

Comparison of Donor Standards

The tables are populated with data from the FACT-JACIE (4th ed.), Netcord-FACT (4th ed.), WMDA and AABB (4th 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 |
|---|--|---|---------------|--|
| General Requirements-All Donors | | | | |
| Voluntary and unpaid | X | Required for EU under applicable regulations | | |
| Written criteria required for autologous and related allogeneic donor selection, evaluation, and management | | X | X | X |
| Written criteria required for unrelated allogeneic donor selection, evaluation, and management | X | X | X | X |
| Requirements for personnel: | | | | |
| Performing donor selection | | Not specified | | Must be performed by qualified and competent personnel |
| Performing donor evaluation and screening | By a physician who is not a member of a team who has cared for the patient | Not specified | | Must be performed by qualified and competent personnel |
| Final donor authorization and informed consent | By a physician who is not a member of a team who has cared for the patient | Licensed physician or other health care provider familiar with the collection procedure | Not specified | Donor's physician; not specified for consent but donor must have access to donor advocacy services |
| Understandable written consent to donate is required | X | X | X | X |

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|--|--------------------------------|-------------------------|---------------------------------|----|
| Donor Age limits | X | | | |
| Anonymity of unrelated donors | X | As required by registry | As required by registry | X |
| Donor consent document must include: | | | | |
| Benefits and risks | 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 |
| 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 | | |
| Obtained by licensed physician or other health care provider familiar with the collection procedure | X | X | Not specified | |
| 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 |
| Provision of documentation of consent to collection staff prior to the collection procedure | X | X | X | X |
| Donor Suitability Requirements | | | | |
| Testing for ABO group and Rh Type (All donors) | X | X | 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 | | X |
| 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 |

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|---|--|-----|------|------------------|
| Potential risks shall include where relevant: | | X | | X |
| Possible need for venous access | X | X | | X |
| Mobilization | X | X | | X |
| Anesthesia | X | X | | X |
| Pregnancy assessment for all female donors with childbearing potential within seven (7) days prior to starting mobilization (as applicable) and, as applicable, with 7 days prior to initiation of recipients conditioning regimen. | X (during work up stage- it is not mandatory within 7 days prior) | X | | X |
| 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 |
| Requirement that use of donor not meeting established safety criteria includes documented rationale for selection by the transplant physician | | X | X | X |
| Issues of donor health pertaining to safety of collection procedure communicated in writing to collection staff. | | X | | |
| Policy for donor follow-up that induces routine management and management of donation-related adverse events | 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 |
| 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 | | 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 ndonor 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 updated to time of delivery for cord blood donors within 14 days of delivery | X | | X | X |
| Risk factors for all donors to include: | | | | |
| Vaccination history | | X | | X |

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|--|--|-----|--|--|
| 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 |
| Treponema pallidum (syphilis) | X | X | X | X |
| If required by applicable laws and regulations testing must be performed for: | | | | |
| Human T cell lymphotropic virus I | | X | X | X |
| Human T cell lymphotropic virus II | | X | X | X |
| West Nile Virus | | X | X | X |
| Trypanosoma cruzi (Chagas' Disease) | | X | X | X |
| Additional tests must be performed as required to assess the possibility of other transmissible infectious or non-infectious diseases | X (as defined by national health authorities) | X | 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 | | X | X | |

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

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|---|---------------------------|-----|--|---------------------------|
| applicable laws and regulations. | | | | |
| Additional Requirement of Allogeneic Donors include: | | | | |
| 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 |
| Red blood cell compatibility testing with the recipient when appropriate | | X | NA | X |
| Hemoglobinopathy screening for cord blood donors | X | | 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 |
| 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 |
| 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 |