Comparison of Objectives, Scope, Definitions
The tables are populated with data from the FACT-JACIE, Netcord-FACT, WMDA and AABB Standards

Definitions	**Abbreviation**
WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries Version January 2014	**W**
FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing and Administration 6th Edition	**F-J**
Netcord-FACT International Standards for Cord Blood Collection, Banking and Release for Administration 6th Edition	**NC-F**
AABB Standards for Cellular Therapy Services 6th Edition	**AA**
Specific definition not addressed in the standards	**Not defined**

Definitions are meant to clarify how terms that may not be in common usage are used to understand the standards

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OBJECTIVE	These standards are aimed at enhancing the quality of Registries assisting the grafting physician responsible for patient treatment in the international search for an unrelated donor for their patient	To promote quality medical and laboratory practice in hematopoietic progenitor cell transplantation and other therapies using cellular products.	To promote quality medical and laboratory practices throughout all phases of cord blood collection, banking, and release for administration to achieve consistent production of high quality placental and umbilical cord blood units for administration.	The goal of the *CT Standards* is to maintain and enhance the quality and safety of procurement, processing, storage, and administration of cellular therapy products.
SCOPE	These standards promote the quality of procedures necessary to obtain, in the shortest possible time, the appropriate quality and quantity of hematopoietic stem cells of the best unrelated donor suitable for engrafting a patient while protecting the anonymity, health and well-being of the volunteer donors.	FACT-JACIE Standards are now called FACT-JACIE *International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration*, also referred to as the Hematopoietic Cell Therapy Standards. The purpose of the name change is to define the scope	The scope of the Standards includes only the use of cord blood for clinical use. For cord tissue storage, these Standards only apply to tissue samples retained for testing or research purposes. Collection and storage of cord tissue for therapeutic intent fall under the scope of the FACT Common	Uses a quality systems framework to address overall facility operations and technical activities The standards address the procurement, processing, storage, and administration of cellular therapy products while emphasizing quality and patient safety. These standards can be applied to all cellular

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		of these requirements due to an increasing number of accredited facilities that support non-hematopoietic cellular therapies and because FACT now has a separate set of Standards for those services (the Common Standards for Cellular Therapies). The scope of the Hematopoietic Cell Therapy Standards includes: i. Collection, processing, and administration of hematopoietic progenitor cells (HPCs), whether minimally or more than minimally manipulated, for hematopoietic indications. ii. Collection, processing, and administration of cellular therapy products for donor lymphocyte infusion (DLI).	Standards for Cellular Therapies. The Standards explicitly added "for testing" to clearly state why cord tissue is referenced. (B5.9.2). The Cord Blood Bank (CBB) must have a policy or procedure to request the following information (in addition to previous requirements) for every CB unit released for administration for hematopoietic reconstitution: (E7.1). The CBB must have a policy to request outcome data that is relevant to other uses for which the CB unit was released. (E7.2)	therapy products, but provide more specific technical requirements for hematopoietic progenitor cells, including those derived from apheresis, marrow, and cord blood
DEFINITIONS				
Accompany	Not defined	To go, be together with, or be available to the appropriate individual(s) electronically, but not affixed or attached. Written or printed information that must accompany a cellular therapy product must be in a sealed package with, or	To go or to be together with, but not attached. Information that must accompany the cord blood unit in a sealed package may alternatively be attached or affixed.	Not defined

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		alternatively, be attached or affixed to, the cellular Therapy product container.		
Accreditation Cycle	Not in the standards, but in the "WMDA ACCREDITATION POLICIES & PROCEDURES"…	The period of time from the awarding of accreditation until its expiration as set, and subject to change, by FACT or JACIE. At publication of these Standards, this period is three (3) years for FACT-accredited programs and four (4) years for JACIE-accredited programs	Not in definitions, in Introduction to the standards	Not in the standards; defined in Accreditation Program Policy Manual
Advanced Practitioner	Not defined	Advanced Practitioner of Nursing: includes certified nurse anesthetist, nurse practitioner, certified nurse midwife, and clinical nurse specialist.	Not defined	Not defined
Active Labor	Not defined	Not defined	Not defined	For the purposes of donor consent, the time when the cervix dilates from 4 cm to 8 cm and contractions are ≤5 minutes apart, lasting up to 60 seconds. The time when the parent's contractions are ≤5 minutes apart, lasting up to 60 seconds.
Administration	Not defined	Not defined, but term used in title and throughout document to mean delivery of product into a recipient.	Delivery of a cord blood unit to the recipient (via routes such as infusion).	With respect to cellular therapy products, the act of delivering the product into a recipient, including, but not limited to, infusion,

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				transplantation, implantation, or injection.
Adventitious agent	Not defined	Not defined	Any extraneous microbiological, chemical, or radiobiological substance introduced into the cord blood unit during collection, processing, or administration.	Not defined
Adverse event / serious adverse event	SAE (serious adverse event): Any untoward occurrence associated with the procurement, testing, processing, storage, and distribution of tissues and cells that might lead to the transmission of an infectious disease, to death or life threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity.	Any unintended or unfavourable sign, symptom, abnormality, or condition temporally associated with an intervention that may or may not have a causal relationship with the intervention, medical treatment, or procedure. Adverse reaction is a type of adverse event.	Any unintended and unfavourable sign, symptom, abnormality, or condition temporally associated with an intervention, medical treatment, or procedure that may or may not have a causal relationship with the intervention, medical treatment, or procedure. Adverse reaction is a type of adverse event.	A suspected or proven unfavourable response to the procurement or administration of cellular therapy products, manifested by signs or symptoms.
Adverse reaction / serious adverse reaction	SAR: (serious adverse reaction): An unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.	A noxious and unintended response suspected or demonstrated to be caused by the collection or infusion of a cellular therapy product or by the product itself.	A noxious and unintended response to the collection or infusion of any cord blood unit for which there is reasonable possibility that the cord blood unit caused the response.	See “adverse event”

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Affix	Not defined	To adhere in physical contact with the cellular therapy product container.	To adhere in physical contact with the cord blood unit container.	Labelling standards differentiate between permanently affixed and affixed or attached.
Agreement	Not defined	Not defined	Not defined	A contract, order, or understanding between two or more parties, such as between a facility and one of its customers. Agreements can be written or verbal, though verbal agreements should be documented (eg, a written summary of the agreement should be available.)
Allogeneic	Not defined	The biologic relationship between genetically distinct individuals of the same species.	Obtained from an infant donor and intended for infusion into a genetically distinct recipient.	Allogeneic Donor: An individual from whom cellular therapy products intended for another person are procured. This individual may or may not be genetically related to the recipient.
Analyte	Not defined	Not defined	Not defined	Substance or chemical constituent that is assayed.
Apheresis	Not defined	A medical technology in which the blood of a donor is separated into its component parts, the desired component is removed, and the remaining components are returned to the donor.	Not defined	Not defined

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Applicable Law	Not defined	Not defined	Any local, national, or international statute, regulation, or other governmental law that is applicable to cord blood donor management including recruitment or eligibility, or to cord blood collection, processing, testing, cryopreservation, storage, listing, search, selection, reservation, release, or distribution that is relevant to the location or activities of the Cord Blood Bank, Cord Blood Collection Site, or Cord Blood Processing Facility.	Not defined
Aseptic technique	Not defined	Practices designed to reduce the risk of microbial contamination of products, reagents, specimens, patients, or donors.	Practices designed to reduce the risk of microbial contamination of products, reagents, specimens, patients or donors.	Aseptic Methods: Methods designed to eliminate the risk of microbial contamination to a product, reagent, specimen, or person in a laboratory or clinical-care setting.
Assessment	Not defined	Not defined	Not defined	A systematic and independent examination to determine whether activities comply with planned activities and whether these activities are implemented effectively and are suitable to achieve objectives. Assessments also include comparison of results to expected results. Types of

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				assessments include external assessments, internal assessments, peer reviews, and self-assessments.
Attach	Not defined	To fasten securely to the cellular therapy product container by means of a tie tag or comparable alternative. Any information required to be attached to a cellular therapy product container may alternatively be affixed.	To fasten securely to the cord blood unit container by means of a tie tag or comparable alternative. Any information required to be attached to a container may alternatively be affixed	See "Affix." Labelling standards differentiate between permanently affixed and affixed or attached.
Audit	Not defined but referenced in that a quality system must include a process to audit the system.	Documented, systematic evaluation to determine whether approved policies or procedures have been properly implemented and are being followed.	Documented, systematic evaluation to determine whether approved policies, Standard Operating procedures, or operations have been properly implemented and are being followed.	Assessment: A systematic and independent examination to determine whether activities comply with planned activities and whether these activities are implemented effectively and are suitable to achieve objectives. Assessments also include comparison of results to expected results. Types of assessments include external assessments, internal assessments, peer reviews, and self-assessments.
Autologous	Not defined	Derived from and intended for the same individual.	Derived from and intended for the same individual.	Autologous Donor: A person who acts as his or her own cellular therapy product donor.

