

NMDP

U.S. Apheresis and Collection Center Participation Criteria

NMDP has established these criteria to address qualification of U.S. cellular therapy apheresis and marrow collection centers (center) for general participation in NMDP activities. Each participating center will be required to sign an NMDP Participation Agreement (Agreement) which incorporates these criteria by reference.

Review and acceptance of NMDP apheresis and marrow collection center applications by NMDP will be based on the following requirements:

- The center meets the minimum participation criteria
- The center is willing to comply with the requirements within the Agreement
- The establishment of the center meets the business needs of NMDP

At the time of initial application and throughout the terms of the center's participation with NMDP, the applicant center must meet the following criteria and agree to the participation requirements as outlined in the Agreement:

1. The center must be accredited by the Foundation for the Accreditation of Cellular Therapy (FACT) and/or the Association for the Advancement of Blood & Biotherapies (AABB) based on the type of cellular therapy collections and scope of NMDP services that will take place at the center.
2. The center must use facilities which are licensed, certified, and/or accredited in accordance with applicable governmental laws and regulations for all NMDP donor activities.
3. The 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).
4. The center must have a site-specific business continuity plan to ensure no disruption to scheduled collection activities, including but not limited to electronic records management, power failure contingencies, and staff coverage.
5. The centers performing apheresis collections must have a site-specific plan for unanticipated central line placement and apheresis.
6. The center must be willing to submit to an onsite audit by NMDP staff and NMDP study sponsors prior to initiation of collections and any time thereafter as coordinated with the center. Regular onsite and/or remote audits as well as random onsite and/or remote audits may be requested at the discretion of NMDP staff and/or study sponsors.

NMDP may, as delegated by the Membership Review Committee, approve deviations from these criteria on a case-by-case basis.