

## NTRUS – DEFINITIONS OF TERMS

### From A2.000 DEFINITIONS OF TERMS

Words that are defined here appear throughout the survey.

**ACQUISITION (BT)** – The point after delivery at which *tissue* is under the control of the *tissue bank*.

**ADVERSE OUTCOME** – An undesirable effect or untoward complication in a *recipient* consequent to or reasonably related to *tissue transplantation*.

**ALLOGENEIC** – Used as an adjective to modify donation, *tissue*, *donor* or *recipient* when *transplantation* is intended for a genetically different person.

**ALLOGRAFT** – *Tissue* intended for *transplantation* into a genetically different person.

**AORTOILIAC GRAFT (C)** - The distal segment of the abdominal aorta including the bifurcation and proximal segments of both the left and right common iliac arteries.

**ARTERIAL GRAFT (V)** – A segment of peripheral artery that is recovered, processed and *preserved*.

**AUTHORIZATION** – Permission given after *adequate information* concerning the donation, *recovery* and use of *tissues* is conveyed.

**AUTHORIZING PERSON** – Upon the death of the *donor*, the person, other than the *donor*, authorized by law to make an anatomical gift.

**AUTOGRAFT (A)** – *Tissue* intended for implantation, *transplantation* or infusion into the *living donor* from whom it was *recovered*.

**AUTOLOGOUS** – Used as an adjective to modify donation, *tissue*, *donor* or *recipient* when donation is intended only from him/herself and *transplantation* is intended only to him/herself.

**BIRTH TISSUE (BT)** – gestational *tissue* donated at the time of delivery of a living newborn. This includes placenta, Wharton’s jelly, amniotic fluid, chorionic membrane, amniotic membrane, placental/chorionic disc, umbilical veins, and umbilical cord tissue.

**CARDIAC TISSUE (C)** – *Tissue* type that includes, but is not limited to, *valved conduits*, *non-valved conduits*, *aortoiliac grafts*, and *patch grafts*.

**CELLULAR TISSUE (CT)** – viable cells that are *autologous* or *allogeneic*, committed or uncommitted, and non-expanded.

**CRYOPRESERVED** – Frozen with the addition of, or in a solution containing, a *cryoprotectant* agent such as glycerol or dimethylsulfoxide.

**DESICCATION** – The removal of water from *tissue*. For example, desiccation methods *may* include

chemical (alcohol), critical/supercritical drying, simple air drying, or drying in a desiccator.

**DISTRIBUTION** – A process that includes receipt of a request for *tissue*, selection of appropriate *finished tissue*, preparation for transport, any required inspections, and subsequent shipment and delivery of *tissue* to another *tissue bank*, *tissue distribution intermediary*, *tissue dispensing service*, or *end-user*.

**DONOR ELIGIBILITY ASSESSMENT** – The evaluation of available information about a potential *donor* to determine whether the *donor* meets qualifications specified in the *AATB Standards*

**DONOR REGISTRY** – A database established in accordance with law, consisting of legally valid *documents of gift*.

**DURA MATER (DM)** – A type of soft *tissue* that includes the pachymeninx (thick, membranous) tissue covering the brain.

**END-USER** – A health care practitioner who performs *transplantation procedures*.

**FINISHED TISSUE** – *Tissue* that has been fully *processed*, enclosed in its final *container*, *labeled*, and released to *distribution* inventory.

**INFORMED CONSENT** – Permission given by a *living donor (LD)* or *client depositor* who is presented with a description of the scope, use and any risks or benefits to her or him of the proposed donation, and who has been given the opportunity to ask questions and receive accurate answers. An LD who gives her or his *informed consent* to donation *shall sign* a record of the *informed consent*.

**LIVING DONOR (LD)** – A person who consents to the *recovery* or *collection* of his or her *tissue*, where *recovery* or *collection* is to take place while she or he is alive. For all *living donors*, (LD) standards apply, then *tissue-specific* standards apply. A *living donor* is a type of *donor* and, unless otherwise specified, standards that apply to *donors* in general apply to *living donors*.

**LYOPHILIZED** – *Tissue* dehydrated for *storage* by conversion of the water content of frozen *tissue* to a gaseous state under vacuum that extracts moisture.

**NONCONFORMITY** - A finding that identifies non-fulfillment of an accreditation requirement, a standard, policy, process, *procedure*, or specification.

**NON-TERMINAL IRRADIATION** – Ionizing radiation used to reduce microbes prior to *processing*.

**NON-VALVED CONDUIT (C)** – A length of cardiac outflow tract (aortic or pulmonic) from which the valve structure has been removed or intentionally rendered completely non-functional.

**OSTEOARTICULAR GRAFT** – A weight bearing *allograft* with intact articular surfaces, consisting of a joint with associated soft *tissue* and bone.

**PATCH GRAFT (C)** – A segment of cardiac *allograft* conduit to be used in cardiovascular repair, replacement, construction, or reconstruction.

