# Proposed Guidance Regarding Broad Consent for the Storage And Use of Data and Human Biological Materials

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## Purpose

The purpose of the following guidance is to introduce broad consent and describe how it can comply with the principles of the TCPS.

## Introduction

Broad consent is a term used around the world to mean consent for unspecified research. It is widely used in the context of data repositories and biobanks. At one time, international ethics norms recommended seeking consent from participants only for a specific, clearly defined research project, referred to in this guidance as 'specific consent.' Now, however, there is general approval for seeking broad consent for the use of stored data and human biological materials for less or un- specified research that may be conducted in different and unspecified contexts, now or in the future.

Although this may seem to be a departure from the principles of specific consent, in fact the principles underlying broad consent are the same. "An important mechanism for respecting participants' autonomy in research is the requirement to seek their free, informed and ongoing consent. This requirement reflects the commitment that participation in research, including participation through the use of one's data or biological materials, should be a matter of choice and that, to be meaningful, the choice must be informed" (Article 1.1). This is as true for broad consent as it is for specific consent. The difference is the nature and scope of what is being discussed by the researcher and participant during the consent process.

The informed aspect of broad consent focuses on the discussion with participants of the risks and potential benefits associated with unspecified research that is in a much broader context than specific consent. Broad consent recognizes that the details (e.g., research objectives, methods) of future research projects may be of less interest to participants who are volunteering their contributions over the long term, than other aspects of the research, such as who will have access to their contributions and in what jurisdictions. This means information about the nature and governance of the repository may take on a greater significance for some participants.

The following discussion explores how to apply the TCPS guidance that consent be voluntary (Article 3.1), informed (Article 3.2) and ongoing (Article 3.3) in the context of seeking consent for the storage of data or human biological materials for unspecified research.

## The shared responsibility to protect participants

Researchers, data custodians, and biobanks have a shared responsibility to protect participants. In specific research, the researcher has a responsibility to ensure that the terms of participant consent are respected (Respect for Persons) and that participant welfare is protected (Concern for Welfare) throughout the life of the research project. Where data or human biological materials are being stored for use in research, the repository assumes those responsibilities. When the stored data and human biological materials are used for new research, the researcher associated with the new project takes on the same responsibilities, i.e., that the terms of participant consent continue to be respected and that participant welfare continues to be protected throughout the new research life cycle.

In general, the TCPS requires research involving stored data or human biological materials to undergo REB review (Articles 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 manage Agency funds. Researchers who intend to make their collections of data or human biological materials available to other researchers not subject to the TCPS must consider the repercussions of this decision for participants. The consent process must reflect the intention of the researcher collecting the data or human biological materials. For example, if a researcher assures participants that all subsequent research will undergo REB review, then that researcher must make sure procedures are in place to realise that assurance (e.g., through governance policies, or contractually). Alternatively, if the researcher is unable to make such an assurance, they must make that clear to participants during ~~in~~ the consent process.

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 respect existing agreements. See Articles 9.1 and 9.11 on research involving First Nations, Inuit and Métis Peoples of Canada. This guidance can be applied to other communities when appropriate (Article 2.11).

## Voluntary broad consent

### *Withdrawal*

In general, participants must be able to withdraw from research at will and without reprisal (Article 3.1). In practical terms, this means they must be able to request withdrawal of their stored data or human biological materials from the repository. The withdrawal of their data or human biological materials may not be possible after a certain point in time. For example, their data may have been anonymized prior to storage and cannot be separated from the pool of participant data. Or, their contributions may have been widely disseminated. Researchers must justify any limitations to the withdrawal of data or human biological materials to their REB. These limitations must be explained to participants during the consent process.

### *Free of coercion and undue influence*

Consent must be free of coercion and undue influence (Article 3.1). Sometimes researchers collect data or human biological materials for a specific research project, and with the intention of subsequently storing those data or materials (or excess materials not used for the specific purpose) in a repository for subsequent unspecified research. In this situation, both

specific and broad consent must be sought. Participating in a specific and known research project must not be contingent on the participant consenting to unspecified research.

**Informed broad consent**

The notion of broad consent raises the question of what information is meaningful to participants in deciding whether they wish to have their contributions stored for unspecified research. Like specific consent, the broad consent process must focus on what is relevant to participants' decision-making. In general, this would include informing them of potential benefits of the research, risks to participants, how their interests will be protected and any limitations to those protections. They should also be informed about potential uses, and any limitations to the range of uses, if known at the time of seeking broad consent.

However, sometimes not all of this information is known at the time of seeking 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. For example, when little is known about the nature of the future research, there is a risk that the participant's contributions could be used for a purpose that the participant might not agree with or support. However, participants who care only that their contributions are to be used for research in the broadest sense, may wish to consent despite this risk. In determining what might be relevant to participants' decisions to participate, 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 shape the participant's life (Chapter 1, Section C).

The repository is an important part of the shared responsibility to protect participants. However, it must be acknowledged that not all participants are interested in the details of a repository's governance and their inclusion in the consent form may distract from information that is more relevant to the participant at the time of initial consent. The researcher should consider what information is meaningful to the participant's decision to participate at the time of consent, and what information might be more appropriate as an addendum, which may be of more interest to them later. Researchers should provide a means for participants to obtain ongoing repository information as the repository's governance may change. This could be accomplished by providing participants with a repository contact and information about how to find repository information, should they wish it, in the future, e.g., a website.

