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Health System

Title	Submission Guideline: Broad Consent for Future Unspecified Research (TCPS 2 Article 3.13)
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Approved By:	REB Chair

1.0 PURPOSE

This guideline is to support research teams preparing submissions to the Osler REB that seek broad consent for the future unspecified use of data and human biological materials. It summarizes TCPS2 Article 3.13 requirements and outlines the information that must be included in consent forms to ensure participants are fully informed and to promote timely, consistent REB review.

This guideline is not a substitute for TCPS 2. Research teams and sponsors must review the full TCPS 2, including Chapter 3, to ensure compliance with all relevant ethical requirements.

2.0 TCPS 2 POLICY SUMMARY

As per TCPS 2, broad consent allows storage and future unspecified research use of participant data or biological materials with 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). **Blanket consent, meaning unrestricted future use for any purpose, is not permitted.**

Broad consent is used primarily in data repositories and biobanks, where the specific details of future research may not be known at the time of consent. This uncertainty means participants must be informed of what is known, what is unknown, and where future risks may arise so they can make an informed decision.

Examples of Broad vs. Blanket Consent

- **Broad consent (permitted):**
"Your de-identified data may be used in future studies that examine chronic inflammatory diseases."

- **Blanket consent (not permitted):**

"Your de-identified data and samples may be used for **any** future health-related research."

3.0 CHECKLIST: REQUIRED ELEMENTS FOR FUTURE USE (TCPS2 Article. 3.13)

The items below outline the additional information that must be included in submissions when seeking broad consent for the storage and future unspecified use of data and human biological materials. These elements are required in addition to the general consent requirements in TCPS 2 Articles 3.2 and 12.2. **Research teams should use this checklist to ensure that all applicable Article 3.13 requirements are addressed prior to submitting documents to the REB.**

Please note, including the items listed in TCPS 2 Article 3.13 **may not** be sufficient to meet all REB requirements. The REB will determine whether all of these elements, and/or additional elements, are needed for the consent process for a particular research project. This may include information about potential commercialization or benefits to the entity or group conducting future research.

Article 3.13 states:
"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:

Checkbox	Requirement (TCPS2 Article 3.13)	Acceptable Examples	Not Acceptable Example
☐	a. Describe the type, identifiability, and amount of data and human biological materials being collected and stored for re-use, and for what potential purpose.	*"Your de-identified blood samples left over from the main study will be stored for future research focused on heart disease. No additional blood draws are needed."*	*"Your de-identified data will be used for research focused on finding new ways to detect, treat, prevent or cure health problems."*

Checkbox	Requirement (TCPS2 Article 3.13)	Acceptable Examples	Not Acceptable Example
☐	b. State that broad consent is voluntary and explain any limits on withdrawal (e.g., not possible once anonymized).	*"Consent for future use of your data/samples is optional and separate from your consent to participate in the main study. If you decide you no longer want your samples used, please tell the research team. Any sample(s) that remain(s) in the bank will be destroyed. If tests have already been done on your sample and included in an analysis or publication, it will not be possible to withdraw these results."*	*"You cannot withdraw permission for future use."*
☐	c. Provide a general description of nature and types of future research that may be conducted, including whether the research might be conducted outside of Canada (if known).	*"Stored de-identified samples and data may be used in future REB-approved studies on heart diseases. The samples and data may be sent to other countries. Your name or any other information that could directly identify you will not be given to these researchers."*	*"Stored samples may be used for any studies conducted anywhere in the world."*
☐	d. Describe any risks related to storage, re-identification, or future unspecified use. Identify potential benefits, if any (may be limited). Note any uncertainties (e.g., risks of future technologies).	*"There is a risk that someone could get access to the personal information in your personal health records or other information researchers have stored about you.* *"There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. Due to the rapid pace of technological advances, the potential future use of genetic information is unknown and therefore the potential future risks also are unknown."* *"You will not benefit directly from taking part in this optional research study. Researchers might make discoveries that could benefit people in the future.*	*"There are no risks associated with storing your samples. Future research will only benefit you and other participants."*

