

European Network of Competent Authorities for Tissues and Cells

HPC

Glossary



Allogeneic use: cells removed from one person and applied to another.

<u>Autologous use</u>: cells removed from and applied in the same person.



Banking: Processing, preservation, storage and distribution of cells for human application or other purposes, including research and training.

<u>Bone Marrow:</u> Tissue at the centre of large bones. It is the place where new blood cells are produced. Bone marrow contains two types of stem cell: haematopoietic (which can produce blood cells) and stromal (which can produce fat, cartilage and bone). In this collection: as a source of hematopoietic stem cells or mesenchymal stem cells.



<u>Cells</u>: means individual human cells or a collection of human cells when not bound by any form of connective tissue.

<u>Collection:</u> any procedure for procuring a cellular therapy product regardless of technique or source (Synonym: harvest).

<u>Competent Authority</u> (or Health Authority/Regulatory Authority/Regulatory Agency): the body which has been delegated with the responsibility for ensuring that tissue and cell donation, banking and human application are appropriately promoted, regulated and monitored in the interests of donor and patient safety and public transparency on a national or regional basis by their government.

<u>Cord Blood</u>: Blood collected from placental vessels and umbilical cord blood vessels after the umbilical cord is clamped and/or severed as a source of haematopoietic progenitor cells.

<u>Cord Blood Bank:</u> An organisation responsible for donor management and the collection, processing, testing, cryopreservation, storage, listing, reservation, release, and distribution of cord blood units.

<u>Cryopreservation:</u> Preservation and storage of viable tissues and cells (including gametes and embryos) to preserve viability, either by freezing or vitrification, or alternatively (to extend their viable life) by low-temperature storage.



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<u>Distribution:</u> transportation and delivery of tissues or cells intended for human applications.

<u>Donation</u>: donating human tissues or cells intended for human applications.

<u>Donation centre:</u> An organisation responsible for donor recruitment, consenting, testing, management and the collection of donor personal, genetic, medical data.

Donor: Every human source, whether living or deceased of human cells.

Donor Registry: An organisation responsible for coordination of the search for haematopoietic stem cells from donors (including cord blood) unrelated to the potential recipient.



HPC Transplant Centre: A medical facility where a patient (recipient) receives a transplant (graft) with HSC from an unrelated donor or from an umbilical cord blood unit. The TC oversees the immediate medical treatment and provides long-term follow-up of the recipient. The search unit undertakes the search for an unrelated donor for specific patients using criteria defined and documented by the TC. This entity may be contained within a TC or may be separate from the TC. If separate, the search unit may coordinate searches for one or several TCs. In the standards, reference to a TC should be interpreted as a TC and/or a search unit as appropriate. Transplant centres/search units seeking an international donor work through the registry in their country.

<u>Hematopoietic Progenitor Cells (HPC):</u> Primitive haematopoietic cells capable of self-renewal as well as maturation into any of the haematopoietic lineages, including committed and lineage-restricted progenitor cells, unless otherwise specified and regardless of tissue source. Also referred to as 'haematopoietic stem cells.

<u>Human Application:</u> The use of tissues or cells on or in a human recipient.

<u>Human tissues and cells for human application</u>: Material containing or consisting of human tissues and/or cells intended for implantation, transplantation, infusion, or transfer into a human recipient.



<u>Number of cells distributed</u>: the total number transported or delivered to a clinical unit (as Article 3 (k) of Directive 2004/23/EC defines. **Distribution**: "means transportation and delivery of tissues or cells intended for human applications" (Article 3 (k) Directive 2004/23/EC), whereas 'human application' is defined in the same article as follows: "means the use of tissues or cells on or in a human recipient and extracorporeal applications'.)



<u>Organisation responsible for human application:</u> means a healthcare establishment or a unit of a hospital or another body which carries out human application of human tissues and cells



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<u>Peripheral Blood</u>: in this collection: HSC hematopoietic stem cells collected in peripheral blood by apheresis.

<u>Potential donor:</u> Any person who has no medical contraindications for organ, tissue or cell donation and who meets the definition of a deceased heartbeating donor, deceased non-heartbeating donor or living donor.

<u>Procurement organisation:</u> means a health care establishment or a unit of a hospital or another body that undertakes the procurement of human tissues and cells and that may not be accredited, designated, authorised or licensed as a tissue establishment.



Recipient: Person to whom human tissues, cells or reproductive cells and embryos are applied.

<u>Related:</u> Existence of a genetic relationship between donor and recipient.



Search Performed: Number of searches for compatibility performed in the marrow registry.



<u>Transplantation/implantation/grafting:</u> Transfer (engraftment) of human tissues or cells from a donor to a recipient with the aim of restoring function(s) in the body.

<u>Transplant Centre:</u> See Organisation responsible for human application.



<u>Unique donation number</u>: The unique number attributed to a specific donation of tissues and cells in line with the system in place in each Member State for allocating such numbers, as further specified in Annex VII to Commission Directive (EU) 2015/565.

Unrelated: Where there exists no genetic relationship between donor and recipient.