

UBC Policy on Mandatory Tissue Banking

Effective Date: September 15, 2015

Background: This policy is being developed to clarify UBC's position on mandatory tissue banking as part of a potentially therapeutic research study when the banking of samples is not necessary to answer the primary research question(s). For the purposes of this policy, banking should be understood as the collection and storage of biological samples for future undefined research or for research unrelated to the study for which consent was obtained. There has been increased pressure (particularly from industry sponsors) to make participation in clinical trials contingent upon trial participants agreeing to such banking. It is UBC's position that requiring such mandatory banking as a precondition to participating in studies is always ethically problematic but that it is coercive and unethical in the context of studies that may offer some potential therapeutic benefit to participants. 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. UBC's position also echoes the position of the US Office of Human Research Protections (OHRP), which is that "it is impermissible for sponsors to condition subject participation in a research study that offers subjects the prospect of direct benefit, upon the subject's willingness to consent to have his/her biospecimens/PHI [Personal Health Information] used to create a research repository for any and all unspecified future research."¹

Instead, the sponsor may provide participants the option of donating a tissue sample for future research purposes but this must be completely voluntary and the option must be presented by way of a separate consent form in order to make it clear to the participant that they may participate in the main study regardless of whether they choose to participate in the optional banking component.

UBC's position in relation to such mandatory banking provisions is consistent with the prohibitions on this practice established by (among others) the US Department of Health and Human Services Common Rule (45 CFR 46), the U.S. Health Insurance Portability and Accountability Act (HIPAA), as well as the principles for free and informed consent as outlined in key ethical guidelines including the TCPS2 (for example, Article 3.1).

By way of clarification, this policy does not apply to the mandatory collection of tissue samples where this 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 trial participants to undergo a biopsy for evaluation of scientific end points related to the clinical trial in question. This and other similarly important questions will be addressed in UBC's broader guidance on Collection and Use of Human Biological Materials (in development).

¹ Dr. E. Bartlett, OHRP's International Human Research Liaison, in response to an email query by the Co-Chair of the UBC CREB (February 2015).

Policy:

Mandatory banking of tissue samples (includes blood) is only permitted if the banking is necessary for the study at hand; that is, the banking must be for purposes integral to the study.

It is unethical to require that participants agree to the banking of their tissue for future undefined research or for research unrelated to the study at hand as a condition for entry into a trial that offers the potential participant the prospect of some direct benefit. Such practice constitutes a coercive method of obtaining tissue samples by making access to a potentially therapeutic opportunity contingent upon the donation of the sample to the bank.

Where a research sponsor insists that mandatory banking (as described above) is appropriate within the context of a specific trial, 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 banking 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 banking is ethically acceptable will be made by the REB.

Suggested wording for email/provisos to Investigators where Sponsors are requiring Mandatory Banking:

Please note that UBC affiliated Research Ethics Boards adhere to UBC's policy on Mandatory Banking. Pursuant to this policy, potentially therapeutic studies that make enrolment contingent upon participants' agreement to have their tissue sample (includes blood) banked for future unspecified research or research unrelated to the study at hand are considered coercive and will not be approved by the REB. UBC's Mandatory Banking policy is in line with the principles of Free and Informed Consent outlined in key ethics guidance documents including the TCPS2, as well as with regulatory prohibitions established by, among others, US Health and Human Services Regulations 45 CFR part 46 as well as the U.S. Health Insurance Portability and Accountability Act (HIPAA).

For sponsors who wish to submit studies that include Mandatory Banking for REB consideration, please be advised that the REB will require a detailed explanation (which may include a legal opinion if the REB deems this to be necessary) as to why the proposed banking component does not violate the regulatory and ethical prohibitions. Such justification must be provided prior to the REB considering any approval on a case by case basis. The final determination as to whether the proposed mandatory banking is ethically acceptable will be made by the REB.