

Guidance Document	Delegated Level 1 – Retrospective Chart and/or Sample Review Studies
Effective Review	HSREB
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OVERVIEW

A Delegated Level 1 retrospective research study intends to utilize information for purposes that are different from that of their origination (i.e., secondary use of information). The intervention of a retrospective study is the action of using information that has been previously collected, for research activities. It is often the case that the information required to support the research investigation was collected during non-research interactions or regular clinical care. In these instances the Health Sciences Research Ethics Board (HSREB) would consider these to be retrospective chart and/or sample review studies.

To be considered a retrospective chart and/or sample review study all required variables, data, samples, and any other information required to complete the study objectives must have already been collected prior to the initial submission of the REB application. If any information will be prospectively acquired a Delegated Level 2 submission is required.

REQUIREMENTS OF CONSENT

The default, to preserve the autonomy of research participants is to obtain consent. Ideally, all participants should be adequately informed of a research study and have provided informed consent. *A retrospective chart and/or sample review study is not inherently exempt from the requirement to obtain consent for research purposes.* However, exceptions may occur and there are occasions where a waiver of consent is acceptable. A research team must justify to the HSREB why they are requesting a waiver of consent in accordance with Tri-Council Policy Statement (TCPS) 2, article 5.5A/B.

DATE EXTENSIONS

A retrospective chart and/or sample review study may extend the approved range of dates only once. This date range extension is permitted as a courtesy if the study team needs to access additional information to either improve the statistical power and/or attain the expected sample size. Beyond the first date change, any further date range extensions will require a new Delegated Level 2 submission for the collection of prospective study data.

NOTE: for any other changes to the REB application (e.g., collection of additional information, data to be transferred, etc.) the study team is required to submit a formal amendment.

REFERENCES

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2018 (TCPS2); Articles 3.7, 5.5, 6.12, 9.19, 12.3;
2. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Parts 46.113, 46.116;
3. US Food and Drug Administration (FDA) CFR Title 21 Part 56.105, 56.110, 56.111.