Western Research

Guidance Document	REB Guidelines on Secondary Use of Information and/or Samples for Research Purposes
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WHAT IS 'SECONDARY USE'?

Some research projects propose to re-use human data or samples that were originally collected for another purpose (e.g., clinical care, or another research study) for a new research project. This is referred to as *secondary use*, where previously collected information or materials are used to address new research questions.

The secondary use of information or samples can be beneficial in research. This may reduce the need for duplicative data or sample collection, thereby minimizing participant burden. It can also support the validation, corroboration or critique of original findings; enable analysis of changes over time; facilitate the application of new methods or testing of novel hypotheses that were not available at the time of original data collection; and help confirm the integrity and authenticity of existing data[I].

WHAT IS A RETROSPECTIVE CHART REVIEW?

A retrospective chart review is a specific type of secondary use study where a researcher proposes to use information that was originally collected for routine medical care and is contained in medical records ('charts') for a research purpose. "Retrospective" means that all of the information researchers need was collected **before the initial submission of the REB application**. To be considered a 'retrospective' study, all data that will be used in the research study must already exist in the medical record at the time of REB submission. If any information used in the research study will be added to the medical record after REB submission, then the research project is not considered 'retrospective' (it is 'prospective').

It is not appropriate for researchers to repeatedly request to extend the date range to avoid consenting participants, or to continue to describe the study as 'retrospective' when it would be more appropriately considered a prospective study. However, the REB recognizes that an unexpected situation could arise where researchers need to extend the date range after the initial REB approval. For example, if the study team needs to access additional information to improve the statistical power, or attain the necessary sample size. <u>One date range extension will be permitted and must be submitted as a formal amendment</u>. The information must still have been collected prior to submission of the amendment. If a waiver of consent is requested, the researchers must explain why the waiver for the extended date range is justified according to TCPS Article 3.7b[II].

WHEN IS REB APPROVAL REQUIRED FOR SECONDARY USE RESEARCH?

Researchers are typically required to obtain REB approval for <u>any</u> secondary use research that involves human participants or samples.

Limited exceptions to the requirement for REB review include:

1. The secondary use of information that is publicly available through a mechanism set out by legislation or regulation and that is protected by law; or in the public domain and the individuals to whom the information refers have no reasonable expectation of privacy, if the conditions outlined in TCPS 2, Article 2.2 are met[III].
2. The research relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information[IV].

Important notes:

- REB review **is required** for the secondary use of anonymized or de-identified/coded information – the exception is specifically limited to anonymous information.
- REB review **is required** for any secondary use of data or materials identifiable as originating from an Indigenous community, Peoples or people is subject to REB review[V].
- REB review **is required** where the researcher seeks data linkage of two or more anonymous sets of information or human biological materials, and there is a reasonable prospect that this could generate identifiable information[IV, VI].

WHAT ARE THE RISKS TO PARTICIPANTS?

There are some ethical considerations to consider when reusing information that has already been collected. For example, the participant's right to privacy and confidentiality should always be respected. Researchers have an obligation to safeguard the information and to not misuse or wrongfully disclose it. This is true for all research studies.

Participant confidentiality must be maintained, and the researcher must ensure appropriate measures are in place to safeguard the information and/or samples for its entire lifecycle. Researchers must take reasonable steps to ensure that the information and/or samples are protected against theft, loss and unauthorized use and disclosure.

WHAT ARE THE OBLIGATIONS OF RESEARCHERS?

Researchers must:

- Follow the approved research plan, including any conditions imposed by the REB. The information and samples can only be used for the purposes approved within the plan.
- Implement the safeguards for protecting information and/or samples that are outlined in the plan. Typically, at a minimum this means:
    - Ensuring that any information and/or samples are de-identified/coded or anonymized, and maintained securely for the lifecycle of the study;
    - Not publishing or sharing information in a way that could reasonably allow others to identify the individuals whose information was used in the research;
    - Only disclosing information if required by law;
    - Not contacting individuals whose information is used in the research unless they have obtained approval to do so from the REB and specific requirements are met.

- Be familiar with the applicable regulations and guidelines and ensure that they have completed any training required by the institution(s)/health information custodian(s)(HIC) holding the information/samples.
- Comply with any additional requirements outlined in the applicable regulations/guidelines or required by the institution(s)/health information custodian(s)(HIC) (including obtaining any other necessary permission for the secondary use for research purposes, if applicable).
- Collect only the information and/or samples necessary to achieve the study objectives, and for which approval has been obtained from Western's REB.
- Only access information and/or samples from the period and source approved by Western's REB;
- Comply with any known preferences previously expressed by individuals about any use of their information and/or sample(s).
- Notify the REB and the applicable Privacy Office if a privacy breach occurs.

It is the Local Principal Investigator's responsibility to ensure all obligations are met, even if specific research activities are conducted by other members of the research team.

WHEN IS INFORMED CONSENT REQUIRED?