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Available for distribution	Not defined	The time at which the cellular therapy product may leave the control of the facility.	The time at which the cord blood unit may leave the control of the facility.	The determination that a product has met all relevant requirements (e.g., donor eligibility, product processing, etc.) and can be issued for clinical use.
Biohazard legend	Not defined	Not defined	The universal biohazard symbol	Not defined
Biologic Mother	Not defined	Not defined	Defined as genetic mother: "The woman from whose egg the infant donor develops; the egg donor."	The female who is the source of the ovum.
Birth Mother	Not defined	Not defined	The woman who carries the infant donor to its delivery; may be the genetic mother or a surrogate mother	The female carrying the fetus to term.
Biologic Agent	Not defined	Not defined	Not defined	A biologic agent is a protein-based substance that is made from a living organism or its products and is used in the prevention, diagnosis, or treatment of cancer and other diseases. Biologic agents include antibodies, interleukins, and vaccines.
Biological product deviation	Not defined	Any event associated with the manufacturing of a cellular therapy product, including testing, processing, packing, labeling, or storage, or with the holding or distribution, of a licensed biological product, if that event meets all the following criteria:	For unlicensed cord blood units, a deviation from Applicable Law, standards, or other established specifications that relate to the prevention of communicable disease transmission or cord blood unit contamination; or an unexpected or unforeseeable	Nonconforming Product or Service: A product or service that does not satisfy one or more specified requirements, such as an unacceptable cellular therapy product, test run, or apheresis procedure; a product with a lower cell dose

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		Either:
		• Represents a deviation from current good manufacturing practice (or current good tissue practices), applicable regulations, applicable standards, or established specifications that may affect the safety, purity, or potency of that product; or
		• Represents an unexpected or unforeseeable event that may affect the safety, purity, or potency of that product; and
		  ○ Occurs in your facility or another facility under contract with you; and
		  ○ Involves a distributed biological product.
			event that may relate to the transmission or potential transmission of a communicable disease or may lead to cord blood unit contamination.
			
			For licensed cord blood units, a deviation from current good manufacturing practice, applicable regulations, applicable standards, or established specifications that may affect the safety, purity, or potency of the product.
				than expected; or a positive bacterial culture of a product.

Blood collection centre	A medical facility at which blood intended for transfusion is drawn and stored	Not defined	Not defined	Not defined
By products	Not defined	Not defined	Not defined	Portions of the original cellular therapy product retained for nonclinical use. Examples include cell fractions and removed plasma.
Cadaveric donors	Not defined	Not defined	Not defined	A deceased individual from whom cellular therapy products or organs are

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				procured. If donation occurs following cardiac death, infectious disease testing must be performed using test kits that are specifically cleared or approved for use in cadaveric donors.
Calibrate/ Calibration	Not defined	To set measurement equipment against a known standard.	To set measurement equipment against a known standard. / Periodic scheduled activity to check and maintain the accuracy against at known standard	To set or align measurement equipment against a known standard.
CD34	Not defined	The 115 kD glycoprotein antigen, expressed by 1-2% of normal bone marrow mononuclear cells, that is defined by a specific monoclonal antibody (anti-CD34) using the standardized cluster of differentiation (CD) terminology.	The 115 kD glycoprotein antigen, expressed by a small portion of cord blood cells, that is defined by a specific monoclonal antibody (anti-CD34) using the standardized cluster of differentiation (CD) terminology. Hematopoietic progenitor cells are largely contained within the CD34 cell population of cord blood units.	Not defined
Cells / Human cells, tissues, or cellular or tissue-based products (HCT/Ps)	Not defined. WMDA Standards defines only "Hematopoietic progenitor cells"	Articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.	See "Cellular Therapy Product"	See "Cellular Therapy Product." Cellular Therapy Product: Somatic cell-based products (i.e., stem or differentiated cells) that are procured from a donor and intended for

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				manipulation and/or administration.
Cell Processing Unit	A medical laboratory facility where HPC are manipulated prior to transplantation. These activities may include the depletion of specific cell types from the graft, selection for specific cell types for infusion, ex vivo manipulation of cells in the graft, or concentration of the cell product.	See Processing Facility: A location where cellular therapy product processing activities are performed in support of the Clinical Program. A Processing Facility may be part of the same institution as the Clinical Program or may be part of another institution and perform these functions through contractual agreement.	See Cord Blood Processing Facility: The location where cord blood processing activities are performed in support of the Cord Blood Bank. A Cord Blood Processing Facility may be part of the same institution as the Cord Blood Bank or may be part of another institution and performs these functions through contractual agreement.	See "Facility." Facility: A location where any activities covered by these CT Standards are performed. These activities include determination of donor eligibility, procurement, processing, storage, distribution, issue, and administration. AABB accreditation is granted to specified facilities for specific activities.
Cellular therapy	Not specifically defined	The administration of products with the intent of providing effector cells in the treatment of disease or support of other therapy.	Not defined	See "Medical Therapy."
Cellular therapy product	Not defined	Somatic cell-based product (e.g. mobilized HPC, therapeutic cells, cord blood cells, mesenchymal stromal cells) that is procured from a donor and intended for processing and administration	A somatic cell-based product, including cord blood, that is procured from a donor and intended for processing and administration.	Cellular Therapy Product: Somatic cell-based products (i.e., stem or differentiated cells) that are procured from a donor and intended for manipulation and/or administration.
Central venous catheter (CVC)	A catheter placed in a vein in the neck (internal jugular vein), chest (subclavian or	Not defined	Not defined	Not defined

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	axillary vein) or in the groin (femoral vein).			
Certified by CMS	Not defined	Not defined	Not defined	Having met the requirements of the Clinical Laboratory Improvement Amendments of 1988 through inspection by the CMS, a deemed organization, or an exempt state agency.
Circular of Information	Not defined	An extension of container labels that includes the use of the cellular therapy product, indications, contraindications, side effects and hazards, dosage, and administration recommendations.	An extension of container labels that includes handling instructions for the use of the cord blood unit, indications, contraindications, side effects and hazards, dosage, and administration recommendations.	Not defined
Clinical Activities	Not defined	Not defined	Not defined	The tasks performed by integrated patient care teams linked by a uniform quality management system and reflected in the organizational structure.
Clinical Program Also see Transplant Program	Defined as Transplant Center	An integrated medical team housed in geographically contiguous or proximate space with a single Clinical Program Director and common staff training programs, protocols, and quality management systems. The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with	An integrated medical team that administers cord blood units as a source of cells for its patients.	Clinical Facility: The facility(ies) responsible for the administration of the product and related patient care activities.

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		respect to their interactions with the Clinical Program. Clinical Programs that include non-contiguous institutions shall demonstrate evidence of regular interaction and common protocols, staff training procedures, quality management systems, and review of clinical results.		
Colony forming unit (CFU)	Not defined	Not defined	A clonogenic cell able to produce hematopoietic colonies in vitrounder specific conditions in the presence of appropriate colony stimulating factors and defined by the type of mature progeny that develop	Not defined
Collection kit	Not defined	Not defined	Package of all materials required to collect a single cord blood unit.	Not defined
Collection Facility (Collection Centre)	A medical facility where HPC collection from volunteer donors actually takes place. This collection might include marrow aspiration or apheresis. The collection centre, or designee, performs the medical work-up of the volunteer donor and provides the final approval of the volunteer donor for collection. The collection centre packages	An entity providing the service of cellular therapy product collection. A Collection Facility may be part of the same institution as the Clinical Program or may be part of another institution and perform cellular therapy product collection services through contractual agreement.	See Cord Blood Collection Site	Procurement Facility: Either a facility that is directly responsible for the performance of donor eligibility determination, donor screening, and the procurement of cellular therapy products or a facility that ensures, through agreements, that one or more of these activities is/are performed in conformance with these CT Standards.

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	the donation for transport to the transplant centre.			
Communicable disease	Not defined WMDA defines IDM	Not defined	A disease or disease agent for which there may be a risk of transmission by a cord blood unit either to a recipient or to the people who may handle or otherwise come in contact with the cord blood unit.	Not defined
Competency	Not defined	Ability to adequately perform a specific procedure or task according to direction	Ability to adequately perform a specific procedure or task according to directions.	Ability of an individual to perform a specific task according to procedures evaluated on an ongoing basis.
Competent Authority	Not defined	Not defined	Not defined	The agency responsible under its national law for regulations applicable to cellular therapy.
Complaint	Not defined	Any written, oral, or electronic communication about a problem associated with a cellular therapy product or with a service related to the collection, processing, storage, distribution, or infusion of a cellular therapy product.	Any written, oral, or electronic communication about a problem associated with a distributed cord blood unit or with a service related to donor management or the collection, processing, testing, cryopreservation, storage, listing, search, reservation, release, distribution, or administration of a cord blood unit.	Not defined
Conformance	Not defined	Not defined	Not defined	Fulfillment of requirements.
Consenter(s)	WMDA defines Signed valid informed consent: Signed documentation indicating that a volunteer donor or the maternal donor of umbilical	Not defined	Not defined	Individual(s) whose consent is obtained for the procurement of cellular therapy products. For cord blood procurement, this may include, but is not

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	cord blood has been provided with information on the procedure and tests performed the risks and benefits of the procedure, that they have understood the information provided, have had an opportunity to ask questions, have been provided with satisfactory responses and have confirmed that all information provided is true to the best of their knowledge. The consent is valid when it complies with national regulation.			limited to, the infant donor's birth mother, biologic mother, surrogate mother, and any legal custodians (when applicable). For cadaveric donors, this may include the donor, the donor's next of kin, or a legally authorized representative.
Contiguous segment	Not defined	Not defined	A sealed length of tubing integrally attached to the cord blood unit that contains a sample representative of the cord blood unit that may be used for testing.	Not defined
Continuous monitoring	Not defined	Not defined	Not defined	A mechanism that allows for surveillance of a process or system intended to ensure proper operation and the detection of control exceptions.
Controlled rate freezing	Not defined	Not defined	Not defined	A procedure using a device to control the temperature of a product during the freezing process.
Cord blood	Not defined	The whole blood, including HPC, collected from placental and umbilical cord blood	The infant's blood remaining in the placenta and umbilical	The portion of the blood of a fetus or neonate that remains in the placenta or umbilical

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		vessels after the umbilical cord has been clamped	cord after the umbilical cord has been clamped.	cord following delivery of the neonate and clamping of the umbilical cord. Umbilical cord blood is typically rich in hematopoietic progenitor cells.
Cord blood donor	Defined as "Donor":A person who is the source of cells or tissue for a cellular therapy product. Donors are unrelated to the patient seeking a transplant. These Standards refer to three types of donors: 1. volunteer donors of HPC; 2. infant donor whose placenta and/or umbilical cord the cord blood is obtained; 3. maternal donor who carries the infant donor to delivery.	See donor	See donor: A person who is the source of the cells or tissue for a cellular therapy product.	The infant who is the source of a cellular therapy product.
Cord Blood Bank	The facility responsible for the collection, processing, testing, banking and release of cord blood units.	Not defined	An integrated team under a single Cord Blood Bank Director responsible for donor management and the collection, processing, testing, cryopreservation, storage, listing, search, selection, reservation, release, and distribution of cord blood units.	See "Facility." Facility: A location where any activities covered by these CT Standards are performed. These activities include determination of donor eligibility, procurement, processing, storage, distribution, issue, and administration. AABB accreditation is granted to specified facilities for specific activities.

