Comparison of Donor Standards
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 2017	**W**
FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing and Administration5th Edition	**F-J**
Netcord-FACT International Standards for Cord Blood Collection, Banking and Release for Administration5th Edition	**NC-F**
AABB Standards for Cellular Therapy Services 6th Edition	**AA**
Cord Blood Bank	**CBB**
Requirement is addressed in standards	**X**
Requirement is not addressed in standards	**-**

REQUIREMENTS	W	F-J	NC-F	AA
General Requirements-All Donors				
Voluntary and unpaid	Required for EU and US under applicable regulations	Required for EU and US under applicable regulations	Required for EU and US under applicable regulations	Donation is voluntary and consent can be withdrawn at any time; Does not specify that the donor must be unpaid
Written criteria required for selection, evaluation, and management of all donors	X	X	X	X
Requirements for personnel:				
Performing donor selection	2.05 The registry must have a qualified and trained health care professional readily available to assist with routine medical decisions regarding donor selection and donation. 4.02 Recruitment of maternal donors is usually done by a cord blood bank, cord blood	B6.4.12 Physician	Unit distributed only with written request by physician, designee, or registry	Must be performed by qualified and competent personnel

REQUIREMENTS	W	F-J	NC-F	AA
	collection centre or maternal donor physician			
Performing donor evaluation and screening	Guidance to standard 2.05 The registry must have an individual assisting with donor selection and donation in specific situations. This person/s must be experienced in donations and/or transplant medicine.	Evaluation primarily by Clinical Program, Screening by Clinical and Collection	Trained collection facility personnel	Must be performed by qualified and competent personnel
Final donor authorization and informed consent	2.05 The registry must have a qualified and trained health care professional available to assist with routine medical decisions regarding donor selection and donation. 3.11.1 At work-up must include the signature(s) of qualified staff involved in donor counselling.	General:healthcare professional familiar with the collection procedure Allogeneic donor suitability: Healthcare professional who is not the primary person overseeing care of the recipient.	Informed consent by trained collection facility personnel, final authorization by CBB Director and Quality Manager	Donor's physician; not specified for consent but donor must have access to donor advocacy services
Requirement for an understandable written consent to donate	Valid signed informed consent must be obtained at the time of recruitment, meet established criteria and be written in terms understood by the donor.	XB6.2.1 under Donor Consent section specifies procedure be explained in terms donor can understand and D6.2.4 requires consent be written	X	X
Family members may not serve as interpreters or translators to obtain consent	-	-	X	-
Donor Age limits	X (who have passed a minimum age established by national law or their eighteenth (18th) birthday when no regulation exist and not exceed 60)	-	-	-

REQUIREMENTS	W	F-J	NC-F	AA
Anonymity of unrelated donors	X	As required by registry	As required by registry	X
Donor consent document must include:				
Benefits and risks (e.g., administration of G-CSF)	X	X	X	X
Tests and procedures to protect health of donor and recipient	X	X	X	X
Rights of donor to review test results	X	X	X	
Alternative collection methods (if applicable)	X	X	X	X
Protection of donor medical information and confidentiality	X	X	X	X
Intent of the donation for related allogeneic or autologous use	-	Not required	X	X
Intent of the donation for unrelated allogeneic use	X	Not required	X	X
Information whether blood/DNA is reserved for research purposes	X	-	-	Consent must specify ownership, transfer, and/or disposition of the product
Donor consent process must include:				
Opportunity to ask questions	X	X	X	X
Right to refuse to donate	X	X	X	X
Information regarding the potential consequences of not donating to the potential recipient	X	X	-	X
Obtained by licensed physician or other health care provider familiar with the collection procedure	X	X	Trained individual at collection site	-
Minor consent obtained from parents or legal guardian according to applicable laws and regulations	X (for cord blood donation)	X	X	X
Consent and authorization from donor in advance to releasing health information to transplant physician and recipient as appropriate	X	X	X applies to CBB personnel	X

REQUIREMENTS	W	F-J	NC-F	AA
Provision of documentation of consent to collection staff prior to the collection procedure	X	X	X	X
Mother donating cord blood informed to contact CBB if infant donor develops serious disease post donation	X	-	X	-
Donor Suitability Requirements				
Established criteria and evaluation procedures to protect the safety of the donor	X	X	X	X
Abnormal findings during workup reported to prospective donor with recommendations for follow-up care	X	X	X	X
Evaluation to include potential risks of the collection procedure.	X	X	X	X
Potential risks shall include where relevant:				
Possible need for venous access	X	X	-	X
Mobilization	X	X	-	X
Anesthesia	X	X	-	X
Donor Evaluation for Transmissible Disease (Eligibility)				
Procedures in place for evaluation of risk of disease transmission from donor products	X	X	X	X
Risk factors evaluated by medical history, physical examination, examination of relevant medical records, and laboratory testing.	X	X	X	X
Evaluation of risk of hemoglobinopathy	X (performed on the infant donor or the cord blood unit)	X	X	X
Pregnancy assessment for all female donors with childbearing potential within seven (7) days prior to donor mobilization or initiation of recipients	X (during work up stage- it is not mandatory within 7 days prior)	X	-	X

