NATIONAL MARROW DONOR PROGRAM® (NMDP)/BE THE MATCH®
U.S. APHERESIS CENTER PARTICIPATION CRITERIA

This document refers to criteria required by National Marrow Donor Program (NMDP)/ Be The Match (referred to as NMDP throughout the remainder of the document). NMDP may, in its discretion, approve deviations from these criteria on a case-by-case basis upon demonstration by the center of extenuating circumstances.

NMDP has established apheresis center participation criteria to address qualification of centers for participation in the NMDP network. NMDP has also established standards, policies, procedures, guidelines, protocols, and participation agreements that may impose additional requirements for centers and support laboratories.

FACILITY CHARACTERISTICS

1. Center must be registered with the Food and Drug Administration (FDA) as a manufacturer of human cells, tissues, and cellular and tissue-based products (HCT/Ps), if appropriate.
2. Center must have adequate staff, resources, space, equipment, and supplies to perform and manage collection-related activities.
3. Center must have secure record storage.
4. Center must have at least two consecutive days available per week to manage NMDP collection activity.
5. Centers participating in human subject research must hold a Federalwide Assurance (FWA) filed with the Office for Human Research Protections (OHRP).

PERSONNEL AND APHERESIS COLLECTION TEAM

6. Center must designate a medical director who is a licensed physician and:
    a. Has at least one year experience in the collection procedure.
    b. Participates annually in educational activities related to the field of hematopoietic cell collection or transplantation (at least one CME credit hour per year).
    c. Assures physician designees are trained and qualified; any responsibility(ies) of the center medical director may be fulfilled by a designated center physician.
    d. Completes training in human subject protection if center uses the NMDP IRB.
7. A licensed physician must be available for direct or telephone discussion throughout mobilizing agent administration and donor monitoring. Administration of mobilization agents must be under the supervision of a licensed physician experienced in their administration and in the management of complications in persons receiving these agents.
8. Center medical director, physician designee, or examining practitioner must perform and/or review a complete medical evaluation of the donor to determine if the donor is an acceptable candidate for HPC(A) collection, including evaluation of the donor for risks of donation and evidence of disease transmissible by transplantation. For purposes of this criterion, an examining practitioner is defined as a licensed physician, physician's assistant, or nurse practitioner, consistent with applicable law. The evaluation and test results must be reviewed and approved by the apheresis center medical director/physician designee and the donor center medical director or designee.

9. The apheresis center medical director (or designee) is responsible for:
   a. Protecting the safety of the donor and product(s).
   b. Interpretation and application of NMDP participation requirements.
10. Apheresis center physician supervising the apheresis collection must be qualified by training and experience to perform HPC(A) collections and:
   a. Be a licensed physician in the state where the collection occurs.
   b. Have performed or supervised at least ten cellular product apheresis collection procedures within the last three years.
   c. Be available on-site or by telephone for the duration of the collection procedure(s) and for follow-up as needed.
   d. Participate annually in educational activities related to the field of hematopoietic cell collection or transplantation (at least one CME credit hour per year).
11. An appropriately licensed and credentialed physician qualified by training and experience must place any required central venous catheters. ~~A licensed physician must also oversee the monitoring and removal of central venous catheters.~~ An appropriately licensed and credentialed healthcare provider must oversee the monitoring and removal of central venous catheters.
12. Center's collection team must:
   a. Be trained in the administration of mobilizing agents to donors.
   b. Have experience in the collection and handling of mononuclear cells by apheresis and management of apheresis donors including those with central venous catheters.
   c. Have performed at least three collections of mononuclear cells by apheresis in the past year.
13. Center must provide daily and emergency coverage by a designated coordinator(s) who is proficient in English, and sufficient in number to meet the needs of the center's activities.
14. Center personnel must comply with NMDP training requirements.
15. All center personnel involved with the completion and submission of NMDP data collection forms must complete the human subject protection training if center uses the NMDP IRB.
16. Center must document staff and volunteer training, continuing education, and continued competency for relevant skills.

SUPPORT SERVICES

17. Center must use a hospital accredited by an organization granted deemed status by Centers for Medicare and Medicaid Services (CMS) for placement of any required central venous catheters and subsequent collection.
18. Center must use facilities that are licensed, certified, or accredited in accordance with applicable governmental laws and regulations and NMDP requirements which include:

a. Laboratory(ies) certified by Centers for Medicare & Medicaid Services (CMS) for tests required by the NMDP.

b. Laboratory(ies) used for measuring the quantity of CD34-positive cells in the product collected must have documented proficiency for CD34-positive testing.

c. Laboratory(ies) used for infectious disease marker (IDM) testing must be an NMDP-contracted laboratory.