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Cord blood banking	Not defined	Not defined	The processing, testing, cryopreservation, storage, listing, search, selection, reservation, release, and distribution of cord blood units intended for administration.	Not defined
Cord blood collection	Not defined	Not defined	The procurement of cord blood for banking and administration before and/or after the placenta is delivered. Ex utero: The collection of cord blood cells from the placental and/or umbilical cord vessels after the placenta has been delivered. In utero: The collection of cord blood cells from the placental and/or umbilical cord vessels after the infant donor has been delivered and separated from the umbilical cord, but before the placenta has been delivered.	See “Procurement”
Cord blood collection site	A location where the infant donor is delivered and the cord blood unit is collected.	Not defined	The location where the infant donor is delivered and the cord blood unit is collected. Fixed Cord Blood Collection Site: A collection site where there is a written agreement between the collection site and the Cord Blood Bank for the	See “Procurement Facility”

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			collection of cord blood units over time. The agreement shall describe the interaction between the Cord Blood Collection Site and the Cord Blood Bank for all aspects of the collection process including, at a minimum, personnel training, record keeping, collection, storage, and transportation or shipping of a cord blood unit. Non-fixed Cord Blood Collection Site: A collection site where the collection of cord blood is initiated by the infant donor's mother and/or family, with documentation that a healthcare professional has agreed to perform the collection in accordance with the Cord Blood Bank collection procedures and has training that covers each aspect of the collection process.	

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Cord blood processing facility	Not defined	See Processing Facility	The location where cord blood processing activities are performed in support of the Cord Blood Bank. A Cord Blood Processing Facility may be part of the same institution as the Cord Blood Bank or may be part of another institution and performs these functions through contractual agreement.	See “Processing Facility”
Cord Blood Unit	Not defined	Not defined	The nucleated cells including stem and hematopoietic progenitor cells harvested from placental and umbilical cord blood vessels from a single placenta after the umbilical cord has been clamped. Unless otherwise specified, the term cord blood unit in this document refers to any cord blood unit regardless of method of collection or intended use.	Cord Blood: The portion of the blood of a fetus or neonate that remains in the placenta or umbilical cord following delivery of the neonate and clamping of the umbilical cord. Umbilical cord blood is typically rich in hematopoietic progenitor cells.
Corrective action	Not defined	Action taken to eliminate the causes of an existing discrepancy or other undesirable situation to prevent recurrence.	Action taken to eliminate the causes of an existing discrepancy or other undesirable situation to prevent recurrence.	An activity performed to eliminate the cause of an existing 19on-conformance or other undesirable situation(s) in order to prevent recurrence.
Critical	Not defined	The quality of any element employed in cellular therapy product manufacturing to potentially change the identity, purity, potency or safety of the	Not defined	Critical Equipment: A piece of equipment that can affect the quality of a facility’s products or services.

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		cellular therapy product if altered or omitted. "Element" includes, but is not limited to, materials, equipment, personnel, documents, or facility. For example, DMSO is a critical reagent because omitting it from the freezing medium will cause loss of cells during freezing and thawing.		Critical Material: A reagent or supply item that can affect the quality of a facility's products or services and is used in a process or procedure to prepare the cellular therapy product or service. Critical Tasks: Elements (such as materials, equipment, or tasks) that directly affect the quality of the product or service.
Cryopreservation	Not defined	Not defined	The processing of viable cells or tissues that consist of cooling the product to a very low temperature where viability is maintained.	The process of low-temperature freezing and storage of cellular therapy products in order to preserve cells that, after thawing, retain a significant measure of their prefreeze viability and function.
Cryoprotectant	Not defined	Not defined	Not defined	A solution or additive that, when combined with living cells, provides protection from damage otherwise induced by the freezing and/or thawing process.
Cultured Cells	Not defined	Not defined	Not defined	Cells that are expanded and/or differentiated in vitro in media requiring monitoring of gas

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				levels, temperature, humidity, and sterility.
Current Good Tissue Practice	Not defined	The methods used in, and the facilities and controls used for, the manufacture of cellular therapy products to prevent the introduction or transmission of communicable diseases, including all steps in collection, donor screening and testing, processing, storage, labelling, packaging, and distribution.	Not defined	Not defined
Current Good Manufacturing Practice:	Not defined	The set of current practices followed by entities producing drug and biologic products, including cellular therapy products, to ensure that the products produced meet specific requirements for identity, strength, quality, and purity. In the US, cGMPs are enforced under Section 501(B) of the Federal Food, Drug, andCosmeticAct(21USC351). Cellulartherapyproductsthatare extensively manipulated or that are used for non-autologous purposes are controlled under cGMP regulations. Similar requirements are enforced by the European Union as EU-	Not defined	Not defined

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		GMP, and other countries such as United Kingdom, Australia, Canada, and Singapore have equally well-developed systems of regulations		
Customer	Not defined	Not defined	Not defined	The receiver of a product or service provided by the supplier. A customer may be internal (ie, another department or person within the same organization) or external (ie, a person or organization that receives a product, a service, or information but is not part of the organization supplying it).
Designee	Not defined	An individual with appropriate education, experience or expertise who is given the authority to assume a specific responsibility. The person appointing the designee retains ultimate responsibility.	An individual with appropriate, experience or expertise who is given the authority to assume a specific responsibility. The person appointing the designee retains ultimate responsibility.	An individual with appropriate experience or expertise who is given the authority to assume a specific responsibility.
Deviation	Not defined	The action of departing from an established course or accepted standard. *Unplanned Deviation:* Occurred without intent. *Planned Deviation:* Was allowed to occur with documented approval as the best course of action when adherence to the	The action of departing from an established course or accepted standard. Unplanned Deviation: Occurred without intent.	Not following the appropriate policies, processes, or procedures. Deviations can be planned or unplanned. Not all deviations result in an unacceptable product or result.

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		established course or accepted standard was not feasible or possible.	Planned Deviation: Was allowed to occur with documented approval as the best course of action when adherence to the established course or accepted standard was not feasible or possible.	
Director	Not defined	Defined in standards: *The Clinical Program Director shall be a physician appropriately licensed or certified to practice medicine in the jurisdiction in which the program is located who has achieved specialist certification in one or more of the following specialties: Hematology, Medical Oncology, Pediatric Immunology, or Pediatric Hematology/Oncology. Physicians trained prior to requirements for specialty training may serve as Clinical Program Director if they have documented experience in the field of hematopoietic cell transplantation extending over ten (10) years.* *Licensed physician with postgraduate training in cell*	Cord Blood Bank Director, Cord Blood Bank Medical Director, Cord Blood Collection Site Director, Cord Blood Processing Facility Director	Laboratory Director: A qualified individual holding a relevant doctoral degree who is responsible for all technical aspects of the cellular therapy product service. Laboratory Medical Director: A qualified licensed physician who has overall responsibility and authority for all medical aspects of the cellular therapy product service. Clinical Program Director: A qualified physician who is board certified and licensed to practice medicine in at least one specialty or subspecialty and who is responsible for all aspects of the clinical program.

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		collection and/or transplantation. *There shall be an Apheresis Collection Facility Director who is an individual with a medical degree or degree in a relevant science, qualified by postgraduate training or experience for the scope of activities carried out in the Apheresis Collection Facility. The Apheresis Collection Facility Director may also serve as the Apheresis Collection Facility Medical Director, if appropriately credentialed.* *There shall be a Processing Facility Director who is an individual with a medical degree or doctoral degree in a relevant science, qualified by training or experience for the scope of activities carried out in the Processing Facility. The Processing Facility Director may also serve as the Processing Facility Medical Director, if appropriately credentialed.*		
Disposition	Not defined	Not defined	The current status, location, or use of a cord blood unit.	For cellular therapy products, the final status or control of a

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				cellular therapy product in a given facility. For records, disposition occurs at the end of their retention period.
Distribution	Not defined	Any transportation or shipment of a cellular therapy product that has been determined to meet release criteria or urgent medical need requirements.	Any transportation or shipment (including importation and exportation) of a cord blood unit that has been determined to meet all applicable release criteria or urgent medical need requirements.	The act of transferring a cellular therapy product that has been determined to meet applicable requirements or which is an authorized nonconforming product.
Document (noun)	Not defined	Not defined	Not defined	Written or electronically generated information (ie, quality manuals, policies, processes, procedures, agreements/contracts, labels, or forms).
Donor	A person who is the source of cells or tissue for a cellular therapy product. Donors are unrelated to the patient seeking a transplant. These Standards refer to three types of donors: 1. volunteer donors of HPC; 2. infant donor whose placenta and/or umbilical cord the cord blood is obtained; 3. maternal donor who carries the infant donor to delivery.	A person who is the source of cells or tissue for a cellular therapy product.	A person who is the source of cells or tissue for a cellular therapy product Infant donor: The infant from whose placenta and/or umbilical cord the cord blood is obtained. Maternal donor: The mother who carries the infant donor to delivery. This may be the genetic or surrogate mother. Unrelated donor: The infant donor whose cord blood is collected and stored for use by	A living or deceased person who is the source of a cellular therapy product.

