CHICKEN SOUP FOR THE BUSY COORDINATOR
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How to Handle Leftover Tissues for Future Unapproved Research and Legacy Human Biological Material (LHBM)

Case Scenario

Prof Chan, a hepatobiliary surgeon from Tan Tock Seng (TTSH) hospital, had completed a HBR study for which tumour tissue were collected from patients who underwent hepatectomy and consented for the study. Part-of the collected tissues were used for study analysis and there were leftover tissue after study completion. As a lot of time, effort and funding was spent on this study, Prof Chan would like to find out from DSRB if he could store the leftover tissue for future unapproved research and thus approached a DSRB member for advice.

The DSRB member explained that if the researchers still require the tissues for analysis for the current completed study even after DSRB's acknowledgment of study closure, such tissues could be retained and used within 12 months of IRB's acknowledgment for study closure. After which, the tissues should be discarded, transferred to a tissue bank or an IRB approved study or registered with the National Healthcare Group Tissue Compliance Committee (NHG TCC).

Handling of Tissue for Future Unapproved Research:

Upon study completion, any leftover human tissue to be stored for future research (research that has **yet to obtain IRB approval**) will need to come under the governance of the **Human Tissue Framework (HTF).** Hence the ICF used to consent the donors of such tissue must have all HBRA 12(2) elements. DSRB member informed Prof Chan that the tissue must be registered with the NHG TCC by submitting the TCC tissue bank application form.

Handling of Legacy Human Biological Material (LHBM):

On the other hand, DSRB explained to Dr Chan that for human tissue that had been obtained and de-identified **prior to 1 November 2019**, it is considered **Legacy Human Biological Material (LHBM).**
The ICF used to consent the donors of such tissue must at least have HBRA 12(2)(a), 12(2)(f) and 12(2)(i) elements. Researchers in possession of LHBMs which are intended to be stored or used for future research are required to submit a LHBM Declaration Form to NHG TCC.
LHBM are exempted from the requirements of HBRA and exceptions will be made for researchers to use such non-identifiable legacy tissues in research without appropriate consent. Once declared, this information will also be shared with DSRB, so that the IRB can use this to verify the tissue sources in subsequent research.

NHG LHBMs that are stored in external facilities must also be declared. The 'De-identification' of LHBM may be reversible or irreversible. Where the health information and/or HBM is de-identified such that a re-identification key remains, the researcher should ensure that an 'effective barrier' exists between the key-holder and any person involved in the conduct of tissue banking activities on the LHBM, to prevent re-identification of the tissue donor without consent. This declaration should be signed off by the person who is responsible and has oversight of these legacy human biological materials.

NB: Research Institutions are to follow their respective Institution's policy for handling Human Tissue.

References:

1. NHG Research Website- Human Tissue Framework (NHG :: RDO :: Human Tissue Framework)
2. 1601-A02 NHG Policy for Tissue Banks version 3, dated 11/2/22

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