

Changes to Standards – Informed Consent for Autologous Tissue 4-19-17

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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