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			a person with no known genetic relationship. Related donor: The infant donor whose cord blood is collected and stored for autologous use by the donor or for allogeneic use by a genetically related recipient.	
Donor Advocacy	Not defined	Defined as donor advocate: An individual distinct from the transplant recipient's primary treating physician whose primary obligation is to help the donor understand the process, the procedures and the risks and benefits of donation. The advocate should protect and promote the interests, well-being, and safety of the donor.	Not defined	A service whereby an individual or a team that possesses working knowledge of cellular therapy and whose interest is centered on the well being of the donor speaks on behalf of the donor. This individual or team has the authority to exclude a specific donation candidate when appropriate.
Donor Center	The organization responsible for recruiting consenting, counselling and coordinating the testing of prospective donors. The Center monitors the short and long term health of adult volunteer donors who have provided hematopoietic stem cells. The Donor Center maintains a register or dataset	Defined in guidance as: Donor centers provide donor management or collection activities of cellular therapy products from living donors.	Not defined	See "Facility." Facility: A location where any activities covered by these CT Standards are performed. These activities include determination of donor eligibility, procurement, processing, storage, distribution, issue, and administration. AABB accreditation is granted to

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	of donors, which may be searched as appropriate.			specified facilities for specific activities.
Donor screening	Not defined	Not defined	The process of identifying risk factors for transmissible disease through review of a current donor medical history interview (to include high-risk behaviors), physical examination results, and other medical records.	Suitability: With respect to donors, evaluation of cellular therapy donors for risks related to the donation process.
Donor Suitability	Not defined	Not defined	The maternal and infant donor's medical fitness to undergo the cord blood collection procedure.	Evaluation of cellular therapy donors for risks related to the donation process.
Educational and Promotional Materials	Not defined	Not defined	Not defined	Information made available by the cellular therapy facility to potential donors, patients, and others including but not limited to therapeutic benefit claims on the facility's website, facility information, in advertisements, in marketing materials, and in enrollment documents, and information provided by the facility to the media that explains the procurement, processing, use, benefits, and alternatives to the donation.
Electronic record	Not defined	Any record or document consisting of any combination of text, graphics, or other data that is created, stored,	Any record or document consisting of any combination of text, graphics, or other data that is created, stored,	Record: Information captured in writing or electronically that provides objective evidence of activities that have been

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		modified, or transmitted in digital form by a computer.	modified, or transmitted in digital form by a computer.	performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed.
Eligible	Not defined	An allogeneic cellular therapy product donor who meets all donor screening and testing requirements related to transmission of infectious disease as defined by applicable laws and regulations.	An infant donor and/or mother for whom all the donor screening and testing has been completed in accordance with Applicable Law and who is free of risk factor(s) for relevant communicable diseases.	Eligibility:With respect to donors, evaluation of cellular therapy donors for risk factors and clinical evidence of relevant infectious disease agents or diseases for the purpose of preventing the introduction, transmission, and spread of infectious disease. A donor may be found eligible, ineligible (see "ineligible donors"), or the determination may be incomplete (eg, screening is incomplete or donor testing is not performed in a timeframe specified by the test kit manufacturer's instructions.)
Engraftment	Not defined	The reconstitution of recipient haematopoiesis with blood cells and platelets from a donor.	The reconstitution of haematopoiesis or other cellular functions with cells from a donor.	The reconstitution of recipient hematopoiesis with white cells, red cells, and platelets from the donor. Engraftment of other types of cells generally will be shown by evidence of graft function specific to the organ of engraftment.
Errors and accidents	Not defined	Any unforeseen or unexpected deviations from applicable regulations, standards, or	Any unforeseen or unexpected deviations from Applicable Law, these standards, or other	See "Nonconformance."

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		established specifications that may affect the safety, purity, or potency of a cellular therapy product.	established specifications that may affect the safety, purity, or potency of a cord blood unit.	Nonconformance: failure to meet requirements.
Establish and Maintain	Not defined	A process to define, document in writing or electronically, implement, follow, review, and, as needed, revise on an ongoing basis.	A process to define, document in writing or electronically, implement, follow, review, and, as needed, revise on an ongoing basis.	Establish: Define, document, and implement, then follow, review, and, as needed, revise on an ongoing basis. Maintain:To keep in the current state; to preserve or retain; to keep in a state of validity.
Executive Management	Not defined	Not defined	Not defined	The highest level of personnel within an organization, including employees and independent contractors, who have responsibility and authority for the facility's operation and the authority to establish or change the facility's quality policy and quality system. Executive management may be an individual or a group of individuals (eg, medical director, laboratory director, chief executive officer, quality assurance committee).
Exceptional release	Not defined	Removal of a product that fails to meet specified criteria from quarantine or in-process status	Not defined	Exception: An action or condition that is not part of normal operations.

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		for distribution. Requires documented approval.		
Expansion	Not defined	Growth of one or more cell populations in an in vitro culture system.	Not defined	Not defined
Extended typing	This HLA typing includes the tests carried out on a specific donor/cord blood unit with the purpose of adding additional information (typing of additional loci or further subtyping at a higher resolution) to an existing HLA assignment. The additional HLA typing may be performed on a stored sample.	Not defined	Not defined	Not defined
Extracorporeal photopheresis:	Not defined	An apheresis technique in which the patient's blood is collected intoaspecializedinstrument,centrifuged,andseparatedintoaleukocyte-depleted fraction (which is returned to the patient unmanipulated) and mononuclear "buffy coat" enrichedplasma.Themononuclearcell-enrichedfractionisincubatedwith8-methoxypsoralen in the presence of ultraviolet A(UVA)radiation, and, upon completion of the procedure, reinfused into the patient	Not defined	Not defined

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Facility	Not defined	A location where activities covered by these Standards are performed. Such activities include determination of donor eligibility or suitability, product collection, processing, storage, distribution, issue, and administration.	Not defined	A location where any activities covered by these CT Standards are performed. These activities include determination of donor eligibility, procurement, processing, storage, distribution, issue, and administration. AABB accreditation is granted to specified facilities for specific activities.
Final Cellular Therapy Product	Not defined	Not defined	Not defined	A cellular therapy product that is ready for issue or final distribution.
Final Inspection and Testing	Not defined	See Release Criteria: The requirements that must have been met before a cellular therapy product may leave the control of the Collection or Processing Facility.	Not defined	An activity (such as measuring, examining, or testing one or more characteristics of a product or service) that compares the results with specified requirements in order to establish whether conformance is achieved for each characteristic.
Fully Informed Consent (Signed informed consent)	Signed documentation that a volunteer donor or the maternal donor of umbilical cord blood has been provided with information on the procedure and tests performed, the risks and benefits of the procedure, that they have understood the information provided, have had an	Discussed in guidance. Defined as: The essential elements of informed consent are that the donor or recipient is told, in terms she or he can reasonably be expected to understand, the reasons for the proposed therapy or procedure, the risks associated with the treatment or procedure, and	Elements of informed consent defined in standards	Elements of consent are defined in Reference Standard 4.5A.

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	opportunity to ask questions, have been provided with satisfactory responses and have confirmed that all information provided is true to the best of their knowledge. The consent is valid when it complies with national regulation.	potential benefits. This requirement applies to both autologous and allogeneic donors. In addition, the donor or recipient should be given the opportunity to ask questions and to have these questions answered to his/her satisfaction. The discussion that ensues is the important part of the process of obtaining informed consent; however, it is the documentation of this process that can be easily audited. Informed consent is to be documented according to institutional standards and criteria.		
Fresh	Not defined	A cellular therapy product that has never been cryopreserved.	Not defined	Not defined
Granulocyte colony-stimulating factor (G-CSF)	Granulocyte colony-stimulating factor is a cytokine that stimulates the bone marrow to produce granulocytes (white cells) and HPC and causes these cells to mobilize (move) to the peripheral blood where they can be collected from the veins for transplantation.	Not defined directly Term not used in standards. Growth factors and mobilization agents are referred to but felt not necessary to define.	Not defined	Not defined
Growth Factors	Defined as GCSF.	Not defined	Not defined	Recombinant cytokines that promote proliferation and/or differentiation of specific cell

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				types or lineages. Certain growth factors can be used in vivo (eg, mobilization of hematopoietic progenitor cells) or ex vivo (eg, cell expansion, vaccine development, and adoptive cellular therapy).
Hematopoietic progenitor cells (HPC):	Not defined. WMDA Standards use the term Hematopoietic stem cells defined as the progenitor cells, which give rise to blood and immune system cells. These cells are found in bone marrow, growth-factor stimulated peripheral blood, and umbilical cord blood. This also includes cells derived from the hematopoietic stem cell preparation which are used in cell therapies (e.g., mesenchymal and dendritic cells) and donor lymphocyte infusions. The collection of hematopoietic stem cells from adult volunteer donors is intended for infusion into a specific recipient.	A cellular therapy product that contains self-renewing and/or multipotent stem cells capable of maturation into any of the hematopoietic lineages, lineage-restricted pluripotent progenitor cells, and committed progenitor cells, regardless of tissue source (bone marrow, umbilical cord blood, peripheral blood, or other tissue source).	Self-renewing and/or multi-potent stem cells capable of maturation into any of the hematopoietic lineages, lineage-restricted pluripotent progenitor cells, and committed progenitor cells regardless of tissue source (bone marrow, umbilical cord blood, peripheral blood, or other tissue source).	Primitive pluripotent hemato-poietic cells capable of self-renewal and/or differentiation as well as maturation into any of the hematopoietic lineages (granulocytes, monocytes, erythrocytes, and platelets) including committed and lin-eage-restricted progenitor cells, unless otherwise specified, regardless of tissue source (eg, marrow, mobilized peripheral blood, or umbilical cord blood).
Hematopoietic progenitor cell therapy	Not defined	The infusion of HPC product with the intent of providing effector functions in the treatment of disease or in support of other therapy.	Not defined	See “Medical Therapy.”

