

Comparison of Cell Collection Standards

The tables are populated with data from the FACT-JACIE (4th ed.), Netcord-FACT (4th ed.), WMDA and AABB (5th ed.)

Definitions	Abbreviation
WMDA 2008	W
FACT-JACIE 4th Ed	F-J
Netcord-FACT 4th Ed	NC-F
AABB 4 Ed	AA
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	Common in all sections	X	N/A
Abide by all applicable laws and regulations?	X	Common in all sections	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?	NA	Min time and activity	Minimum time in operation: 6 months	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?	NA	Min continuous activity	Minimum time in operation: 6 months	N/A
COLLECTION FACILITY				
Facility registered and/or accredited as required by the appropriate governmental authority?	X	Common in all sections	X	X
Appropriate designated areas for collection of cellular therapy products, for the product collected, and for storage of supplies, reagents, and equipment?	NA	X	X	X
Divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products?	NA	X	X	X
Suitable space for confidential donor examination and evaluation?	X	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?	NA	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
Critical facility parameters identified, controlled, monitored, and recorded to demonstrate ongoing compliance?	NA	X	X	X
Environmental conditions controlled and documented?	NA	X	X	X
Adequate equipment and materials for the procedures performed at the facility?	NA	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?	NA	X	X	X
24-hour availability of CMV-appropriate and irradiated blood products?	NA	X	NA	
Access to an intensive care unit and/or emergency services?	NA	X	X	X
SAFETY REQUIREMENTS				
Does the Collection Facility have a written safety manual?	NA	List of types of hazards that should be included	List of types of hazards that should be included	X
Medical waste managed in line with regulations?	NA	X	X	X
Facility maintained in a clean, sanitary, and orderly manner?	NA	X	X	X
Are gloves worn when handling biological specimens?	NA	X	X	X
PERSONNEL				
COLLECTION FACILITY DIRECTOR				
Is there a designated Collection Facility Director?	NA	X	X	X
Minimal educational requirements?	X	Medical or relevant science degree, post graduate training or experience related to activities of facility	A Licensed health care professional, post graduate training or experienced related to the field of donor safety, CB banking, processing and transplantation	Licensed physician, qualified by training or experience and relevant continuing education
Are Collection Facility Director responsibilities defined to include oversight of:	NA	X	X	X
All technical procedures?	NA	X	X	X
Performance of the collection procedure?	NA	X	X	
Supervision of staff?	NA	X	X	X
Administrative operations?	NA	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
The Quality Management Program?	NA	X	X	Executive management responsibility
Compliance with these Standards and other applicable laws and regulations?	NA	X	X	X
Collection Facility Director has at least one year experience and performed or supervised at least ten (10) cellular therapy product apheresis collection s? Procedures within the last three (3) years?	NA	Min time and activity	Min time and activity	
Participate regularly in educational activities?	NA	X	X	X
COLLECTION FACILITY MEDICAL DIRECTOR				
Is there a Collection Facility Medical Director?	NA	X	X	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?	NA	X	X	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?	NA	Min time and activity	Min time and activity	
Participate regularly in educational activities?	NA	X	X	X
STAFF				
Adequate numbers of trained collection personnel available?	NA	Adequate not defined	X	X
Where there are pediatric donors, do physicians and collection staffs have documented training and experience in performing these procedures?	NA	X	X	X
DONOR RECORDS				
Are there requirements for a policy for donor records retention including minimum content required?			X	X
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?	NA	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?	NA	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
DIRECT DISTRIBUTION TO CLINICAL PROGRAM				
Provisions for where cellular therapy products are distributed directly from the Collection Facility to the Clinical Program, without transit via a Processing Facility?	NA	X	X	NA