19. Center is responsible for periodic review and qualification of outside vendors that provide laboratory services, critical equipment, materials, and/or supplies.

20. Center must have prompt technical and operational support for information systems management.

POLICIES AND PROCEDURES

21. Center must have and follow written agreements, [e.g., Universal Procedures of Interaction (UPOI)] defining roles and responsibilities developed in collaboration with participating donor center(s).

22. Center must meet applicable Good Manufacturing Practices (GMP) and Good Tissue Practices (GTP), including but not limited to:

a. Center must maintain written standard operating procedures (SOPs) to address at least the following:

i. Donor evaluation (including peripheral venous access)
ii. Central venous catheter placement, monitoring, and removal
~~ii.~~iii. Mobilizing agent administration (must only use mobilizing agents approved by NMDP)
~~iii.~~iv. Product collection (including prevention and minimization of citrate toxicity)
~~iv.~~v. Management and reporting of adverse events
~~v.~~vi. Product Testing
~~vi.~~vii. Storage (materials, components, and final products are stored in environmentally monitored areas, including temperature and humidity as appropriate)
~~vii.~~viii. Final product labeling (center must adopt NMDP SOPs)
~~viii.~~ix. Intra-center transport of product
~~ix.~~x. Product distribution and release
~~x.~~xi. Emergency medical care for the donor
~~xi.~~xii. Maintenance of apheresis equipment
~~xii.~~xiii. Internal quality auditing
~~xiii.~~xiv. Corrective actions and preventive actions (CAPA)

b. Center must have a quality assurance program designed at minimum to promptly identify, process, report, and prevent, if applicable, the following per NMDP requirements:

i. Adverse Events

ii. Deviations
iii. Product Complaints
iv. Nonconforming products, materials, or services
v. Corrective actions and preventive actions (CAPA)

c. Center must maintain records~~,~~ in accordance with NMDP Standards to ensure the identification and traceability/trackability of each donor and all related cellular therapy products and all related samples from their initial source through each processing and testing step.

d. Center must retain records in accordance with NMDP Standards.

23. Center must have a written policy on the peripheral venous assessment and placement of central venous catheters.

a. The written policy must state that central venous catheters must only be used when peripheral venous access:

i. Is not deemed feasible after skilled assessment
ii. Cannot be obtained
iii. Has failed

b. The policy must also state that placement of central venous catheters requires written justification.

c. Adequacy of line placement must be verified prior to use.

24. Center must maintain a system of strict confidentiality of records that meets or exceeds NMDP requirements to protect the privacy of potential donors (registry members), donors, and patients.

25. Center must provide the donor with post-donation care instructions including appropriate contact names and phone numbers at time of discharge.

ADMINISTRATION

26. Center must comply with NMDP participation requirements, which include NMDP Standards, policies, procedures, guidelines, protocols, and terms of the participation agreement.

27. Center must comply with applicable World Marrow Donor Association (WMDA) Standards.

28. Center must meet established NMDP continuous process improvement (CPI) criteria.

29. Center must provide documentation that it continues to meet NMDP participation requirements on an annual basis.

30. Center must complete and submit NMDP data forms as required.

31. Center must maintain adequate professional and general liability insurance coverage, as required in the participation agreement.

32. Center must promptly report to the NMDP any significant changes in personnel (including but not limited to the medical director and coordinator), facilities, accreditation status, FDA

registration, or other support services. Any change to FACT or AABB accreditation status or FDA registration, must be reported to the NMDP no later than 15 days after receipt of notice.

33. Center must be willing to submit to an on-site audit by NMDP prior to initiation of NMDP collections and anytime thereafter as coordinated with the center.

APPLICANT CENTER

Review and acceptance of new NMDP apheresis center applications by the NMDP will be based on whether the center meets the minimum criteria as stated above, and if the establishment of the center meets the business needs of the NMDP. At the time of initial application, the following is required:

~~32.~~34. Applicant center must provide a letter of agreement from a hospital-based physicians group documenting their agreement to provide the service of central venous catheter placement and removal for NMDP donors including a statement of their experience with the placement, removal, and management of central venous catheters for HPC(A) collections.

~~33.~~35. Applicant center must submit a collection log providing evidence that center performed at least three collections of mononuclear cells by apheresis in the past year.

~~34.~~36. Applicant center's physician performing or supervising the collection must have performed or supervised at least ten cellular product apheresis collection procedures within the last three years.