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High resolution typing	Not defined	Not defined	A high resolution typing result is defined as a set of alleles that encode the same protein sequence for the region of the HLA molecule called the antigen binding site and that excludes alleles that are not expressed as cell-surface proteins. The antigen binding site includes domain 1 and domain 2 of the class I α polypeptides, and domain 1 of the class II α and domain 1 of the class II β polypeptide chains.	Not defined
Human cells, tissues, or cellular or tissue-based products (HCT/Ps)	Not defined	Articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.	Not defined	**Tissue:** Any aggregation of cells and associated intercellular matter that usually form a functional unit, and in the context of cell therapy, intended for transplantationor implantation.
Identity	Not defined	Not defined	Not defined	A set of factors that distinguishes one product from another. For cell therapy products, identity is often stated in terms of specific positive and negative markers expressed by the cells.
Indefinitely	Not defined	Not defined	A timeframe without a fixed or specified limit	Not defined

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Ineligible	Not defined	An allogeneic cellular therapy product donor who does not meet all donor screening and testing requirements related to transmission of infectious disease as defined by applicable laws and regulations.	An infant donor and/or mother for whom all the donor screening and testing has been completed in accordance with Applicable Law and who has identified risk factor(s) for relevant communicable diseases.	Ineligible donor: a designation applied to a donor whose product may be at risk of transmitting an infectious disease as detected by testing and/or by donor screening history.
In Process Label	Not defined	See Partial label: The minimum essential elements that must be affixed to all cellular therapy product containers at all times.	See Partial Label: The minimum essential elements that must be affixed at all times to all cord blood unit containers.	A label used to identify a cell therapy product at any intermediate processing step when a full label cannot be used due to space or size limitations.
Inspect	Not defined	Not defined	Not defined	To measure, examine, or test one or more characteristics of a product or service and compare results with specific requirements.
Institutional Review Board or Ethics Committee	Not defined	A Board or Committee established by an institution in accordance with the regulations of the U.S. Department of Health and Human Services, or other governmental agency where applicable, to review biomedical and behavioral research that involves human subjects and is conducted at or supported by that institution.	A Board or Committee established by an institution in accordance with Applicable Law to review biomedical and behavioral research involving human subjects conducted at or supported by that institution.	Not defined
Intermediate Facility	Not defined	Not defined	Not defined	Any facility other than the procurement facility and administering facility that

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				manipulates or performs any activity covered by these CT Standards.
ISBT 128	Not defined in Standard but in Appendix International Society Blood Transfusion: The international information technology standard for transfusion medicine and transplantation.	The international information technology standard for transfusion medicine and transplantation.	The international information technology standard for transfusion medicine and transplantation. ICCBBA, Inc. (www.iccbba.org) is the organization charged with the international maintenance of this database.	Not defined
Islet Cells	Not defined	Not defined	Not defined	A cellular therapy product consisting of partially purified pancreatic islets of Langerhans. Insulin-producing beta cells within such islets make up the functional component of the product.
Issue / Issuing Facility	Not defined	Not defined	Not defined	**Issue:** To release a final cellular therapy product for clinical use (eg, physical transfer of the cellular therapy product to the medical service responsible for administering the product to the patient by infusion, injection, or other method). **Issuing Facility:** The facility that issues the cellular therapy product for clinical use.
Key position (personnel)	Not defined	A job category with responsibilities that significantly affect the	Personnel with responsibilities that significantly affect the	Not defined

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		provision of service or product safety and quality.	provision, safety and/or quality of a service or product.	
Labelling	Not defined	Steps taken to identify the original cellular therapy product collection and any products or product modifications; to complete the required reviews; and to attach the appropriate labels.	Steps taken to identify the original cord blood unit collection and any products or product modifications; to complete the required reviews; and to attach the appropriate labels.	Information that is required or selected to accompany a cellular therapy product, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, and/or indications for use.
Laboratory Attire	Not defined	Not defined	Not defined	Attire worn in the laboratory as protection against contamination of the person or of the product. This may include gloves, laboratory coats, hair covers, face covers, shoe covers, and sterile sleeves.
Laboratory Director	Not defined	See *Director* above	An individual with a relevant doctoral degree, qualified by training or experience for the scope of activities carried out in the Cord Blood Processing Facility.	A qualified individual holding a relevant doctoral degree who is responsible for all technical aspects of the cellular therapy product service.
Legal Custodian	Not defined	Not defined	Not defined	A person legally responsible for the donor until the donor's age of majority.
Leukocyte Rich Products	Not defined	Not defined	Not defined	Leukocyte rich products are defined at the time of collection/procurement, even if later processing might remove leukocytes. Some examples of

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				leukocyte-rich products include but are not limited to: hematopoietic stem progenitor cells such as apheresis products, bone marrow, umbilical/placental cord blood, and nucleated cell preparations such as DLI. Some organs and tissues can be leukocyte-rich.
Licensed health care professional	Not defined	An individual who has completed a prescribed program of health-care related study and has been certified or licensed by the applicable authority in the jurisdiction in which he or she is performing services to perform duties within the scope of practice of that certificate or license.	An individual certified by the applicable governmental agency to be competent for the duties performed	Not defined
Life-Cycle Requirements	Not defined	Not defined	Not defined	The stages and time span from initial planning of a computer software program to its retirement; ie, from concept, to software development, to business changes, to revisions, to retirement.
Linkage	Not defined	Not defined	The maintenance of basic demographic information, Including name that would allow tracing of a cord blood unit to the identification of the infant donor and the mother.	See “Traceability”

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Listing	Not defined	Not defined	The process of transferring information about a cord blood unit to be available for search.	Not defined
Low resolution typing	Not defined	Not defined	A DNA-based typing result at the level of the digits comprising the first field in the DNA-based nomenclature. Examples include A*01; A*02. If the resolution corresponds to a serologic equivalent, this typing result should also be called low-resolution.	Not defined
Manipulation	Not defined	An ex vivo procedure(s) that selectively removes, enriches, expands, or functionally alters HPC products.	Ex vivo procedure(s) that alter(s) the cord blood unit.	Not defined
Minimally Manipulated	Not defined	Processing that does not alter the relevant biological characteristics of cells or tissues.	Processing that does not alter the relevant biological characteristics of cells or tissues.	Not defined
More than minimally manipulated	Not defined	Processing that does alter the relevant biological characteristics of cells or tissues.	Processing that does alter the relevant biological characteristics of cells or tissues.	Not defined
Unmanipulated hematopoietic progenitor cells	Not defined	HPC as obtained at collection and not subjected to any form of processing	Cord blood as obtained at collection and not subjected to any form of processing.	Not defined
Manufacturing or Processing	Not defined	Manufacturing Includes, but is not limited to, any or all steps in the recovery, processing, packaging, labelling, storage, or distribution of any human	Processing defined as: All aspects of manipulation, packaging, and labeling cord blood units, including microbial testing, preparation	All steps in the preparation and testing of a cellular therapy product, from donor evaluation to making the product available for distribution.

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		cellular or tissue-based product, and the screening and testing of a cell or tissue donor. Processing: All aspects of manipulation, cryopreservation, packaging, and labeling of cellular therapy products regardless of source, including microbial testing, preparation for administration or storage, and removal from storage. Processing does not include collection, donor screening, donor testing, storage, or distribution.	for storage, and removal from storage. For the purpose of these Standards, processing does not include collection, donor screening, donor testing, cryopreservation, storage, or distribution.	
Materials Management	Not defined	An integrated process for planning and controlling all steps in the acquisition and use of goods or supply items (materials) used for the collection or processing of cellular therapy products to ensure these materials are of adequate quality and quantity and available when needed. The materials management system combines and integrates the material selection, vendor evaluation, purchasing, expediting, storage, distribution, and disposition of materials.	An integrated process for planning and controlling all steps in the acquisition and use of goods or supply items (materials) used for the collection or processing of cord blood units to determine whether these materials are of adequate quality and quantity and available when needed. The materials management system combines and integrates the material selection, vendor evaluation, purchasing, expediting, storage, distribution, and disposition of materials.	Not defined

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May	Not defined	The term may is permissive and is used primarily for clarity.	Acceptable but not necessarily recommended	Not defined
Medical Therapy	Not defined	Not defined	Not defined	The direct provision of a medical intervention ordered by a physician (eg, harvest of hematopoietic progenitor cells by apheresis, administration of a pharmaceutical agent to a patient, or administration of a cellular therapy product).
Microbial	Not defined	Related to infectious agents including bacterial and fungal organisms.	Related to infectious agents including bacterial and fungal organisms.	Not defined
Mid-Level Practitioner	Not defined	Physician Assistant, Nurse Practitioner, or other Advanced Practitioner who provides primary patient care with physician oversight.	Not defined	Not defined
Monitoring	Not defined	Not defined	Recording quality parameters or indicators on a regular basis.	Continuous monitoring: a mechanism that allows for surveillance of a process or system intended to ensure proper operation and the detection of control exceptions
Mother	Not defined	Not defined	Any of the following: Birth mother: The woman who carries the infant donor to its delivery; may be the genetic mother or a surrogate mother. Genetic mother: The woman from whose egg the infant donor develops; the egg donor.	See “birth mother”, “biologic mother”

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			Mother: When used unmodified, the term mother refers to the mother who is both the genetic and birth mother. Surrogate mother: The woman who carries an infant donor not genetically her own from an embryo to delivery. Under circumstances of a surrogate mother carrying the infant donor to term and the cord blood unit being collected, both the surrogate and the genetic mother shall be considered for purposes of communicable disease screening and testing; the genetic mother shall be considered for purposes of genetic information.	
Must (see shall)	To be complied with at all times.	Not defined	Not defined	Shall: A term used to indicate a requirement
Myeloablative Therapy	Not defined	Not defined	Not defined	Treatment of a patient with an agent (eg, chemotherapy or gamma irradiation) that causes irreversible bone marrow aplasia.
Negative Selection	Not defined	The manipulation of a cellular therapy product such that a specific cell population(s) is reduced.	The manipulation of cord blood such that a specific cell population(s) is depleted.	Not defined