**PHYSICAL ASSESSMENT** – A recent ante-mortem or postmortem documented evaluation of a deceased *donor's* body that can identify evidence of: high-risk behavior and signs of HIV infection or hepatitis infection; other viral or bacterial infections; or, trauma to the potential *recovery* sites.

**PHYSICAL EXAMINATION** – A recent documented evaluation of a *living donor's* body to determine whether there is evidence of high risk behavior and that determines overall general health of the *donor*. After a *donor risk assessment interview* is completed and if any history is suspect, the physical examination *should* also encompass a directed examination (of a body part or region).

**PLASMA DILUTION** – A decrease in the concentration of the *donor's* plasma proteins and circulating antigens or antibodies resulting from the transfusion of blood or blood components and/or infusion of fluids, e.g., *colloid(s)* and/or *crystalloid(s)*.

**PROCESSING** – Any activity performed on *tissue* other than *donor* screening, *donor* testing, *tissue recovery*, *collection*, or *acquisition* functions, *storage*, *distribution* or dispensing. It includes but is not limited to *disinfecting*, *sterilizing*, *packaging*, *labeling*, and testing *tissue*.

**RECOVERY** – Obtaining *tissue* other than *reproductive tissue* from a *donor* that is intended for use in human *transplantation*, therapy, research or education.

**RECOVERY SITE** – The immediate area or room where a *tissue recovery* takes place (e.g., dedicated *tissue recovery site*, healthcare facility operating room, autopsy suite).

**SATELLITE FACILITY** – A facility operated or owned by the *tissue bank* and located in a physically separate location from its primary address, and where any tissue banking activities occur or where any tissue banking services are provided.

**SKIN (S)** - A membranous soft *tissue* type that includes, but is not limited to epidermis and dermis.

**STORAGE** – The maintenance of *tissue* for future use.

**SURGICAL BONE (SB)** – Any bone from a *living donor* for *allogeneic* use such as a femoral head removed during surgery.

**TISSUE** – A functional group of cells. The term is used collectively in *Standards* to indicate both cells and *tissue*.

**TISSUE BANK** – An entity that provides or engages in one or more services involving *tissue* from living or deceased persons for *transplantation* purposes. These services include obtaining *authorization* and/or *informed consent*, assessing *donor* eligibility, *recovery*, *collection*, *acquisition*, *processing*, *storage*, *labeling*, *distribution* and dispensing of *tissue*.

**TISSUE DISPENSING SERVICE** – Any entity that receives, *stores*, and provides *tissue* directly to an *end-user* for *transplantation*. *Tissue dispensing services* may or may not be *tissue banks*, depending on what other functions they perform.

**TISSUE DISTRIBUTION INTERMEDIARY** – An intermediary agent who acquires and *stores tissue* for further *distribution* and performs no other *tissue banking* functions.

**TRANSPLANTATION** – The transfer of an *allograft* or *autograft* to a *recipient*.

**VALVED CONDUIT (C)** – An *allograft* heart valve with an attached length of cardiac outflow tract (aortic or pulmonic).

**VASCULAR TISSUE (V)** – *Tissue* type that includes, but is not limited to *arterial grafts* and *vein grafts*.

**VEIN GRAFT (V)** – A segment of vein that is *recovered*, *processed* and *preserved*.

### From A3.000 ACRONYMS AND ABBREVIATIONS

**CFR** – Code of Federal Regulations. Published by the Office of the Federal Register, National Archives and Records Administration, Washington, DC.

**e.g.** – *exempli gratia*; for example, such as; the list is not finite.

**FDA** – The United States Food and Drug Administration.

**i.e.** – *id est*; that is; indicates a finite list.

### This term/definition appears in a new AATB Guidance Document (No. 9):

**DEDICATED TISSUE RECOVERY SITE (DTRS)** – A tissue recovery room under control of, and with access restricted by, the tissue recovery agency(ies). Other than tissue recovery or other aseptic activities (e.g., organ perfusion or packaging), no other activities occur here, and controls include cleaning, decontamination, maintenance, and monitoring.

### Definitions specifically developed for use in the NTRUS questions:

**Tissue as a Device** (i.e., products and combination products requiring PMA or 510k clearance; regulated under the FD&C Act as well as under 21 CFR Part 1271 from Section 361 of the PHSA)

**Tissue as a Biological Product** (i.e., products requiring BLA or IND; regulated under Section 351 of the PHSA and/or the FD&C Act, as well as under 21 CFR Part 1271 from Section 361 of the PHSA)

**Tissue as a Drug** (i.e., products requiring IND/NDA; regulated under Section 201 of the FD&C Act, as well as under 21 CFR 1271 from Section 361 of the PHSA)

**Ligaments** (i.e. patellar)

**Tendons** (e.g., Achilles, gracillis, anterior/posterior tibialis, semitendinosus, flexors/extensors, peroneus longus)

**Osteochondral Grafts** (i.e., an allograft consisting of a section, condyle, or plug of bone with an intact articular surface)