THE UNIVERSITY OF BRITISH COLUMBIA	**Policy**

Title:

UBC Policy Regarding Mandatory Biobanking

Policy:

Participants cannot be required to agree to the biobanking of their biospecimens for future research as a condition of entry into a study. Consent for future undefined research on biospecimens must be obtained separately from the main study consent by way of a separate consent form or a separate section for Optional Biobanking within the Main Consent form.

It is unacceptable to require that participants agree to the biobanking of their biospecimens for future undefined research or for research unrelated to the study at hand as a condition for entry into a study.

Background:

This policy has been developed to clarify UBC's position on mandatory participation in biobanking as part of a research study when the biobanking of biospecimens is not necessary to answer the primary research question(s). There has been increased pressure (particularly from industry sponsors) to make study participation contingent upon participants agreeing to such biobanking. It is UBC's position that requiring such mandatory biobanking as a precondition to participating in studies is coercive in the context of studies. In adopting this position, UBC's goal is to ensure that participants have access to those research studies for which they are eligible and wish to participate in, without requiring them to engage in unrelated research activities to which they would not otherwise consent.

Instead, as per TCPS2 article 3.13, participants are to be presented with the option of donating biospecimens for future research purposes – this must be completely voluntary. This option must be presented by way of a separate consent form or a separate section for Optional Biobanking within the Main Consent Form (as determined by the UBC REB). It should be clear to the participant that they may participate in the main study regardless of whether they choose to participate in the optional biobanking component.

UBC's position in relation to such mandatory biobanking provisions is consistent with TCPS2 article 3.13 and the prohibitions on this practice established by the US Department of Health and Human Services Common Rule (45 CFR 46), the U.S. Health Insurance Portability and Accountability Act (HIPAA).

By way of clarification, this policy does not apply to the mandatory collection of biospecimens where it is necessary to answer questions integral to the research study, or to verify eligibility of a participant to be enrolled in a particular study. In addition, this policy does not address the issues associated with requiring study participants to undergo biospecimen collection for evaluation of scientific end points

Version: September 27, 2024

related to the study in question. This and other similarly important questions will be addressed in UBC's broader guidance on Research Involving Human Biospecimens found here.

Recourse – Sponsor Justification Requirement:

Where a research sponsor insists that mandatory biobanking is appropriate within the context of a specific study the REB will require the sponsor to provide a detailed explanation (which may include a legal opinion if the REB deems this to be necessary) as to why the proposed biobanking component does not violate the regulatory and ethical prohibitions. Such justification would have to be provided prior to the REB considering any approval on a case-by-case basis. The final determination as to whether the proposed mandatory biobanking is ethically acceptable will be made by the REB.

Definitions:

Biospecimens are human biological materials which include 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.