Depositing Existing Data in Public Repositories

Guidance in Applying TCPS 2

Panel on Research Ethics
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Under what circumstances can researchers deposit data in a repository for secondary use?

The Tri-Agency Research Data Management Policy refers to data deposit in repositories that "must ensure safe storage, preservation and curation of the data". Researchers can deposit previously collected data in a repository subject to participants' consent and its limits. Where seeking participants' consent is impracticable, researchers may seek research ethics board (REB) approval of an exception. Researchers may be subject to applicable legal and regulatory requirements with respect to protection of privacy, and consent for the collection, use or disclosure of information about participants. Researchers may also be subject to professional and contractual obligations, and other institutional requirements.

The federal research funding Agencies acknowledge the benefits of secondary use of data, including, "avoidance of duplication in primary collection and the associated reduction of burdens on participants; … application of new tests of hypotheses that were not available at the time of original data collection; and confirmation that the data are authentic" (TCPS, Application of Article 5.1). In their Research Data Management Policy, the Agencies also emphasize the importance of responsibly managing and making research data collected through the use of public funds available for reuse by others.

Data sharing can also introduce new risks of privacy breaches for participants. For example, the possibility of re-identification of individuals when their data is used in subsequent research can threaten an individual's privacy, and may lead to stigmatization of individuals or groups. In addition, the secondary use of data in new research contexts can raise unforeseeable risks.

Depositing data in a repository may also mean making it available for future sharing and use in other research in or outside Canada under the terms and conditions set by the repository. Researchers and REBs must be mindful that future research proposing to use the deposited data, if accessible, may or may not be subject to ethics review.

A. Consent issues

In keeping with the principle of Respect for Persons, participants make the final judgement about the acceptability of risks and benefits to them (see Ch. 1, Concern for Welfare). Researchers must inform participants about subsequent uses of data, including any plan to deposit research data in an appropriate repository. Exceptions are possible as outlined below.

Participants' existing consent to future use may be unrestricted, i.e. allow data use in future unspecified research. Participants may also have consented with limitations, for example, consent may be restricted to a particular field of study, to a specific disease, or may prevent use by private industry. Researchers need not seek additional consent for the deposit into a repository for future use, if the terms of participant consent continue to be respected.

Researchers are encouraged to be explicit in the consent process about subsequent uses of participants' data. Researchers are also encouraged to be as specific as possible in the consent process, for example by distinguishing between consent to re-contact from consent to deposit data for future use.

Seeking participants' consent for depositing their data in a repository for future use is the default. If seeking consent for deposit was not part of the consent process, researchers may need to take additional steps depending on which of the following circumstances apply:

1. No known preference regarding deposit or re-contact

If there was no prior mention of data deposit for future research use as part of the consent process, and participants' wishes about re-contact are unknown, researchers must re-contact them to seek their consent for the data deposit (see Articles 3.1, 3.2, and 3.3).

2. No known preference regarding deposit or re-contact, but seeking consent is impracticable

If there is no indication that participants have declined future use, but researchers cannot seek participants' consent because it is impracticable, the researchers can deposit the data subject to REB approval. "Impracticable" refers to undue hardship or onerousness in seeking participants' consent; it does not mean inconvenience for the researchers. It is impracticable when participants or their authorized third party may be deceased or difficult to track due to insufficient identifiers, cost, or time elapsed.

The onus is on researchers to satisfy the REB of the need for the exception to seek consent. In doing so, researchers shall inform the REB of their strategies to assess participants' wishes regarding depositing their data for future use. Researchers may consider seeking the opinion of a representative group of participants. This is particularly important when the data are potentially sensitive or relevant to a specific group. Researchers may discuss with people whose perspectives or expertise can inform them about the likelihood for the participant pool to agree to deposit their data. For example, researchers may consult patient partners, where available, about their proposed methods to deposit the data and its potential subsequent use. Researchers must satisfy the REB that depositing the data in the absence of consent is unlikely to adversely affect the welfare of participants.

3. No known preference regarding deposit; known refusal of re-contact

If participants indicated that they do not wish to be re-contacted and their preference regarding data deposit is unknown, then researchers must not re-contact them, and generally must not deposit their data for future use. However, there may be circumstances that would justify the deposit of such data. Examples may include:

- data collected in exceptional contexts (e.g. a dataset collected in the first month of a pandemic).

- anonymized non-sensitive data collected from a group known to support data sharing.

The onus is on the researchers to justify to the REB the need for the exception.

Known refusal of consent to deposit for future use

If participants had declined to deposit their data for future use as part of their existing consent, researchers must respect the participants' decision, must not re-contact participants to seek their consent, and must not deposit their data for future use.

B. Issues for the REB to consider

The following are some issues for the REB to consider in making the determination about the deposit of the data for future research use:

- Whether participants would have consented to the data deposit and sharing.
- If the researchers' proposals will continue to respect the terms of consent.
- Whether the researchers provided satisfactory justification that seeking consent would be impracticable.
- The source of the data – whether directly from participants, from other researchers, or from other external sources. This includes taking into account whether consent was obtained, if the terms of consent continue to be respected, or if the terms of use of data permit deposit in repositories.
- The type of data and its potential sensitivity; for example, health or genetic data, or data that reveals political opinions, ethnic origin or sexual orientation. In these circumstances, consultation with a representative group will be particularly relevant.
- The level of identifiability of the data, and mechanisms that will be undertaken to protect privacy; for example, whether and how the researchers plan to strip the identifying information prior to deposit.
- Whether the data is from a specific or unique community or group where the researchers are required to further consult, seek permissions for depositing the data, respect existing agreements, or follow additional data management principles. See Article 2.11, and Articles 9.1 and 9.11 on research involving First Nations, Inuit and Métis Peoples of Canada that can be applied to other communities when appropriate.
- The appropriateness of the repository where the researchers propose to deposit the data. This includes its governance and policies related to access to data and reuse, as well as safety, security and protection measures in place.

In addition to addressing ethics issues following TCPS 2 guidance, "researchers are responsible for compliance with all applicable legal and regulatory requirements with respect to protection of privacy, and consent for the collection, use or disclosure of information about participants. These requirements may vary by jurisdiction" (Chapter 5, Introduction).

See also related interpretations [REB review #11], and [Scope #17].