Comparison of Cell Collection Standards

The tables are populated with data from the standards from FACT-JACIE, Netcord-FACT, WMDA, and AABB. Consult the current versions. EFI standards do not cover these activities. The crosswalks are intended to point out similarities or general principles of the standards and do not necessarily list specific requirements.

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 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
Standards are addressed	X
Standards are not addressed	-
Cord Blood Bank	CBB
Not Applicable	NA

REQUIREMENTS	W	F-J	NC-F	AA
Applies to living donors only?	X	X	X	Cadaveric products covered in Standards
Use cell processing facilities that meet Standards?	X	X	X	X
Abide by all applicable laws and regulations?	X	X	X	X
For initial accreditation, in place and collected at least ten (10) cellular therapy products by apheresis in the twelve (12) months preceding application for initial accreditation?	Searchable donor file of minimal size: Minimum of 500 donors. Minimum of 6 donations and/or cord blood unit shipments within the last three years with 2 of the 6 for	Minimum time 12 months	NA	Minimum time in operation: 6 months

REQUIREMENTS	W	F-J	NC-F	AA
	international patients			
For initial accreditation cord blood banks, need a minimum number of units banked (if yes, please specify)	Searchable donor file of minimal size:100 cord blood units.	NA	Must have 500 units banked	Minimum time in operation: 6 months
For renewal accreditation only: collected on average at least ten (10) cellular therapy products by apheresis per year within the previous accreditation cycle?	Same applies as for initial accreditation (qualification) and accreditation	Minimum average activity	Actively adding units to bank	-
COLLECTION FACILITY				
Facility registered and/or accredited as required by the appropriate governmental authority?	X	Common in all sections	-	X
Appropriate designated areas for collection of cellular therapy products, for the product collected, and for storage of supplies, reagents, and equipment?	-	X	X	X
Divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products?	-	X	X	X
Suitable space for confidential donor examination and evaluation?	-	X	X	X
Provide adequate lighting, ventilation, plumbing, drainage, and access to sinks and toilets to prevent the introduction, transmission, or spread of communicable disease?	-	X	-	X
Critical facility parameters identified, controlled, monitored, and recorded to demonstrate ongoing compliance?	-	X	-	X
Cord Blood collection kit prepared and sent from CBB must contain adequate instructions and materials to collect, label, store, pack, and transport or ship CB unit, associated samples and maternal samples.	-	-	X	-
Cord Blood collection kit reagents and supplies shipped to collection site in validated container and stored at site according to manufacturer's recommendations.	-	-	X	X

REQUIREMENTS	W	F-J	NC-F	AA
Environmental conditions controlled and documented?	-	X	-	X
Adequate equipment and materials for the procedures performed at the facility?	-	X	X	X
Process to control storage areas to prevent mix-ups, contamination, and cross-contamination of all products during quarantine, prior to release or distribution?	-	X	X	X
24-hour availability of CMV-appropriate and irradiated blood products?	-	X	-	X
Access to an intensive care unit and/or emergency services?	-	X	X (emergency and safety procedures required)	X
SAFETY REQUIREMENTS				
Does the Collection Facility have a written safety manual?	-	X	Requires Safety Procedures	X
Medical waste managed in line with regulations?	-	X	X	X
Facility maintained in a clean, sanitary, and orderly manner?	-	X	X	X
Are gloves worn when handling biological specimens?	-	- covered in Guidance	X	X
PERSONNEL				
COLLECTION FACILITY DIRECTOR				
Is there a designated Collection Facility Director?	-	X	X	X
Minimal educational requirements?	-	X Medical or relevant science degree, post graduate training or experience related to activities of facility	X Health care professional responsible for communicating with CBB Medical Director	X Licensed physician, qualified by training or experience and relevant continuing education
Are Collection Facility Director responsibilities defined to include oversight of:				
All technical procedures?	-	X	CBB Med Director	X
Performance of the collection procedure?	-	X	CBB Med Director	X

REQUIREMENTS	W	F-J	NC-F	AA
Supervision of staff?	-	X	X	X
Administrative operations?	-	X	CBB Med Director	X
The Quality Management Program?	-	X	CBB Quality Unit Manager	Executive management responsibility
Compliance with these Standards and other applicable laws and regulations?	X	X	CBB QM Supervisor	X
Collection Facility Director has at least one year experience and performed or supervised at least ten (10) cellular therapy product apheresis collection procedures within the last three (3) years.	-	Minimum time 12 months and minimum activity 10 procedures	Must be trained, minimum numbers not defined	Must be qualified by training and experience, minimum numbers not defined
Participate regularly in educational activities?	X	X	X	X
COLLECTION FACILITY MEDICAL DIRECTOR				
Is there a Collection Facility Medical Director?	-	X	CBB Medical Director	X
Is the Collection Facility Medical Director or designee directly responsible for the medical care of patients undergoing apheresis, including the pre-collection evaluation of the donor at the time of donation and care of any complications resulting from the collection procedure?	-	X	NA for apheresis is responsible for donor	X
At least one year experience in cellular therapy product collection procedures and performed or supervised at least ten (10) cellular therapy product apheresis collection procedures within the last three (3) years?	-	Minimum time 12 months and minimum activity 10 procedures	CBB Med Director numbers not defined	Must be qualified by training and experience, minimum numbers not defined
Participate regularly in educational activities?	X	X	X CBB Med Director	X
STAFF				
Adequate numbers of trained collection personnel available?	X	X	Must be trained health care professional	X
Where there are pediatric donors, do physicians and collection staffs have documented training and experience in performing these procedures?	-	X	-	X
DONOR RECORDS				
Are there requirements for a policy for donor records retention including minimum content required?	X	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
RECORDS IN CASE OF DIVIDED RESPONSIBILITY				
If two (2) or more facilities participate in the collection, processing, or transplantation of the cellular therapy product, do the records of each facility show plainly the extent of its responsibility?	X The registry must have an agreement in place with the Collection Centres, and policies and procedures in place describing what information should be passed on to the transplant centre and how that communication will take place.	X	X	X
Does the Collection Facility furnish to the facility of final disposition a copy of all records relating to the collection procedures performed in so far as they concern the safety, purity, or potency of the cellular therapy product involved?	X The registry must have an agreement in place with the Collection Centres	X	X	X
Maintain listing of names, addresses, and responsibilities of other facilities.	X The registry must have an agreement in place with the	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
	Collection Centres			