The default position is to obtain informed consent from research participants, to preserve their autonomy and respect their rights. **Secondary use studies are not inherently exempt from the requirement to obtain informed consent for research purposes.**

Secondary Use of Identifiable Information

To waive the requirement to obtain informed consent for the secondary use of identifiable information (which includes retrospective chart reviews), the researcher must provide justification to the REB that all of the following conditions have been met:

- That the identifiable information and/or sample is essential to the research[VIII, IX]/That the objectives of the research cannot be accomplished without using the personal health information[X];
- The researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information and/or sample[VIII, IX]/That, at the time the research is conducted, adequate safeguards will be in place to protect the privacy of the individuals whose personal health information is being disclosed and to preserve the confidentiality of the information[X];
- The use of identifiable information and/or sample without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates[VIII, IX];
- The balance between the public interest in conducting the research and the public interest in protecting the privacy of the individuals whose personal health information is being disclosed.[X]
- It is impossible or impracticable to seek consent from individuals to whom the information and or sample relates[VIII, IX]/That obtaining the consent of the individuals whose personal health information is being disclosed would be impractical[X];
- The researchers will comply with any known preferences previously expressed by individuals about any use of their information and/or sample[VIII, IX]; and

- The researchers have obtained any other necessary permission for secondary use of information and/or sample for research purposes[VIII, IX].

Secondary Use of Non-Identifiable Information

Researchers are required to seek REB review, but are not required to seek participant consent, for research that relies exclusively on the secondary use of non-identifiable information[VIII].
Anonymized information and samples are generally considered non-identifiable. De-identified/coded information would only be considered non-identifiable if the researchers do not have access to the study key. The onus is on the researcher to establish to the satisfaction of the REB that, in the context of the proposed research, the information is non-identifiable for all practical purposes.

Seeking Waivers of Consent for Secondary Use of Information[VIII, IX]

If seeking a waiver for secondary use of identifiable or non-identifiable information, researchers should consider the following in providing their rationale:

- **Sample size**. If the sample size is very large, or if members of the group are likely to be deceased, geographically dispersed, or difficult to track.
- **When the individual was last in contact**. Individuals may be difficult to reach if significant time has passed since their last interaction (e.g., participation in a study, receipt of services), whereas more recent participants may be more readily contactable. If there is a lack of an existing or continuing relationship between prospective participants and the data holder who would need to contact them, consent may be impracticable.
- **Previous consent**. When re-using research data, researchers must consider the content of the initial consent process. For example, whether participants were asked about future contact for research, and/or whether the consent restricted or permitted the re-use or sharing of information or samples.
- **The potential impact of re-contact**. Depending on the context of the original data collection or the topic of the research, contact from the research team may cause distress, discomfort, confusion, or other unintended consequences. Researchers should also consider whether attempting to obtain consent could introduce new privacy risks (e.g., by revealing prior participation or sensitive information).
- **Bias**. Researchers should consider whether requiring consent could introduce systematic bias (e.g., differential response rates) that may compromise the validity or integrity of the research.

SECONDARY USE OF INFORMATION OR HUMAN BIOLOGICAL MATERIALS IDENTIFIABLE AS ORIGINATING FROM FIRST NATIONS, INUIT, and/or METIS COMMUNITIES OR PEOPLES[V, VI]

When seeking to undertake research involving secondary use of data identifiable as originating from a specific First Nations, Inuit and/or Métis community or segment of the Indigenous community at large, researchers shall, through community engagement as appropriate, address any potential inadvertent identification of communities, or misuse of traditional knowledge.

Researchers must engage the community from which the data or samples and associated identifiable information originate, prior to starting the research study and prior to submitted to the REB, where:

- secondary use has not been addressed in a research agreement and has not been authorized by the participants in their original individual consent; or
- there is no research agreement; and
- the data are not publicly available or legally accessible.

The conditions for individual participant consent are the same as identified above, i.e., informed consent must be obtained unless certain conditions have been met.

Where research relies only on publicly available information that is protected by law, or on information that is in the public domain with no expectation of privacy as defined in TCPS 2, Article 2.2, community engagement is not required. Where the information can be identified as originating from a specific community or a segment of the Indigenous community at large, seeking culturally informed advice may assist in identifying risks and potential benefits for the source community[XI].

The conditions described above for secondary use apply even when the information and/or samples are already in the researcher's possession.

Researchers who wish to re-use the information or samples in their possession for a new purpose must obtain REB approval before they begin the new study. As described above, informed consent is generally required for this secondary use, unless the conditions have been met for a waiver of consent. Researchers should also consider whether **broad consent**[XII] for future research use was obtained at the time of the original collection. Where broad consent was in place, its scope and any associated limitations (e.g., types of research permitted, governance conditions, or restrictions on sharing) should inform the proposed secondary use[XII].

For researchers planning primary data or sample collection, consideration should be given to whether seeking broad consent for future unspecified research use is appropriate, as this may facilitate ethical secondary use in future studies. In cases where broad consent was not obtained, researchers must address this in their rationale if they plan on seeking a waiver of consent for secondary use [XII].

GLOSSARY[XIII]

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

Anonymized: The information is 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.

De-identified/coded: Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants' code names with their actual names so data can be re-linked if necessary).

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.

Research: An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.

Secondary Use: The use in research of information originally collected for a purpose other than the current research purpose.

REFERENCES

[I] TCPS 2 (2022) Chapter 5, Section D
[II] TCPS2 (2022) Article 3.7b
[III] TCPS2 (2022) Article 2.2
[IV] TCPS 2 (2022) Article 2.4
[V] TCPS 2 (2022) Article 9.20
[VI] TCPS 2 (2022) Article 9.22
[VII] TCPS 2 (2022) Article 5.5B
[VIII] TCPS2 (2022) Article 5.5A
[IX] TCPS2 (2022) Article 12.3A
[X] PHIPA (2004) 44(3)
[XI] TCPS2 (2022) Article 9.21
[XII] TCPS2 (2022) Article 3.13
[XIII] TCPS2 (2022) Glossary