify specific individuals (e.g., a principal investigator retains a key that links the coded material with a specific individual if re-linkage is necessary).
- **Directly identifying information or identified human biological materials:** the information/materials are or are labelled with a direct identifier (e.g., name, personal health number). Materials and any associated information are directly traceable back to a specific individual.
- **Embryo:** a human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from such an organism that is used for the purpose of creating a human being.
- **Fetal tissue:** includes membranes, placenta, umbilical cord, amniotic fluid and other tissue that contains genetic information about the fetus.
- **Fetus:** a human organism during the period of its development beginning on the 57th day following fertilization or creation, excluding any time during which its development has been suspended, and ending at birth.
- **Human biological materials** - includes tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells (including pluripotent stem cells), hair, nail clippings, urine, saliva, other body fluids, embryos, fetuses, fetal tissue, and reproductive materials from a living or deceased human
- **Human reproductive materials:** a sperm, ovum or other human cell, or a human gene, and includes a part of any of them.
- **Indirectly identifying information:** information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g. date of birth, place of residence).
- **Impracticable:** Incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience.
- **Non-identifiable human information/biological materials:** the information/materials are either anonymous (never had identifiers), anonymized (key to the identifiers has been destroyed) or the information/material is coded but the information/material recipient/holder does not have access to the key.
- **Research:** 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.
- **Secondary use:** refers to the use in research of human information or biological materials originally collected for a purpose other than the current research purpose.