Canada's Drug Agency
L'Agence des médicaments du Canada

Drugs, Health Technologies, Health Systems

Methods and Guidelines

Considerations When Developing Consent Forms for Registry Participants

Table of Contents

This document concerns the developing or revising of consent forms for patient and disease registry participants. It supplements the guidance provided in the report Linking Registry Data With Administrative Health Services Data to Support Evidence-Informed Decision-Making.

Proposed Consent Form Elements

To link patient and disease registry data with administrative health services datasets, several elements must be carefully considered when developing or revising the informed consent form. These elements are presented in the following outline and are based on existing guidance.[1]

This outline provides a starting point for understanding the scope of informed consent for registry participation. It should not be viewed as comprehensive or even applicable to all registries. For example, if a registry is to be housed within an academic centre (hospital or university), then the consent form template from that centre's research ethics board is the best choice. Some registries will need to modify this outline to meet specific needs, while others may follow a consent procedure similar to 1 used for traditional clinical trials. It is important to note that the responsibility for obtaining and assuring appropriate informed consent is shared by multiple parties, including the registry team, sponsors, researchers, Protocol Review Committees, and ethics boards.[1] Despite the large number of elements listed in the outline, every effort should be made to keep consent forms as short as possible and at approximately a fifth grade reading level.

Examples of wording pertaining to linking registry data with administrative health services data can be found in the "Guidelines: Informed Consent Wording for Administrative Data Linking" that were developed by Health Data Research Network Canada and are available on the Health Data Research Network (HDRN) Canada's website.[2]

The following elements should be considered:

- A statement that the individual is being asked to take part in a registry (or a research study, if applicable), including:
  - the name of the specific registry for which consent is being obtained
  - an explanation of the purposes of the registry (why it was created, who will be included)
  - the expected duration of participation
  - a description of the procedures involved (e.g., data that will be collected, surveys that may be administered, and the frequency at which data will be collected from the participant)
  - the approximate number of individuals involved (if applicable)
  - whether the registry data will be linked in the future with administrative health services datasets or other data and for what purpose(s).
- A description of the governance structure overseeing the registry operations and decision-making process on the use and disclosure of registry data and any changes in registry scope. This is particularly relevant for registries pursuing broad consent.

- A description of any foreseeable risks or inconveniences (specifically risks related to any potential breach of confidentiality related to the data being collected, used, and disclosed, if applicable).
  - When human genetic research is anticipated, information should include possible consequences of genetic testing (e.g., insurance risks, paternity determinations, potential risks to family and community) and other related confidentiality risks.
- A description of the types of research that the repository will support, including research originating from linking registry data with administrative health services datasets or other data, and any benefits to the participants or to others that may reasonably be expected, including:
  - A statement about whether and how findings will be communicated to participants.
- A statement describing the extent to which confidentiality of data or biospecimens identifying the participant will be maintained (including a description of the operations of the repository—how data/specimens will be stored and managed), including:
  - If applicable, a statement about whether registry results will be published.
  - A statement about the impact of participation on the individual's access to their medical records (e.g., that access may be limited until all work on the registry is completed).
- The conditions and requirements under which data and/or specimens will be shared with recipient researchers, including:
  - If applicable, a description of the data or specimens will be broadly shared and may be used for future research that is not yet identified.
  - The fact that the data or specimens may be transferred to other institutions, an explanation of a data transfer security plan, and the fact that data sharing agreements will govern the transfer.
- A description of when recontact might be necessary and how recontact will be handled.
- A statement of whether there are any costs to participation and/or any payment or compensation for participation.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
  - The consequences of a participant's decision to withdraw from the research, including the possibility that the previously collected data will continue to be used and procedures for orderly termination of participation by the participant.
  - An option for the participant to refuse to have their data linked with administrative health services datasets.
- Details on whom to contact for answers to pertinent questions about the research and research subjects' rights (e.g., the research ethics board that approved the registry protocol and materials).

Legislative and Ethical Considerations Around Consent

Privacy refers to an individual's right to be free from intrusion or interference by others. It is a fundamental right in a free and democratic society.[4] Consent functions as a way for individuals to protect their privacy by exercising control over their personal information.[3] Privacy is respected if an individual has an opportunity to exercise control over their personal information by consenting to or withholding consent for, activities including but not limited to the collection, use, and/or disclosure of their personal information.[4]

In Canada, there are numerous pieces of across-country and provincial or territorial privacy legislation that govern 1) the collection, use, and disclosure of personal information in a manner that recognizes the right of privacy of individuals with respect to their personal information, and 2) the need of organizations to collect, use, or disclose personal information for the purposes that a reasonable person would consider appropriate in specific circumstances. It is essential for a registry team to identify the correct legislation they are required to follow to ensure that personal information and personal health information they intend to collect (or are collecting) as part of their registry is appropriately protected and that the legislated safeguards are followed.

