

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

(relevant part only)

D2.000 AUTHORIZATION

D2.400 Core Elements for Authorization

The *Document of Authorization* shall contain *Adequate Information*. No *Document of Authorization* from an *Authorizing Person* shall be acted upon if it does not contain the following *Core Elements*. These *Core Elements* also apply to Standard D2.500.

Core Elements:

- 1) the name of the *Donor*;
- 2) the name, address, and telephone number of the *Authorizing Person*, and his/her relationship to the *Donor*;
- 3) an explanation that the tissue is a gift, and that neither the *Donor's* estate nor the *Authorizing Person* will receive monetary compensation or valuable consideration for it;
- 4) a description of the general types of tissue to be recovered;
- 5) a description of the permitted use(s) of the recovered tissues (i.e., transplant, therapy, research, or education);
- 6) an explanation that recovery of tissue requires the following actions, and the *Document of Gift/Authorization* thus specifically authorizes:
 - a) access to, and required disclosure of, the *Donor's* medical and other relevant records;
 - b) testing and reporting for transmissible diseases;
 - c) the removal of specimens which may include, but are not limited to, the spleen, lymph nodes, and blood samples, for the purpose of determining suitability and/or compatibility of donor and recipient;
 - d) the release to the tissue bank of any and all records and reports of a Medical Examiner, Coroner or Pathologist; and
 - e) such other requirements as may be applicable for the specific donation or tissue bank, such as transport of body, archiving of samples, etc.
- 7) contact information for the organization represented by the *Donation Coordinator*; and
- 8) any additional information required by laws or regulations.

The following information should be provided to an *Authorizing Person*:

- 1) a general description of the recovery e.g., timing, relocation of donor if applicable, contact information, etc.;
- 2) an explanation that costs directly related to the evaluation, recovery, preservation, and placement of the tissues will not be charged to the family;
- 3) an explanation regarding the impact the donation process may have on burial arrangements and on appearance of the body; and
- 4) an explanation that the *Document of Authorization* is available.

Any explanation required by law, such as an explanation that multiple organizations (nonprofit and/or for profit) may be involved in facilitating the gift(s) and/or reference to the possibility that tissue may be transplanted abroad, must be included.

When an Organ Procurement Organization (OPO), or other entity (e.g., hospital), has initiated the process of obtaining *Authorization* for a potential organ and tissue donation, the *Tissue Bank* for which the *Authorization* is being obtained shall request that the OPO or other entity follow the procedure and utilize a *Document of Authorization* that satisfies the requirements of Standard D2.000.

For a *Donor* one month (28 days) of age or less, adequate consent pursuant to law shall be obtained for collection of blood from the birth mother needed for testing.