Checkbox	Requirement (TCPS2 Article 3.13)	Acceptable Examples	Not Acceptable Example
☐	e. Include a general description of the repository, including storage location and governance practices.	*"Samples will be stored at the XYZ Biobank, a research repository at XYZ institution. Access to samples is controlled by the Biobank Governance Committee, which reviews all future-use requests. Qualified researchers can submit a request to use the materials stored in the biobank. Your samples and related health information will be used only by researchers whose requests have been accepted by the sponsor/biobank."*	*"Data will be stored for future research as needed."*
☐	f. State whether participants will or may be re-contacted for additional studies. Provide an option for participants to indicate their preference.	*"You may choose if you wish to be contacted in the future about additional research. You can indicate your preference below."* *"Any future research studies will be submitted to and approved/overseen by a research ethics committee"*	*"If you agree to future use, you also agree to be contacted about future studies."*
☐	g. State whether data/ human biological materials may be shared with researchers that are not subject to TCPS2.	*"Any samples and/or information, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be the same as in Canada. However, all study samples and/or information that is transferred outside of Canada will be de-identified. De-identified means it will not contain your personal identifying information such as your name, address, medical health number or contact information. Any information will be transferred in compliance with all relevant Canadian privacy laws."*	*"Your data may be shared with researchers worldwide."*
☐	h. Indicate whether future research will or might include whole genome	*"Your de-identified samples may be used in future studies that include whole genome sequencing. This type of DNA testing may increase the chance of identifying someone or finding information they did not expect."*	*"Any future laboratory tests may be performed using your sample."*

Checkbox	Requirement (TCPS2 Article 3.13)	Acceptable Examples	Not Acceptable Example
	sequencing or similar methods. Describe any increased re-identification risk or potential for incidental findings.	*“If any new clinically important information about your health is obtained as a result of your participation in this optional research, you will be given the opportunity to decide whether you wish to be made aware of that information. The researcher will explain the process, which may include genetic counselling to help you understand what this result could mean for you or your blood relatives, such as your siblings and/or children”*	
☐	i. State 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);	*“Your information may be linked with other records about you, like health or administrative data. Only trained staff can do this, and your name and other identifiers will be removed before anyone studies the data.”*	*“Your data may be combined with any other databases for future research.”*
☐	j. Provide 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. These must be clearly separated	*“☐ I agree to participate in this main research study.”* ***Optional:*** *“☐ I agree to the storage of my data for future research focused on heart diseases.”* *“☐ I agree to be contacted about future studies regarding heart diseases.* *Note that for any future studies, a separate consent form will be provided to you for review.”*	*“By agreeing to participate in the main study, you also agree to storage and future use of identifiable data and samples.”*

4.0 ADDITIONAL GUIDANCE

Research teams and sponsors must ensure that consent forms and study materials meet all applicable TCPS 2 requirements. This guideline summarizes the additional elements required under Article 3.13 when seeking broad consent, it does not replace TCPS 2.

Human Genetic Research

Article 3.13 *(h),* states that it should be indicated in the consent form whether future research will or might include whole genome sequencing or similar methods. For further guidance on Human Genetic Research, please see TCPS 2 Chapter 13.

Data Belonging to a Specific or Unique Community or Group

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. Please see Articles 9.1 and 9.11 for further guidance.

For full definitions, examples, and guidance, please consult:

- TCPS 2 Chapter 3 - The Consent Process
- TCPS 2 Chapter 12 - Human Biological Materials
- Definitions of key terms (examples, directly identifying information, de-identified biobank, broad consent) in the TCPS 2 Glossary

Teams are expected to review the full TCPS 2 to ensure accuracy and compliance.

5.0 REVISION HISTORY

Effective Date	**Summary of Changes**
February 2026	Original version