HREBA | Health Research Ethics Board of Alberta

1500, 10104 - 103 Avenue
Edmonton, Alberta, T5J 0H8

Phone: 780-423-5727
Toll-free: 1-877-423-5727

Information Memo: Secondary Use, Quality Assurance, Quality Improvement, Research, Publication

1. What does the Health Information Act say?

Health Information Act: Part 1 – Introductory Matters

Interpretation: Section 1(1), In this Act,

(f) "***custodian***" means

(ix) a health services provider who is designated in the regulations as a custodian, or who is within a class of health services providers that is designated in the regulations for the purpose of this subclause.

(k) "***health information***" means one or both of the following:

(i) diagnostic, treatment and care information;
(ii) registration information.

(r) "***non-identifying***" when used to describe health information, means that the identity of the individual who is the subject of the information cannot be readily ascertained from the information.

Health Information Regulation

Custodians Designated: Section 2(2)

(2) For the purposes of section 1(1)(f)(ix) of the Act, the following are designated as custodians:

(i) regulated members of the College of Physicians and Surgeons of Alberta

Health Information Act:

Part 4 – Use of Health Information

- Use of non-identifying health information

26 - A custodian may use non-identifying health information for any purpose.

Part 5 – Disclosure of Health Information; Division 3 - Research

- Proposed Research Protocol

49 - A person who intends to conduct research using health information in the custody or under the control of a custodian or health information repository must submit a proposed research protocol to a research ethics board for review by that board containing:

(a) the information specified by the regulations, and
(b) any other information required by the research ethics board.

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2. What does TCPS2 say?

TCPS2 (2022): Chapter 2: Scope and Approach

- Research Exempt from Research Ethics Board Review: Article 2.4

  REB review is not required for research that 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.

- Activities Not Requiring Research Ethics Board Review: Article 2.5

  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 constitute research for the purposes of this Policy, and do not fall within the scope of REB review.

So, the questions here are:

- Is this quality assurance or quality improvement?
- How do the secondary use provisions apply?

Please see the related Application discussion sections in TCPS2 (2022) for more information on the application of these provisions.

Also, for a good discussion of what is involved in these considerations, see the web page prepared by the UofA at: Quality Assurance & Quality Improvements Ethics Review | Research + Innovation (ualberta.ca)

3. Is the new usage consistent with what the participants were told, and what they consented to, in the original ICF?

4. Is there any likelihood that you will wish to publish the results in a journal (especially in a foreign journal)?

- If so, despite all the above, several journals (especially foreign journals) are not prepared to consider the above arguments. Instead, they simply look to find out whether you had REB approval or not.
- If the "research" has already been completed, the REB has no authority to go back and provide retroactive approval.

FINAL ANSWER:

You must be confident that you are onside with all the above elements. If any of them give you concern, the simplest approach may be to submit a research proposal, including requesting a waiver of consent. In "research" such as this, the REB will usually be able to proceed with an expedited review on a delegated basis.