SECTION D – AUTHORIZATION, INFORMED CONSENT, DONOR SCREENING, AND TISSUE RECOVERY, COLLECTION, AND ACQUISITION

Current (14th edition)

D3.000 INFORMED CONSENT

D3.100 Requirements

Informed consent to acquire tissues and make them available for transplantation, therapy, research or education shall be obtained from a living donor or their legal representative, or from a client depositor in accordance with applicable laws or regulations. This informed consent shall be documented in a record of informed consent, the original or a copy of which shall be maintained in the donor’s or client depositor’s record at the tissue bank responsible for recovery, collection or acquisition, as well as in the donor’s record at the tissue bank whose Medical Director is responsible for the donor eligibility determination. In the case of an electronic or voice recorded record of informed consent, the original recording should be maintained in reproducible form.

NOTE: For international members, terminology used by the government/competent authority having jurisdiction applies regarding lawful informed consent for donation of tissues for transplantation, therapy, research, or education.

(with amendments)

D3.000 INFORMED CONSENT

D3.100 Requirements

Except for autologous tissue, informed consent to acquire tissues and make them available for transplantation, therapy, research or education shall be obtained from a living donor or their legal representative, or from a client depositor in accordance with applicable laws or regulations. This informed consent shall be documented in a record of informed consent, the original or a copy of which shall be maintained in the donor’s or client depositor’s record at the tissue bank responsible for recovery, collection or acquisition, as well as in the donor’s record at the tissue bank whose Medical Director is responsible for the donor eligibility determination. In the case of an electronic or voice recorded record of informed consent, the original recording should be maintained in reproducible form.

NOTE: For international members, terminology used by the government/competent authority having jurisdiction applies regarding lawful informed consent for donation of tissues for transplantation, therapy, research, or education.
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D5.210 Verification Procedures

D5.211 Confirmation
Prior to recovery or collection, staff shall confirm that in the case of a deceased donor, authorization for donation has been obtained and documented in a document of gift/authorization. In the case of a living donor, informed consent must be obtained and documented prior to the initial collection. If informed consent was not obtained prior to recovery (e.g., autologous tissue, surgical bone) or acquisition, it must be obtained as soon as practical after recovery or acquisition.

(with amendments)

D5.210 Verification Procedures

D5.211 Confirmation
Prior to recovery or collection, staff shall confirm that in the case of a deceased donor, authorization for donation has been obtained and documented in a document of gift/authorization. Except for autologous tissue, in the case of a living donor, informed consent must be obtained and documented prior to the initial collection from living donors. If informed consent was not obtained prior to recovery (e.g., autologous tissue, surgical bone) or acquisition, it must be obtained as soon as practical after recovery or acquisition.

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