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Noncompetent	Not defined	Not defined	Not defined	With respect to donors, an individual who lacks the legal ability to make medical decisions for himself/herself.
Nonconformance (ing)	Not defined	Not defined	Any cord blood unit that does not completely meet the requirements specified by these Standards, the Cord Blood Bank, or Applicable Law.	Failure to meet requirements.
Nonconforming product or service	Not defined	Not defined	CB units that do not meet in-process or final endpoints and/or specifications.	A product or service that does not satisfy one or more specificed requirements, such as an unacceptable cellular therapy product, test run, or apheresis procedure; a product with a lower cell dose than expected; or a positive bacterial culture of a product.
Nurse Practitioner	Not defined	A nurse with a graduate degree in advanced practice nursing providing patient services in defined areas of practice in collaboration with other health professionals.	Not defined	Not defined
New Patient	Not defined	An individual undergoing the specified type (allogeneic, autologous, or syngeneic) of transplantation for the first time in the Clinical Program whether or not that patient was previously treated by that Clinical Program.	Not defined	Not defined

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Novel Method	Not defined	Not defined	Not defined	An innovative method or procedure being evaluated and introduced into practice at a facility. The method may not have undergone internal or external peer review or approval by institutional review board.
Orientation	Not defined	An introduction to guide one in adjusting to new surroundings, employment, activity, or the like.	Not defined	Not defined
Outcome analysis	Not defined	The process by which the results of a therapeutic procedure are formally assessed.	The process by which the results of a therapeutic procedure are formally assessed.	Not defined
Partial label	Not defined	The minimum essential elements that must be affixed to all cellular therapy product containers at all times.	The minimum essential elements that must be affixed at all times to all cord blood unit containers.	Defined in Reference Standard 5.9.1A
Patient specific product	Not defined	Not defined	Analogous to Directed: Related units collected and stored for the directed use by a specific individual recipient or family member of the donor	A product collected and/or prepared exclusively for a particular autologous or allogeneic recipient
Physician Assistant	Not defined	A person formally trained to provide diagnostic, therapeutic, and preventive health care services with physician supervision.	Not defined	Not defined
Policy(ies)	Not defined	Document(s) that define the scope of an organization, explain how the goals of the organization will be achieved,	Document that defines the scope of an organization, explain how the goals of the organization will be achieved,	A documented general principle that guides present and future decisions.

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		and/or serve as a means by which authority can be delegated.	and/or serve as a means by which authority can be delegated.	
Positive selection	Not defined	The manipulation of a cellular therapy product such that specific cell populations are enriched.	The manipulation of cord blood such that a specific cell population(s) is enriched.	Not defined
Potency	Not defined	The therapeutic activity of a product as indicated by appropriate laboratory tests or adequately developed and controlled clinical data.	The therapeutic activity of a cord blood unit as indicated by appropriate laboratory tests or adequately developed and controlled clinical data.	Not defined
Preparation for administration	Not defined	Not defined	Not defined	The preparation of a distributed cellular therapy product for administration. Preparation steps typically are minimal and occur immediately before a product is issued for administration.
Preparative regimen	Not defined	Not defined though term is used throughout	Not defined	Any regimen of immunosuppressive and/or myelosuppressive chemotherapeutic agents and/or radiation therapy that is given to prepare the recipient prior to the administration of a cellular therapy product,
Preventive Action	Not defined	Action taken to eliminate the cause and prevent occurrence of a potential discrepancy or other undesirable situation.	Not defined	An activity performed to eliminate the potential for nonconformance or other undesirable situations.
Procedure	Not defined	A document that describes in detail, the process or chronological steps taken to	A document that describes in detail the process or chronological steps taken to	A description of how an activity is to be performed; ie,

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		accomplish a specific task; a procedure is more specific than a policy.	accomplish a specific task. A procedure is more specific than a policy.	a standard operating procedure.
Process	Not defined	A goal-directed, interrelated series of actions, events, or steps.	A goal-directed, interrelated series of actions, events, or steps.	A set of related tasks and activities that accomplishes a work goal; ie, that transforms input into output products and services. This transformation can be achieved by an activity or a series of interrelated activities.
Process control	Not defined	The standardization of processes in order to produce predictable output.	The standardization of processes in order to produce predictable output.	Efforts made to standardize and control processes in order to produce predictable output.
Process development	Not defined	The series of procedures performed in order to develop a final process that achieves the required results.	The series of procedures performed in order to develop a final process that achieves the required results.	See “process control.”
Processing	Not defined	All aspects of manipulation, cryopreservation, packaging, and labelling of cellular therapy products regardless of source, including microbial testing, reparation for infusion or storage, and removal from storage. Processing does not include collection, donor screening, donor testing, storage, or distribution.	All aspects of manipulation, packaging, and labelling cord blood units, including microbial testing, reparation for storage, and removal from storage. Processing does not include collection, donor screening, donor testing, cryopreservation, storage, or distribution.	Any activity performed on a cellular therapy product other than recovery, donor screening, donor testing, storage, labelling, packaging, or distribution, such as testing for microorganisms, preparation, sterilization, steps to inactivate or remove adventitious agents, preservation for storage, and removal from storage.
Processing facility	The Cell Processing Unit is a medical laboratory facility where hematopoietic stem cells are manipulated prior to	A location where cellular therapy product processing activities are performed in support of the Clinical	Not defined	The facility involved in receipt of the product from the procurement facility. The processing facility may

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	transplant. These activities may include the depletion of specific cell types from the graft, selection for specific cell types for infusion, in vivo manipulation of cells in the graft, or concentration of the cell product.	Program. A Processing Facility may be part of the same institution as the Clinical Program or may be part of another institution and perform these functions through contractual agreement.		perform further manufacturing, testing, and/or distribution of the product.
Procurement	Not defined	See Collection: Any procedure for procuring and labeling cellular therapy products, regardless of technique or source.	See Collection: Any procedure for procuring and labeling cellular therapy products, regardless of technique or source.	The act of obtaining a cellular therapy product(s) from a donor by facility-approved methods, including, but not limited to, apheresis, marrow harvest, cord blood procurement, or organ or tissue harvest from a donor.
Procurement Container	Not defined	Not defined	Not defined	Any receptacle suitable for the procurement of a specific product.
Procurement Endpoint	Not defined	Not defined	Not defined	The product characteristics (eg, volume or number of cells) that meet the procurement goal or that can safely be obtained.
Procurement Facility	Defined as Collection center	See Collection Facility	See Cord Blood Collection Site	Either a facility that is directly responsible for the performance of donor eligibility determination, donor screening, and the procurement of cellular therapy products or a facility that ensures, through agreements, that one or more of these activities is/ are

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				performed in conformance with these CT Standards.
Product (s)	Not defined	Not defined	The proper name for each class (broad descriptions of product) is as follows:* HPC, Cord Blood: Umbilical cord blood and/or placental blood collected as a source of hematopoietic progenitor cells.	A tangible result of a process or procedure. Note: the cellular therapy product provided to an intermediate facility by the procurement facility is a product for the procurement facility but a material for the intermediate facility.
Product sample	Not defined	A representative quantity of product removed from the cellular therapy product; an aliquot.	See reference sample and retention sample: Aliquots of cells, plasma, serum, or cellular material from the cord blood unit, the umbilical cord, or the placenta that can be used to confirm the identity, HLA typing, or genetic or communicable disease information associated with a single cord blood unit. Such samples may or may not be contiguous segments. A retention sample replicates the final cord blood unit and can be used to test for viability, potency, or stability	Not defined
Product Proper name	Not defined	SHOULD OBEY ISBT128 nomenclature Note definitions of broad class included in 5th Ed. Definitions are those of ISBT 128. Manipulations and other	SHOULD OBEY ISBT128 nomenclature	Not defined

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		attributes are Not defined, rather referenced		
Proficiency test	Not defined	A test to ensure the adequacy of testing methods and equipment and the competency of personnel performing testing.	A test to ensure the adequacy of testing methods and equipment and the competency of personnel performing testing.	The structured evaluation of laboratory methods that assesses the performance of the test system.
Protocol	Not defined	A written document describing steps of a treatment or procedure in sufficient detail such that the treatment or procedure can be reproduced repeatedly without variation.	A written document describing steps of a treatment or experimental procedure in sufficient detail such that the treatment or procedure can be reproduced repeatedly without variation.	Not defined
Purity	Not defined	Relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product	Relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product.	Dominance of a targeted cellular population defined by a specific cell marker and with minimal to no contamination of cells negative for the same markers.
Qualification	Not defined	The establishment of confidence that equipment, supplies, and reagents function consistently within established limits.	The establishment of confidence that equipment, supplies, and reagents function consistently within established limits.	With respect to individuals, the aspects of an individual's education, training, and experience that are necessary for the individual to successfully meet the requirements of a position. Specifically for equipment, verification that specified attributes required to accomplish the desired task have been met.

