CHICKEN SOUP FOR THE BUSY COORDINATOR

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How Should Consent Be Obtained for the Collection of Tissue?

Scenario:

Dr Z from a NHG public healthcare institution is considering to collect tissue samples for future research. He approached NHG Tissue Compliance Committee (TCC) for advice on the informed consent requirements and informed consent process during recruitment.

Dr X: Who should obtain consent from donors?

TCC: Informed Consent discussion should be conducted by the Tissue Collection Applicant (TCA) or a trained team member who is listed in the approved Tissue Collection Application Form and delegated by the TCA to obtain consent from donors.

Dr X: Is there an Informed Consent Form (ICF) template I can use?

TCC: Yes. You may refer to 1705-04 Informed Consent Form for Donation of Biological Material Template. It is important to ensure that the required HBRA Section 12(2) elements are included in the informed consent form (ICF) . The ICF should be submitted to TCC for approval together with the Tissue Collection application form.

Dr X: How should the informed consent discussion be conducted?

TCC: The most current version of the ICF approved by the TCC should be used as a guide while describing to the donors all the necessary information that they need to make an informed decision about participation in the tissue donation.
The discussion should be conducted in a conducive environment, presented in a language that is understandable to the donor and given adequate time to consider and ask questions before making a decision. A witness should be present as required.

The ICF should be signed and personally dated by the donor or the person who consented on behalf of the donor, witness (if applicable), and by the person who conducted the informed consent discussion prior to any tissue banking activities. Each donor or the person who consented on behalf of the donor should receive a signed copy of ICF. The informed consent process* should also be documented to assure that donors are fully informed before deciding to volunteer as donors in tissue donation.

**the tissue collection/protocol reference number, date of informed consent, informed consent process (e.g. for use of substituted consent/impartial witness/ prescribed witness/translator, verification of the appropriate legal representative for consent), as well as the fact that a copy was given to the donor in the donor's source records (e.g. medical records).*

References:

**NHG PCT SOP 1501-C01 Informed Consent Form and Process Requirements version 2.1, dated 01 Mar 2024.*
**Tissue Compliance Circulars – Issue 01/2020 What is Appropriate Consent Taking with Tissue Donors?*
**NHG OHRPP Website – Tissue Compliance Circulars*
**These documents can only be accessed via the NHG Intranet. Please refer to respective Institution's policy and requirement.*

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