

CHICKEN SOUP FOR THE BUSY COORDINATOR

May 2023

Storage/Usage/Supplying of Leftover Human Tissue from Current HBR

Scenario:

Principal Investigator (PI), Dr Y, would be collecting blood from subjects who had consented to participate in his Human Biomedical Research (HBR) research study. Dr Y would like to find out from the National Healthcare Group Tissue Compliance Committee (NHG TCC) on the actions required if he intends to store the leftover blood for future research.

Storage/Usage/Supplying of Leftover Tissue for Future Research

The NHG TCC secretariat apprised Dr Y of the following:

If Dr Y is storing leftover tissues from his completed study for future research, where the future research has not been approved by the Institutional Review Board (IRB) yet or where leftover tissue will be supplied to an IRB approved research (HBR, Clinical Trial (CT)) for which Dr Y is not a PI, Co-Investigator or collaborator, such tissue banking activities would be under the oversight of the NHG TCC.

Dr Y should ensure the following:

1. For human tissue collected before 01 Nov 2019, donors had consented with an Informed Consent Form (ICF) containing the HBRA core elements 12(2)(a), 12(2)(f) and 12(2)(i).
2. For human tissue collected from 01 Nov 2019, donors had consented with an ICF containing all the HBRA 12(2) elements. If the current ICF is not 12(2) compliant, to amend it accordingly using the sample statements provided in the *NHG TR 1704-15 Optional Consent Form for the Donation of Leftover Biological Samples template* and submit it to NHG DSRB for approval before use.

Usage of Leftover Tissue After Study Closure (within Scope of Completed Research)

After Dr Y had completed his research study and would like to use any leftover tissue within the scope of the completed research (i.e. for data validation), he may do so for a period up to 12 months after the IRB's acknowledgment of study closure. After which, he would need to either:

1. Discard the leftover tissue if consent requirements are not met;
2. Transfer the leftover tissue to another of the researcher's own IRB-approved study;
3. Transfer the leftover tissue to another researcher's IRB-approved study in which the Dr Y is also part of the study team; or
4. Store the leftover tissue in a tissue bank registered with the NHG TCC.

Note: For non-NHG institutions, please refer to your respective research institutional policies.

References:

1. HBRA 2015
2. ^NHG 1601-A02 NHG Policy for Tissue Banks version 3, dated 11 February 2022
3. ^NHG TR 1704-15 Optional Consent Form for the Donation of Leftover Biological Samples
4. ^NHG PCT SOP 1501-B02 Interactions with NHG Tissue Compliance Committee
5. NHG Research Website-Human Tissue Framework (NHG :: RDO :: Human Tissue Framework)

^These documents can only be accessed via the NHG Intranet.

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****Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental. Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/guidelines relating to the above scenarios/case study.***