

## E. Broad Consent for the Storage of Data and Human Biological Materials for Future Unspecified Research

For the purposes of this Policy, broad consent is defined as consent for future unspecified research (subject to applicable law). Unlike blanket consent, which is typically unrestricted, broad consent always includes specific restrictions (e.g., consent may be restricted to a particular field of study, to a specific disease, or may prevent use by private industry). Broad consent applies to the storage and secondary use of participants' data and human biological materials collected for research purposes. The use of broad consent is in the context of future research using data and human biological materials with no direct contact or intervention with participants at that time. While blanket consent is not permitted under the TCPS, broad consent is permitted.

### Article 3.13

To seek broad consent for the storage and future unspecified use of data and human biological materials, researchers shall provide prospective participants, or authorized third parties, with applicable information as set out in Articles 3.2 and 12.2, as well as the following details, as appropriate to the particular research project:

- the type, identifiability, and amount of data and human biological materials being collected and stored for re-use, and for what potential purpose;

- the voluntariness of the participant's consent, including any limitations on the feasibility of withdrawal;

- a general description of the nature and types of future research that may be conducted, including whether the research might be conducted outside of Canada (if known);

- the risks and potential benefits of storage of data and human biological materials, and of their use in future unspecified research, including areas of uncertainty where risks cannot be estimated;

- access to a general description of the repository and its governance;

- a statement regarding participants' preference to being re-contacted for additional future research;

- whether the data or human biological materials could be shared with researchers who are not subject to the TCPS;

- whether the research will (if known) or might include whole genome sequencing or similar technologies that may pose a substantial risk of re-identification of the participant or identification of material incidental findings (when appropriate);

- whether linkage of data gathered in the research or derived from human biological materials with other data about participants – either contained in public or personal records – is anticipated (Article 5.3); and

separate options for consenting to participate in a specific research project and for consenting to the storage of data and human biological materials for future unspecified research.

## Application

The general requirements for consent to be free, informed, and ongoing apply to all types of consent and are explained in Chapter 3 of the TCPS. The key elements to include in the consent process are outlined in Article 3.2 (general requirements) and Article 12.2, (additional requirements for research involving human biological materials). Broad consent must align with these principles. Similar to consent for a specific research project, the broad consent process must focus on what is relevant to an individual participant's decision-making process. In general, this would include informing them of potential benefits of the research, risks, how their interests will be protected and any limitations to those protections. Participants should also be informed about potential uses, and any limitations to the range of uses, if known at the time of seeking broad consent. Not all the listed elements are required for all research. It is up to the REB to consider whether all elements listed, or additional elements, are necessary to the consent process of the research project.

The difference between the principles as applied to specific consent and those applied to broad consent is the nature and scope of the information that is being provided to the participant by the researcher during the consent process. For example, there is a distinction between details of the research that are known versus details of the research that are uncertain or cannot be specified at the time of consent. An important part of the consent process, therefore, is informing participants of areas of uncertainty that may be relevant to their decision to participate. Researchers should consider what information is meaningful to the participant's decision to participate at the time of consent. In determining what might be relevant to participants' decisions to participate in research, researchers must be mindful of the perspective of the participant and their willingness to accept uncertainty. This may involve considering the various contexts (e.g., social, economic, cultural) that may shape participants' decisions (Chapter 1, Section C). Researchers are encouraged to be as specific as possible during the consent process, for example by distinguishing between consent to re-contact from consent to deposit data for future use. When in doubt about the essential information to be provided to prospective participants, researchers should consult with their REB.

Where data or human biological materials are being stored for use in future unspecified research, the researcher, the relevant authority of the repository, and future researchers share the responsibility of ensuring that the terms of participant consent are respected (Respect for Persons) and that participant privacy and confidentiality, as well as participant welfare are protected (Concern for Welfare) throughout the life of the research project. This shared responsibility to protect participants includes the responsibility to abstain from attempting to re-identify participants, where data and human biological materials have been de-identified, unless required by law.

Where future communication is contemplated (e.g., re-contact, follow-up with participants, return of research results), researchers should invite participants to maintain and update their contact information with a designated individual. As the elements of informed consent may change over time, repositories and researchers have a duty to provide participants who wish it, with information relevant to their consent throughout the storage and use of their data and human biological materials for research (Article 3.3). This includes providing participants with options about obtaining information and details of the research and/or repository, or clearly explaining that access to this type of information will not be possible. Moreover, ensuring that appropriate mechanisms to maintain informed and ongoing consent are in place is an important consideration in the context of evolving capacity (Article 3.3). In some cases, repositories may not be able to keep in contact with participants, making ongoing consent impracticable. In this case, consent is, in effect, limited to a one-time event that takes place when the data or human biological materials are collected.

The creation of a repository requires REB review and is subject to continuing research ethics review, in accordance with a proportionate approach to research ethics review (Article 6.14). In its review, the REB should address issues related to the risks and potential benefits associated with the collection and storage of human biological materials, the nature and governance of the repository, and elements of the consent process. Appropriate mechanisms and procedures should be clearly outlined in the governance of the repository to ensure that subsequent use of the data and human biological materials is in accordance with the original terms of participant consent.

The TCPS requires research involving stored data or human biological materials to undergo REB review (Article 5.5A, 5.5B, 12.3A, 12.3B). However, such research may not receive REB review if conducted in jurisdictions that are not subject to the TCPS (i.e., research in other countries or research conducted under the auspices of institutions that are not eligible to administer Agency funds). Researchers and/or repositories who intend to make their collections of data or human biological materials available to other researchers not subject to the TCPS should consider the repercussions of this decision for participants. Participants must be informed of this possibility. Researchers must also comply 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, which may vary by jurisdiction (Chapter 5, Introduction).

When seeking consent for a specific research project at the same time as seeking consent for storage of data and human biological materials for future unspecified research, prospective participants must be provided with an option to consent to each separately, either through separate consent forms or separate sections on the same form. Footnote 3

Where the data or human biological materials are from a specific or unique community or group, researchers and repositories may be required to further consult with, or seek permissions from, such groups, or to respect existing agreements (see Articles 9.1 and 9.11).