The elements of informed broad consent listed below are the same elements associated with specific consent listed in Article 3.2, only they are broader in scope.

For broad consent to be informed, it must include information about:

- What is being collected and stored for reuse, and why;
- Voluntariness and the ongoing nature of the participant's consent, including options for withdrawal (if any);
- Risks and potential benefits of storage of data and human biological materials and of their use in unspecified research, including areas of uncertainty where risks cannot be estimated;
- Information about the repository and its governance (if known).

The following is a more detailed description of these requirements that can be used to make sure that key issues associated with broad consent are considered.

***What is being collected and stored for unspecified research and why***

- Description of what data and human biological materials will be stored for research, for what purpose, if known, and whether they can be identified as being from a specific or unique community or group.
- Description of potential uses. Consideration should be given to whether the research could involve technologies that would compromise participant privacy/confidentiality, such as whole genome sequencing or other emerging technologies, as these may increase participant risk**.**
- Description of any potentially identifying information that will be stored.
- Length of time the data and human biological materials will be stored, location of storage, process for disposal, how any human biological materials will be preserved, and whether the human biological materials will be converted to information, e.g., DNA sequencing.

***Voluntariness and the ongoing nature of consent***

- Assurance that prospective participants are under no obligation to agree to the storage of their data or human biological materials for research.
- Assurance that not agreeing to storage will not jeopardize participants' chances to receive any current or future services.
- Explanation of how participants may withdraw their consent for research, including any limitations to the withdrawal of their data and human biological materials from storage.
- Explanation of what and how to obtain information that will be provided as part of ongoing consent (e.g., details of research) or that participants will not have access to this information.
- Description of how the terms of consent will be respected in research (e.g., contractually, through governance mechanisms).
- Assurance that participants have not waived any rights to legal recourse in the event of harms associated with the storage and research use of their data or human biological materials.

***Risks and potential benefits of storage and participation in unspecified research, including areas of uncertainty where risks cannot be estimated;***

- Description of the reasonably foreseeable risks that may arise from the storage and research use of the data and human biological materials, for example:
    - Risks of re-identification;
    - Possibility that participant data or human biological materials will be used for research of which the participant is unaware and to which the participant might object.
- Description of the potential benefits of the research, to the degree possible.
- Discussion of areas of uncertainty, where the risks are unknown, that may be relevant to participants' decision to participate.

***Information about the repository and its governance***

- Purpose of the repository.

- Information about the type of research supported by the repository.
- Identification of sponsors or funders associated with the repository and any conflicts of interest between the sponsor and the repository.
- Description of how privacy and confidentiality will be protected during storage and research, and any limitations to that protection.
- Description of whether results will be disseminated and if so, how.
- Description of how or if material incidental findings will be handled.
- Description of how stored data and/or human biological materials will be shared with other researchers and under what conditions.
- Information about whether the data or human biological materials will be shared with researchers in other jurisdictions who are not subject to the TCPS. A description of how or whether participant autonomy will be respected and how or whether participant privacy will be protected in the new jurisdiction, e.g., by contractual arrangement.
- Information concerning whether the repository financially benefits from the commercialization of findings, the data or human biological materials or products derived from them and whether participants will financially benefit.
- Any requirements the repository may have to provide data or human biological materials to third parties for non-research purposes (e.g., as required by law) and its process for informing participants when this is required.
- Information about what would happen to the data or human biological materials if the repository were to be closed, if known.
- Who to contact at the repository for information.

**Ongoing broad consent**

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 or human biological materials for research (Article 3.3). Participants should have the option of indicating (and periodically confirming or withdrawing) their consent to being re-contacted over the years and their consent for the continued use of their materials for research. Researchers must respect the wishes of participants who do not want to be re-contacted. For practical reasons, the onus may be on the participant to provide the repository with any updates to their contact information, and to confirm their ongoing consent. 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.

Change in participant capacity is an important element of ongoing consent. For example, longitudinal studies may involve children who have assented to research and whose decision-making capacity is maturing to a point where they can consent for themselves whether to continue to participate in research, without an authorized third party (Article 3.9). Mechanisms should be in place to accommodate such changes.

Any deviations from, or limitations to, the notion of ongoing consent must be justified to an REB and must be explained to participants as part of the consent process.

## Summary

Broad consent is used when data or human biological materials are collected for storage for unspecified research. In this situation, the responsibility to protect participants is shared between the researcher who is collecting the data or human biological materials, the repository, and future researchers. The principles underlying broad consent and specific consent are the same. In both cases, consent should be free, informed and ongoing. The difference is the nature and scope of what is being discussed by the researcher and participant during the consent process.

## Glossary

Consistent with the TCPS:

- Biobank means a collection of human biological materials. A biobank may also include "associated information about individuals from whom biological materials were collected" (Glossary). The term biobank as defined in the TCPS applies regardless of the size or location of the collection. It includes small collections held by an individual as well as large collections held by commercial institutions. It includes collections intended for research as well as collections not intended for research.
- Consent means free, informed and ongoing consent (Articles 3.1-3.3).
- Human biological materials are tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials (Article 2.1.b).

For the purposes of this guidance:

- Broad consent means consent for unspecified research;
- Specific consent means consent for a specific research project, the details of which are known at the time of consent;
- A repository is a data repository or biobank;
- A data repository is a collection of research data.