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Quality	Not defined	Conformance of a product or process with pre-established specifications or standards.	Conformance of a product or process to pre-established specifications or standards.	Characteristics of a product or service that affect its ability to meet requirements, including those defined during agreement review.
Quality assurance	Not defined	The actions, planned and performed, to provide confidence that all systems and elements that influence the quality of the product or service are working as expected individually and collectively.	The actions, planned and performed, to provide confidence that all systems and elements that influence the quality of the product or service are working as expected individually and collectively.	Confidence that the policies, processes, and procedures that influence the quality of the product and service are work-ing as expected, both individually and collectively.
Quality assessment	Not defined	The actions, planned and performed, to evaluate all systems and elements that influence the quality of the product or service.	The actions, planned and performed, to evaluate all systems and elements that influence the quality of the product or service.	See “Assessment.”
Quality audit	Not defined	A documented, independent inspection and review of a facility’s quality management activities to verify, by examination and evaluation of objective evidence, the degree of compliance with those aspects of the quality program under review.	A documented, independent inspection and review of a facility’s activities. The purpose of a quality audit is to verify, by examination and evaluation of objective evidence, the degree of compliance with those aspects of the quality program under review.	See “Assessment.”
Quality control	Not defined	A component of a quality management program that includes the activities and controls used to determine the accuracy and reliability of the	A component of a quality program that includes the activities and controls used to determine the accuracy and reliability of the	A component of a quality management program that includes the activities and controls used to determine the accuracy and reliability of the

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		establishment's personnel, equipment, reagents, and operations in the manufacturing of cellular therapy products, including testing and product release.	establishment's personnel, equipment, reagents, and operations in the manufacturing of cord blood units, including testing and product release.	establishment's reagents, materials, analytical procedures, and equipment to ensure their proper function.
Quality Handbook	Not defined	A document describing the application of general principles of quality management in cellular therapy programs using templates, scenarios, and sample documentation. It is an adjunct to help cellular therapy programs prepare for and maintain FACT or JACIE accreditation. May also be referred to as a quality guide or manual.	A document describing the application of general principles of quality management in cellular therapy programs using templates, scenarios, and sample documentation. It is an adjunct to help cellular therapy programs prepare for and maintain FACT-Netcord accreditation. May also be referred to as a quality guide or manual.	See "Quality Manual." Quality Manual: A document that describes a facility's quality system.
Quality improvement	Not defined	The actions, planned and performed, to implement changes designed to improve the quality of a product or process.	The actions, planned and performed, to develop a system to review and improve the quality of a product or process	Not defined
Quality management	Not defined	An integrated program of quality assessment, assurance, control, and improvement.	An integrated program of quality assessment, control, and improvement.	Not defined
Quality management plan Could also be called *Manual*, *Handbook*	Not defined	A written document that describes the systems in place to implement the quality management program. May also be referred to as the quality management manual or handbook.	A written document that describes the systems in place to implement the Quality Management Program. May also be referred to as the quality management manual or handbook.	Not defined

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Quality management program Could also be called a *Quality system*	Quality System: Organization structure, personnel requirements including qualifications, training and competency, responsibilities, procedures, process and resources defined for implementing and managing quality within the Registry including all activities contributing to the quality, directly or indirectly. The quality system must cover detection, reporting and corrective action related to adverse events and complaints; identification, labelling and tracking of individuals and products; development, implementation, and review of policies and procedures; creation, review, control and maintenance of records; outcome analyses; facilities; and safety. The quality system must be described by the Registry in written documents and a process to audit the quality system must be in place.	An organization's comprehensive system of quality assessment, assurance, control, and improvement. A quality management program is designed to prevent, detect, and correct deficiencies that may adversely affect the quality of the cellular therapy product or increase the risk of communicable disease introduction or transmission. May also be referred to as the quality management system.	An organization's comprehensive system of quality assessment, assurance, control, and improvement. A quality management program is designed to prevent, detect, and correct deficiencies that may adversely affect the quality of the cord blood unit or increase the risk of communicable disease introduction or transmission.	Standard 1.2.2
Quality Manual	Not defined	See Quality Management plan: A written document that describes the systems in place	See Quality Management Plan: A written document that describes the systems in place	A document that describes a facility's quality system.

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		to implement the quality management program. May also be referred to as the quality management manual or handbook.	to implement the Quality Management Program.	
Quality Policy	Not defined	Not defined	Not defined	The overall vision, intentions, and direction of an organization to achieve quality, formally expressed by executive management.
Quality System	Organization structure, personnel requirements including qualifications, training and competency, responsibilities, procedures, process and resources defined for implementing and managing quality within the Registry including all activities contributing to the quality, directly or indirectly. The quality system must cover detection, reporting and corrective action related to adverse events and complaints; identification, labelling and tracking of individuals and products; development, implementation, and review of policies and procedures; creation, review, control and maintenance of records; outcome analyses; facilities; and safety. The quality system	See Quality management program: An organization's comprehensive system of quality assessment, assurance, control, and improvement. A quality management program is designed to prevent, detect, and correct deficiencies that may adversely affect the quality of the cellular therapy product or increase the risk of communicable disease introduction or transmission. May also be referred to as the quality management system.	See Quality management program: An organization's comprehensive system of quality assessment, assurance, control, and improvement. A Quality Management Program is designed to prevent, detect, and correct deficiencies that may adversely affect the quality of the cord blood unit or increase the risk of communicable disease introduction or transmission.	The organizational structure, responsibilities, policies, processes, procedures, and resources established by executive management to achieve the quality policy.

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	must be described by the Registry in written documents and a process to audit the quality system must be in place.			
Quality unit	Not defined	Not defined	Personnel with responsibility for and authority to approve or reject in-process materials, all components, cord blood unit containers, closures, packaging material, labeling, and cord blood units.	Not defined
Quality unit supervisor	Not defined	Not defined	A qualified individual who establishes methods to review, modify, approve, and implement all Standard Operating Procedures related to Quality Management and to monitor compliance with these Standards	Not defined
Quarantine	Not defined	The identification or storage of a cellular therapy product in a physically separate area clearly identified for such use, or through use of other procedures such as automated designation to prevent improper release of that product. Also refers to segregated storage of products known to contain infectious disease agents to reduce the likelihood of cross-contamination.	The segregation of a cord blood unit to prevent cross-contamination or improper release. Quarantine can be temporal, physical, or a designation within the cord blood unit record.	Storage of cellular therapy products, reagents, or materials, in order to prevent improper release and/or cross contamination, in a physically separate area clearly identified for such use, or identification of a product through the use of other procedures, including automated designation, for the same purpose.

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Reagent	Not defined	Not defined	Not defined	A substance used to perform an analytical or manufacturing procedure. A substance used (as in detecting or measuring a component or preparing a product) because of its biological or chemical activity. Reagents can be either purchased ready for use or prepared within the facility (in house).
Recipient	Not defined	Not defined although used extensively to indicate the individual to receive the cellular therapy product	The individual into whom the cord blood unit was administered.	Patient: An individual undergoing medical treatment. In these CT Standards, a patient is an individual who may receive a cellular therapy product and related care. The individual may also be a research subject.
Receiving Facility	Not defined	Not defined	Not defined	A facility receiving products or services.
Record	Not defined	Documented evidence that activities have been performed or results have been achieved. A record does not exist until the activity has been performed.	Not defined	Record: Information captured in writing or electronically that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed.
Registry	An organization responsible for coordination of the search for haematopoietic progenitor cells from donors (including	Not defined	An organization that publishes or makes available the description of cord blood units available for administration	An organization that maintains a database of cellular therapy donors or products and coordinates the acquisition of

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	cord blood) unrelated to the potential recipient.		and may conduct searches of the available cord blood units, either exclusively or in conjunction with the Cord Blood Bank as defined in their agreement.	cellular therapy products for transplantation.
Release	Not defined	Removal of a product from quarantine or in-process status when it meets specified criteria.	The removal of a cord blood unit from quarantine or in-process status when it meets specified criteria.	Removal of a product from quarantine or in-process status for the purpose of distribution.
Release criteria	Not defined	The requirements that must have been met before a cellular therapy product may leave the control of the Collection or Processing Facility.	Not defined	Not defined
Responsible person	Not defined	A person who is authorized to perform designated functions for which he or she is trained and qualified.	Not defined	Not defined
Reservation	Not defined	Not defined	A temporary allocation of a cord blood unit to a specific recipient to prevent consideration of that cord blood unit for another recipient.	Not defined
Rework	Not defined	Not defined	Not defined	May include reprocessing, retesting (other than infectious disease testing), or other steps in the manufacturing process that are out of the normal processing sequence or that are not specifically provided for in the process.

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Rh	Not defined	Rhesus systems of human red cell antigens; used in this document to refer to the Rh(D) antigen only, unless otherwise specified (in abbreviations)	The abbreviation for the Rhesus system of human red cell antigens; is used in this document to refer to the Rh (D) antigen only unless otherwise specified.	Not defined
Safety	Not defined	Relative freedom from harmful effects to persons or products	Relative freedom from harmful effects to persons or products.	Not defined
Search	The process of identifying a suitable donor to donate HPC for a patient in need of a transplant.	Not defined	The process used to produce a report of cord blood units that are potential matches for a recipient.	Not defined
Selection	Not defined	Not defined	The process of identification of a donor or cord blood unit according to defined criteria.	Not defined
Sepsis	Not defined	Not defined	Not defined	Systemic inflammatory response due to an infectious agent and accompanied by characteristic clinical and laboratory findings.
Service	Not defined	Not defined	Not defined	Work or activities performed to fulfill the needs of a customer. The intangible result of a process.
Shall	"Shall" indicates that deviations are not acceptable	Defined in introduction to standards: used to indicate that the Standard is a requirement and that the Standard is to be complied with at all times	To be complied with at all times.	A term used to indicate a requirement.
Shipping	Not defined	The physical act of transferring a cellular therapy product within or between facilities. During shipping the product leaves the control of trained	The physical act of transferring a cord blood unit within or between facilities during which the unit leaves the control of trained personnel at	The physical act of transferring a cellular therapy product within or between facilities. During shipping the product leaves the control of trained

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		personnel at the transporting or receiving facility.	the distributing or receiving facility.	personnel at the originating or receiving facility.
Shipping Facility	Not defined	Not defined	See shipping	A facility responsible for delivering a product in its custody to another location.
Should	Recommended or advised, but effective alternatives may exist.	The term should indicates an activity that is recommended or advised, but for which there may be effective alternatives	Recommended or advised, but effective alternatives may exist.	Not defined
Significant warming event	Not defined	Not defined	Any event when a cryopreserved cord blood unit reaches Not defined120° C or warmer during the life of the cryopreserved cord blood unit.	Not defined
SOP *See also Procedure*	Standard Operating Procedures (SOP): A compilation of written detailed instructions describing the steps in a process, including materials and methods to be used and the expected end product. The SOP must include a process to regularly review and update procedures. Changes to standard operating procedures must be documented and validated.	Written detailed instructions required to perform a procedure.	Written detailed instructions required to perform a procedure.	See "Procedure."
Specified Requirements	Not defined	Not defined	Not defined	The expectations for products or services. Specified requirements may be defined by customers, regulatory agencies (such as the FDA), practice standards, or

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				accrediting organizations (such as the AABB).
Stability	Not defined	Not defined	Not defined	The ability of a product to maintain quality characteristics and resist change or deterioration.
Stability Program	Not defined	Not defined	Not defined	An ongoing sampling program intended to assess the capacity of a cellular therapy product to remain within specifications throughout the retest period or expiration date, as appropriate. Parameters assessed in a stability program may include all or any of the following; identity, viability, potency, sterility, and container integrity.
Standard Operating Procedures Manual	See Above	A compilation of the current Standard Operating Procedures.	A compilation of policies and procedures with written detailed instructions required to perform procedures. The SOP Manual may be in electronic or paper format	See “Quality Manual.”
Standards	See SOP	The current edition of the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration, which may be referred to herein as “Standards” or “FACT-JACIE Standards.	The current edition of the International Standards for Cord Blood Collection, Banking, and Release for Administration published by Netcord and FACT.	A set of specified requirements upon which a facility may base its criteria for the products, components, and/or services provided.

