



# Ethics in Research and Evaluation

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# Table of contents

Introduction .....	4
Privacy and confidentiality .....	4
Consent .....	5
Strategies for risk management.....	6
References.....	9

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# Introduction

Conducting research in an ethical way involves:

1. Protecting participants' privacy and confidentiality
2. Collecting voluntary and informed consent from participants
3. Minimizing risk to participants

Most health and social science researchers and evaluators in Canada abide by the 2014 *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* ("TCPS 2").

## Privacy and confidentiality

Privacy is defined by the TCPS 2 (2014) as: "an individual's right to be free from intrusion or interference by others. It is a fundamental right in a free and democratic society. Individuals have privacy interests in relation to their bodies, personal information, expressed thoughts and opinions, personal communications with others, and spaces they occupy" (p. 57).

Privacy risk can happen at all the stages of research and evaluation, including data collection, data analysis, dissemination of results, storage and retention, and disposal of information.

All research participants have a legal right to privacy. Several legal acts protect the public's privacy in Alberta, including:

- The Freedom of Information and Protection of Privacy Act (FOIP Act), which governs public bodies.
- The Personal Information Protection Act (PIPA), which applies to private businesses, non-profit organizations, and professional regulatory organizations.

The ethical duty of confidentiality refers to “the obligation of an individual or organization to safeguard entrusted information” (TCPS 2, p. 58).

Privacy in evaluations is protected through anonymity and confidentiality. This is done by separating participants’ names from their responses and not disclosing their personal information to the public. Names are usually replaced by a code or ID number. It is important to consider that it may still be possible to identify unique people by their responses (for example, a survey in a small community with few visible minorities).

Participants who know that their personal information will be protected are more likely to participate and respond truthfully. Codes of ethics and procedures for protection of privacy and confidentiality can also protect the researcher (for example, demands to release the names of participants).

Under the FOIP Act, the public must be made aware of:

- “the specific legal authority for the collection of information” (who is collecting their information)
- “the specific purposes for which the information will be used”
- “the title, business address and telephone number of an official in the public body who can answer questions about the collection of personal information” (FOIP Guidelines and Practices, 2009, p. 321).

The FOIP Act also specifies:

- “...ensure that the minimum amount of personal information necessary to carry out the program or activity is collected” (p. 320).
- “...collect personal information directly from the individual the information is about except in certain limited circumstances” (p. 320).
- “The personal information in a system or program must be used only for the purpose for which it was collected or for a use consistent with that purpose” (p. 325).
- “There should be documented procedures for collecting, processing, accessing, transmitting, storing, and disposing of personal information” (p. 324).

Note that AHS and the Government of Alberta have policies on the storage of data and file retention schedules.

# Consent

Participants are often required to provide voluntary, **informed consent** prior to participating in any research or evaluation project. In some situations, informed consent is not necessary. For example, an evaluation that uses observation methods in a natural setting. In these cases, a sign that alerts individuals that a study is being conducted may be sufficient. Even then, it is important to provide individuals with information about the study (evaluation purpose, methods, how to opt-out, contact information) in case they would like to know more about it.

Typical statements within a consent form includes:

- Purpose, process, and duration of the project
- Any potential risks to the participant
- Guarantee of anonymity and confidentiality
- Researcher's information and contact information
- Indication that their participation is voluntary and they can withdraw at any time
- Information about any benefits and compensation
- Information about how to access results (Newman, 2010)

Verbal consent is most commonly used in interviews. Signed consent is not usually required, but it is a good idea to get it if:

- Your participant is a minor (you would get parental consent with the minor's assent)
- Your participant has a cognitive disability
- The information you are collecting is highly sensitive (Wilder Research, 2009)

Evaluators need to be aware of potential issues when collecting consent, such as:

- Difficulties with language or literacy
- Cognitive disabilities
- Indirect coercion (e.g., children, students, employees, funding recipients) (Newman, 2010)

If you are unsure if the participants are informed, explain everything in plain language and ask the participant to explain it back to you.

# Strategies for risk management

Evaluators are legally and ethically responsible to minimize the risk of harm to participants. In addition to following ethical guidelines and legislation, you can manage risk in other common ways.

## *Threat and risk assessments*

These assessments identify potential risks, the likelihood of them occurring, and the seriousness of the consequences. You can then determine strategies for mitigating identified risks.

Since it is usually not possible to remove all forms of threat and risk, be prepared to address residual risk and potential consequences.

## *Privacy Impact Assessment (PIA)*

PIAs are a way to ensure compliance with the FOIP Act and consider broader privacy implications. According to FOIP Guidelines and Practices (2009):

- “The PIA is an exercise in which the public body identifies and addresses privacy risks that may arise in the course of its operations” (p. 328).
- “A PIA provides documented assurance to the public body, to the Information and Privacy Commissioner and to the public that all privacy issues related to the initiative have been appropriately identified and addressed” (p. 328)
- “Privacy impact assessments are not mandatory under the *FOIP Act* but are recommended for major projects that involve the collection, use or disclosure of personal information” (p. 329).

## **Alberta Research Ethics Community Consensus Initiative (ARECCI) tools**

ARECCI has developed two ethics decision-support tools to help leaders and organizations with their projects:

- *ARECCI Ethics Guidelines Tool*
- *ARECCI Ethics Screening Tool*

Whether a project is evaluation, quality improvement (QI), quality assurance (QA), or research, these decision-support tools will help you incorporate ethical considerations in your project and determine the appropriate ethics review.

These tools should be used to determine the types of ethical risks in the project *before* going to a research ethics board. The ARECCI Screening Tool will produce a score indicating the category of risk for participants and whether the project requires Research

Ethics Board (REB) review (for example, if the project is clearly research and not QI or evaluation).

### *Research Ethics Board (REB) review*

Research projects that involve human participants or their health information must be reviewed by a Research Ethics Board (REB). The REB will review a research proposal to ensure the project has no or minimal risk to participants by following ethical guidelines, including sound methodology, and making sure that researchers have the skills and resources to undertake the proposed research.

According to the TCPS 2 (2014), “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” (p. 18). However, if the collected data is later proposed for research purposes, it is considered secondary use of information not originally intended for research, and may require REB review at that time (TCPS 2, 2014).

There are three designated REBs in the province:

- Health Research Ethics Board of Alberta (HREBA) is a provincial ethics board that oversees the following three committees:
  - HREBA – Cancer Committee (CC): Reviews all new protocols and annual renewals involving adult human subjects and/or research requiring access to personal information submitted by cancer researchers throughout Alberta.
  - HREBA – Community Health Committee (CHC): A multi-disciplinary committee with members from both rural and urban Alberta that provides scientific and ethical review of proposed health research in communities across the province.
  - HREBA – Clinical Trials Committee (CTC): Provides scientific and ethical review of research proposals submitted by registered Alberta physicians who are conducting research involving human subjects.
- University of Alberta Health Research Ethics Board (HREB) administers the ethics review process for all faculty, staff, and students of the University of Alberta as well as researchers from, or studies involving, Alberta Health Services and Covenant Health resources.
- University of Calgary Conjoint Health Research Ethics Board (CHREB) administers the ethics review process for researchers at the University of Calgary in the Faculties of Kinesiology, Medicine, and Nursing.



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