HDRN Canada has compiled a table of privacy legislation across Canada, which can be used as a starting point for understanding the potential requirements in the jurisdictions where a registry operates.[5] In addition, the Office of the Privacy Commissioner of Canada has also developed a web tool to help individuals find the right organization individuals can contact to discuss privacy issues.[6]

Under privacy laws, organizations are generally required to obtain consent for the collection, use, and disclosure of personal information. There might also be specific provisions around consent. For instance, in Ontario, for consent to be valid, it must be:

- the consent of the individual (or substitute decision-maker if the individual is incapable)
- understood by the individual (i.e., they know the purpose of the collection, use, or disclosure and know that they have the right to give, refuse, or withdraw consent)
- related to the information that is collected, used, or disclosed
- not be obtained through deception or coercion.[7]

Furthermore, in Ontario, a capable person, regardless of age, is permitted to consent to the collection, use, or disclosure of their own personal information. Capacity is the ability to understand information relevant to deciding whether to consent to the collection, use, or disclosure and the ability to appreciate the reasonably foreseeable consequences of giving, not giving, or withdrawing consent. Under the Ontario Personal Health Information Act, capacity is presumed unless the health information custodian has reasonable grounds to believe the person is incapable of consenting.[8]

In 2018, the Office of the Privacy Commissioner of Canada and its counterparts in Alberta and British Columbia [the Offices of the Information and Privacy Commissioner of Alberta (“OIPC-AB”) and British Columbia (“OIPC-BC”)] developed Guidelines for obtaining meaningful consent.[9]

The following checklist is provided in the *Guidelines for obtaining meaningful consent*,[9] which separates obligations arising from legal requirements (must do) and best practices (should do).

Must Do

To obtain meaningful consent and meet their related obligations under the Canadian privacy law, organizations must:

- make privacy information readily available in complete form while giving emphasis or bringing attention to 4 key elements:
  - What personal information is being collected, with sufficient precision for individuals to meaningfully understand to what they are consenting.
  - With which parties personal information is being shared.
  - For what purposes the personal information is being collected, used or disclosed in sufficient detail for individuals to meaningfully understand to what they are consenting.
  - Risks of harm and other consequences.
- Provide information in manageable and easily accessible ways.
- Make available to individuals a clear and easily accessible choice for any collection, use, or disclosure that is not necessary to provide the product or service.
- Consider the perspective of your consumers to ensure consent processes are user-friendly and generally understandable.
- Obtain consent when making significant changes to privacy practices, including the use of data for new purposes or disclosures to new third parties.
- Only collect, use, or disclose personal information for purposes that a reasonable person would consider appropriate under the circumstances.
- Allow individuals to withdraw consent (subject to legal or contractual restrictions).

Form of Consent

- Obtain explicit consent for collection, use, or disclosure, which generally:
  - involves sensitive information
  - are outside the reasonable expectations of the individual; and/or
  - create a meaningful residual risk of significant harm.

Consent and Children

- Obtain consent from a parent or guardian for any individual unable to provide meaningful consent themselves and ensure that the consent process for youth able to provide consent themselves reasonably considers their level of maturity.

Should Do

- Allow individuals to control the amount of detail they wish to receive and when.
- Design or adopt innovative and creative ways of obtaining consent, which are just-in-time, specific to the context, suitable to the type of interface, and approved by the research ethics board.

- Periodically remind individuals about the consent choices they have made and those available to them.
- Periodically audit privacy communications to ensure they accurately reflect current personal information management practices.
- Stand ready to demonstrate compliance – in particular, that the consent process is understandable from the perspective of the user (i.e., registry participant).
- In designing consent processes, consider:
  - Consulting with registry participants and seeking their input;
  - Pilot testing or using focus groups to evaluate the understandability of documents;
  - Involving user interaction/user experience (UI/UX) designers;
  - Consulting with privacy experts and/or regulators; and/or,
  - Following established best practices or standards.