REQUIREMENTS	W	F-J	NC-F	AA
conditioning regimen, whichever occurs earliest				
Laboratory testing by laboratory accredited or licensed in accordance with applicable laws and regulations using tests approved or cleared by relevant governmental authority	X	X	X	X
Donor advocate to represent allogeneic donors who are minors or who are mentally incapacitated	-	X	-	Donor must have access to donor advocacy services
Requirement that use of donor not meeting established safety criteria includes documented rational for selection by the transplant physician	X	X	X	X
History obtained and documented from maternal cord blood donors at a time when the mother is able to concentrate on the information and is not distracted by aspects of labor	X	NA	X	X
Issues of donor health pertaining to safety of collection procedure communicated in writing to collection staff.	X	X	-	-
Policy for donor follow-up that induces routine management and management of donation-related adverse events	X	X	X	X
Communicable disease risk behavior history obtained in a confidential manner from all donors	X	X	X	X
Obtained from surrogate maternal donor carrying an infant donor not genetically hers	-	-	X	X
Obtained from sperm, egg, or embryo donor if applicable	-	-	X	X (egg donor)
Previously obtained history for communicable disease transmission risk	X	-	X	X

REQUIREMENTS	W	F-J	NC-F	AA
updated to time of delivery for cord blood donors within 14 days of delivery				
Infant donor of Cord Blood data to include history of pregnancy and delivery, birth data including gestational age, gender, and results of clinical examination, and any indication suggestive of potentially transmissible disease	X	-	X	-
Additional Requirement of Allogeneic Donors include:				
Written criteria for the selection of allogeneic donors who are minors.	-	X	-	X
Written criteria for the selection of allogeneic donors when more than one donor is available and suitable	-	X	-	-
Information regarding the donation process should be provided to the potential allogeneic donor prior to HLA typing.	X	X	-	-
Testing for ABO group and Rh Type (All donors)	X	X ALLO only	X (prior to listing)	X
Repeat ABO and Rh testing at time of first product collection for products containing RBC at time of administration	X (at the verification typing stage if not previously determined)			X
Testing of Allogeneic donor for CMV unless previously documented to be positive	X	X	X	X
Allogeneic donor typing minimally for HLA-A, B, DR type by a laboratory accredited by ASHI, EFI or equivalent. HLA-C testing for unrelated donor and related donors other than siblings	X (HLA-C not required)	X	X (HLA-C "should" be determined)	X (HLA-C not required)
Class II testing by high resolution DNA molecular typing methods	X	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
Red blood cell compatibility testing with the recipient when appropriate	-	X	-	X
Allogeneic donor eligibility documented in recipient's medical record before initiation of high dose therapy and prior to donor mobilization as applicable	X	X	Must be complete prior to listing	X
Risk factors for all donors to include:				
Vaccination history	-	X	-	X
Travel history	X	X	X	X
Blood transfusion history	X	X		X
Questions to identify persons at high risk for transmission of communicable disease as defined by applicable governmental authority	X	X	X	X
Questions to identify potential to transmit inherited conditions	X	X	X	X
Question to identify potential to transmit hematological or immunological disease	X	X	X	X
Questions to identify a past history of malignant disease	X	X	X	X
Confirmation that information provided is true to the best of the donors knowledge	X	X	X	-
Infectious Disease Testing performed from a sample obtained with 30 days prior to collection to include tests as required by applicable laws and regulations for[1]:	X	X	X (7 days before or after collection)	X (for HPC-A and HPC-M; for others, 7 days before or after procurement)
Human immunodeficiency virus, type 1	X	X	X	X
Human immunodeficiency virus, type 2	X	X	X	X
Hepatitis B virus	X	X	X	X
Hepatitis C virus	X	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
Treponema pallidum (syphillis)	X	X	X	X
If required by applicable laws and regulations testing must be performed for:				
Human T cell lymphotrophic virus I	X	X	X	X
Human T cell lymphotrophic virus II	X	X	X	X
West Nile Virus	X (as defined by national health authorities)	X	X	X
Trypanosoma cruzi (Chagas' Disease)	-	X	X	X
Additional tests must be performed as required to assess the possibility of other transmissionable infectious or non-infectious diseases	X (as defined by national health authorities)	X	X	X
Evaluation of the potential dilution of sample from birth mother (or donor) assessed and acceptance criteria defined	-	-	X	X
Within U. S. or for shipment to the U.S. requirement that donors of products rich in viable lymphocytes, including therapeutic cells and other cellular therapy products be tested for relevant communicable disease agents with 7 days prior to or after collection or in accordance with applicable laws and regulations.	-	X	X	X (all cellular therapy products being shipped within U.S. must adhere to applicable infectious disease testing regulations)
Use of ineligible allogeneic donor requires the following:				
Documentation of rationale for selection and suitability by transplant physician	-	X	X	X
Documentation of urgent medical need	-	X	Requires release by CBB Director or Medical Director	X

REQUIREMENTS	W	F-J	NC-F	AA
Documented informed consent of the donor and the recipient	-	X	X	X
Written communication of donor eligibility and suitability to the collection and processing facilities	-	X	At distribution to clinical program	X
Policy covering the creation, regular review, and retention of allogeneic donor records.	-	X	-	X
Allogeneic donor records shall include donor eligibility determination, including the name of the responsible person who made the determination and the date of the determination.	-	X	-	X
Maintain linkage of the CB unit to the infant donor and mother	-	-	X	X

[1] For cord blood testing must be performed prior to release for administration