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Statistical Techniques	Not defined	Not defined	Not defined	Established mathematical methods used to collect, analyze, and present data.
Sterility	Not defined	Not defined	Sterility Testing: The process used to screen for the presence of microbial agents.	An aseptic condition, meaning an absence of living micro-organisms.
Storage	Not defined	Holding a cellular therapy product for future processing, distribution, or administration.	Holding cord blood units for future processing and/or distribution.	The state of being kept in a place while not being used or transferred, shipped or transported.
Summary of Records	Not defined	Not defined	Not defined	A condensed version of the required testing and screening records that contains the identity of the testing labora-tory, the listing and interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical records, and the name of the person or establishment determining the suitability of the human tissue for transplantation.
Supplier	Not defined	Not defined	Not defined	An organization or individual that provides a product or ser-vice.
Surrogate Mother	Not defined	Not defined	The woman who carries an infant donor not genetically her own from an embryo to delivery.	The female who carries the fertilized ovum of another woman.
System	Not defined	Not defined	Not defined	A subgroup of related activities performed by a particular organization.

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				Activities dealing with maintaining product and service quality are organized into a quality system.
Syngeneic	Not defined	The biologic relationship between identical twins.	Not defined	Not defined
Testing Laboratories	These laboratories perform the histocompatibility, blood group, infectious disease, and other testing of the prospective donors and patients. They may be under the direction of a Registry Donor Center or Transplant Center or may be separate from these entities.	Requirements for testing laboratories defined, but not term itself. Felt to be understood.	Not defined	Not defined
Therapeutic cells:	Not defined	Nucleated cells from any source (marrow, peripheral blood, or umbilical cord and or placental blood) intended for therapeutic use other than as HPC.	Not defined	Not defined
Time of collection	Not defined	The time of day at the end of the cellular therapy product collection procedure.	The time of day that the cord blood collection is completed.	Not defined
Total Nucleated Cell Count	The number of cells with a nucleus in a cord blood unit.	Not defined	The number of cells with a nucleus or nuclei in a cord blood unit.	The total number of nucleated cells in a volume of a cellular therapy product. Nucleated cells include white blood cell (WBC) populations such as neutrophils, monocytes, lymphocytes, eosinophils, and basophils and nucleated red blood cells (NRBCs). The TNC is calculated by the

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				following formula: TNC = (WBCs + NRBCs) × volume. The contribution of NRBCs, if any, should be separately noted.
Trace/Traceability	The ability to locate and identify a donor or recipient, their data and cell product, during any stage of the recruitment, testing, collection, donation, transplantation, and follow-up process. Traceability also includes the ability to identify the organizational entities (e.g. registry, donor centre, collection centre, cell processing unit and transplant centre) involved in the international exchange.	To follow the history of a process, product, or service by review of documents.	To follow the history of a process, product, or service by review of documents.	Traceability: The ability to follow the history of a process, product, or service, by review of documents and records.
Track	Not defined	To follow a process or product from beginning to end.	To follow a process or product from beginning to end.	Not defined
Transfer	Not defined	Not defined	Not defined	The act of relocating a final cellular therapy product or its intermediate in-process precursors.
Transplant Center	The Transplant Center is the medical facility at which a patient (recipient) receives a transplant (graft) with hematopoietic stem cells from an unrelated donor or from an umbilical cord blood unit. The Center oversees the immediate medical treatment and	See Clinical Program:	See Clinical Program: An integrated medical team that administers cord blood units.	See "Facility." Facility: A location where any activities covered by these CT Standards are performed. These activities include determination of donor eligibility, procurement, processing, storage,

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	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 Transplant Center. This entity may be contained within a Transplant Center or may be separate from the Transplant Center. If separate, the Search Unit may coordinate searches for one or several Transplant Centers. The Standards reference to a Transplant Center should be interpreted as a Transplant Center and/or a Search Unit as appropriate. Transplant Centers/Search Units seeking an international donor work through the Registry in their country.			distribution, issue, and administration. AABB accreditation is granted to specified facilities for specific activities.
Transplantation	Not defined	The infusion of allogeneic, autologous, or syngeneic HPC with the intent of providing transient or permanent engraftment in support of therapy of disease.	The administration of allogeneic or autologous cord blood cells with the intent of providing transient or permanent engraftment in support of therapy for disease.	See "Administration" Administration: with respect to cellular therapy products, the act of delivering the product into a recipient, including, but not limited to, infusion, transplantation, implantation, or injection.
Transport	Not defined	The physical act of transferring a cellular therapy product within or between facilities.	The physical act of transferring a cord blood unit within or between facilities. During	The physical act of transferring a cellular therapy product within or between facilities.

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		During transportation the product does not leave the control of trained personnel at the transporting or receiving facility	transportation the product does not leave the control of trained personnel at the transporting or receiving facility.	During transport the product does not leave the control of trained personnel at the originating or receiving facility.
Unique	Not defined	Being the only one of its kind or having only one use or purpose.	Being the only one of its kind or having only one use or purpose.	Not defined
Unique identifier	Not defined	A numeric or alphanumeric sequence used to designate a given cellular therapy product with reasonable confidence that it will not be used for another purpose.	A numeric or alphanumeric sequence used to designate a specific cord blood unit with reasonable confidence that the identifier will not be used for another purpose, including for another cord blood unit.	Not defined
Urgent medical need	Not defined	A situation in which no comparable cellular therapy product is available and the recipient is likely to suffer death or serious morbidity without the cellular therapy product.	A situation in which no comparable cord blood unit is available and the recipient is likely to suffer death or serious morbidity without the cord blood unit.	Procurement and use of a cellular therapy product from an ineligible donor when no comparable product is available and the recipient is likely to suffer serious morbidity or death without receiving the product.
Validation	Establishing documented evidence that particular requirement can consistently be fulfilled. Evaluation and written documentation of the performance of equipment, a reagent, a process or a system with regard to its effectiveness based on its intended use.	Confirmation by examination and provision of objective evidence that particular requirements can consistently be fulfilled. A process is validated by establishing, by objective evidence, that the process consistently produces a cellular therapy product meeting its predetermined specifications.	Confirmation by examination and provision of objective evidence that particular requirements can consistently be fulfilled. A process is validated by establishing, by objective evidence, that the process consistently produces a cord blood unit meeting its predetermined specifications.	Demonstration through objective evidence that the requirements for a particular application or intended use have been met. Validation provides assurance that new or changed processes and procedures are capable of consistently meeting specified requirements before implementation.

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Variance	Not defined	A planned deviation from recommended practice or standard operating procedure	A deviation from recommended practice or Standard Operating Procedure.	See “Deviation”
Verification	Verification typing: This typing includes the tests carried out on a fresh sample of a specific donor or on an attached-segment of a cord blood unit with the purpose of verifying the identity and concordance of an existing HLA assignment. This stage may also be referred to as “Confirmatory Typing (CT)”.	The confirmation of the accuracy of something or that specified requirements have been fulfilled.	The confirmation of the accuracy of something or that specified characteristics have been fulfilled.	Confirmation, by examination of objective evidence, that specified requirements have been met.
Verification typing	This HLA typing includes the tests carried out on a fresh sample of a specific donor or on an attached-segment of a cord blood unit with the purpose of verifying the identity and concordance of an existing HLA assignment. This stage used to be referred to as "confirmatory typing (CT)".	HLA typing performed on an independent sample with the purpose of verifying concordance of that typing assignment with the initial HLA typing assignment. Concordance does not require identical levels of resolution for the two sets of typing but requires the two assignments be consistent with one another.	HLA typing performed on an independent sample (or, for a cord blood unit, from an attached segment or from the unit itself) with the purpose of verifying concordance of that typing assignment with the initial HLA typing assignment. Concordance does not require identical levels of resolution for the two sets of typing but requires the two assignments to be consistent with one another.	Not defined
Viability	Not defined	Living cells as defined by dye exclusion, flow cytometry, or progenitor cell culture.	Viability assessment: The determination of the proportion of living cells using dye exclusion, flow cytometry, or progenitor cell culture methods	Demonstrated capability of living; indicating (either in-vivo or in-vitro) ability to perform physiologic functions.

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Workflow	Not defined	Not defined	Not defined	The planned physical movement of people, materials, or data associated with a process, or the planned temporal sequence of activities associated with a process.
Work-UP	At this stage, a volunteer donor has been identified as an acceptable match for a patient, agrees to donate HPC after a full donor information and counselling session, and is medically evaluated for their fitness to donate HPC.	Not defined	Not defined	Not defined
Written	Not defined	Documentation in human readable form.	Documentation in human readable form	Not defined