Tri-Council Policy Statement

In Canada, in addition to legislative requirements that will vary by jurisdiction, research involving humans can receive funding or operate under the auspices of an institution that receives funding from 1 of the 3 pan-Canadian funding agencies. The 3 agencies, which are referred to as the Tri-Council agencies, are the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada. Registries that are funded by a Tri-Council agency must comply with the guidance provided in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS-2 2022).[4]

The TCPS-2 was developed to promote research that is conducted according to the highest ethical standards. Under the TCPS-2, consent is required for the collection, use, and disclosure of personal information. In addition, consent is to be “free, informed, and ongoing.” Consent shall be given voluntarily and can be withdrawn at any time. Consent shall also be informed as per the information highlighted in the previous section. A research ethics board may permit alterations to the consent requirement or may waive the consent requirements under certain conditions described in TCPS-2 chapter 4 B. Departures from General Principles of Consent.[4]

The guidance states that registry teams must have their registry protocol reviewed by an ethics review board and that informed consent is generally required from potential participants as a condition for their enrolment in the registry.

Registries that did not undergo an ethics review at inception still need to comply with legislation in the jurisdiction where they operate. In Canada, under privacy laws, organizations are generally required to obtain consent for the collection, use, and disclosure of personal information, although exceptions may apply. Please refer to the previous section for more information.

The research team has an ongoing ethical and legal obligation to bring to participants' attention any changes to the research project that may affect them. These changes may have ethical implications, may be germane to their decision to continue research participation, or may be relevant to the particular circumstances of individual participants. Under the TCPS-2, new uses (secondary uses) of identifying information require consent unless all the following conditions are satisfied:

- 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 research team will respond appropriately to protect the privacy of individuals and to safeguard the identifiable information
- the research team will comply with any known preferences previously expressed by individuals about any use of their information
- it is impossible or impracticable to seek consent from individuals to whom the information relates
- the research team has obtained any other necessary permission for secondary use of information for research purposes.

Where record linkage is concerned, researchers shall obtain approval from the research ethics board before carrying out the record linkage.[4]

For more information about ethics or to discuss the particular case of your registry, please contact your institution's research ethics board (if applicable) or an independent research ethics board.

References

1. Gliklich RE, Leavy MB, Dreyer NA, eds. Registries for evaluating patient outcomes: A user's guide, 4th edition. *(Report No.: 19(20)-EHC020)*. Rockville (MD): Agency for Healthcare Research and Quality; 2020: https://www.ncbi.nlm.nih.gov/books/NBK562575/. Accessed 2023 Mar 14.
2. Administrative data linking consent wording tool *(Version 1.1, October 2021)*. Vancouver (BC): Health Data Research Network Canada; 2021: https://www.hdrn.ca/sites/default/files/2021-12/FINAL%20Administrative%20Data%20Linking%20Consent%20Wording%20Tool%20V1.1_20211027.pdf. Accessed 2023 Mar 14.
3. Office of the Privacy Commissioner of Canada. Consent and privacy: A discussion paper exploring potential enhancements to consent under the Personal Information Protection and Electronic Documents Act. 2016; https://www.priv.gc.ca/en/opc-actions-and-decisions/research/explore-privacy-research/2016/consent_201605/. Accessed 2023 Mar 14.
4. Panel on Research Ethics. Introducing the Tri-Council Policy Statement: Ethical conduct for research involving humans – TCPS 2 (2022). 2023; https://ethics.gc.ca/eng/tcps2-eptc2_2022_introducing-presentation.html. Accessed 2023 Mar 14.
5. Health Data Research Network. Privacy legislation by province or territory. 2024; https://www.hdrn.ca/en/dash/resources/privacy/privacy-legislation/#2. Accessed 2023 Mar 14.
6. Office of the Privacy Commissioner of Canada. Find the right organization to contact about your privacy issue. 2014; https://www.priv.gc.ca/en/report-a-concern/leg_info_201405/. Accessed 2023 Mar 14.
7. Information and Privacy Commissioner of Ontario. Elements of consent. 2019; https://www.ipc.on.ca/part-x-cyfsa/consent-and-capacity/elements-of-consent/. Accessed 2023 Mar 14.
8. Government of Ontario. Personal Health Information Protection Act, 2004 (S.O. 2004, c. 3, Sched. A). 2023; https://www.ontario.ca/laws/statute/04p03. Accessed 2023 Mar 14.
9. Office of the Privacy Commissioner of Canada. Guidelines for obtaining meaningful consent. 2021; https://www.priv.gc.ca/en/privacy-topics/collecting-personal-information/consent/gl_omc_201805/. Accessed 2023 Mar 14.