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 Accident: Any occurrence, not associated with a deviation from standard operating procedures (SOPs), standards, or applicable laws and regulations, during donor screening or testing, or tissue recovery, collection or acquisition, processing, quarantining, labeling, storage, distribution, or

dispensing that may affect the performance, biocompatibility, or freedom from transmissible pathogens of the tissue or the ability to trace tissue to the donor.

- Acquisition (BT): The point after delivery at which tissue is under the control of the tissue bank.
- 3. adequate information: Information sufficient for the donor, the authorizing person or the living donor to make a voluntary decision regarding the gift of tissues for transplantation, therapy, research and/or education. The parameters of what constitutes adequate information must include "Core Elements" contained in D2.400 or D3.400, and such additional information as the donor, authorizing person, or living donor requests or which the donation coordinator reasonably believes the donor, authorizing person or living donor should know. When the donor is authorizing the gift of tissue, publicly available information concerning the scope and use of the gift shall be deemed adequate information.
- 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.
- 7. ANNUAL: A frequency of activity defined by each tissue bank as 12 months including reasonable tolerance limits (up to 3 months). Justification for the tolerance limits shall be documented by the tissue bank with consideration for the risk associated with the specific activity scheduled.
- ANONYMOUS DONOR (R): A reproductive donor of tissue whose identity is unknown to the recipient (R).
- 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.
- 11. ARTIFICIAL INSEMINATION (R): The placement of semen within the reproductive tract of a recipient (R).
- 12. ASEPTIC PROCESSING: The processing of tissue using aseptic techniques where tissue, containers and/or devices are handled in a controlled environment in

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Sabine Zange



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