| **Criterion # in Rev. 1** | **Criterion # in Rev. 2** | **Text/Criterion**Underlined is new text; Strikethrough is removed text | **Rationale** |
| --- | --- | --- | --- |
| **intro** | **intro** | 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.~~National Marrow Donor Program / Be The Match® (NMDP)~~ NMDP has established Participation Criteria to address minimum required elements for participation in the NMDP Network as an international product collection center. Applicants must document, through an application process, that these requirements are met. NMDP has also established standards, policies, procedures, guidelines and Participation Agreement that may impose additional requirements for centers. | Added information to be consistent with other NMDP Participation Criteria documents. |
|  |  | In this document, “center” refers to a hospital or other institution that ~~who~~ collects marrow [HPC(M)] and/or PBSC [HPC(A)] products.  | Grammar correction. |
| **21-25** | **1-5** | **FACILITY CHARACTERISTICS** | Moved this entire section from the end of the document in revision 1 to the beginning of the document in revision 2 to be consistent with other NMDP Participation Criteria documents. |
| **1.b** |  | *(regarding the Medical Director)*~~Has post-doctoral training in hematopoietic cell (HPC) Collection or transplantation~~ | Deleted, as this is a requirement that only applies to marrow collection center physicians in the U.S. Collection physician experience is addressed in new section 8. |
| **2.** | **7.** | The medical director (or ~~physician~~ designee) is responsible for: | Physician designee is specified in 6c in revision 2. Moved from #2 to #7. |
|  | **7.b** | Performing and/or reviewing a complete medical evaluation of the donor to determine if the donor is an acceptable candidate for HPC(M) and/or HPC(A) collection, including evaluation of the donor for risks of donation and evidence of disease transmissible by transplantation. | Added per revision to NMDP Standard 5.2300. |
|  | **7.c** | Interpretation and application of NMDP participation requirements. | Added to be consistent with NMDP Standards and U.S. AC/CC criteria. |
| **2.** | **8.** | Various criteria describing requirements of the collecting physician. | Moved from #2 to #8. |
|  | **8.b** | Be available on-site or by telephone throughout mobilizing agent administration, for the duration of each collection, and follow-up as needed (or appoint a physician designee); | Added to be consistent with U.S. AC Participation Criteria. |
|  | **8.c** | Ensure that mobilization agents are administered under the supervision of a licensed physician experienced in their administration and in the management of complications in persons receiving these agents. | Added to be consistent with U.S. AC Participation Criteria and Standards. |
| **2.a.iii** |  | ~~Maintain documented operating room privileges at the collection center~~ | Removed per elimination of Standard 5.3400. |
|  | **8.f** | Be responsible for determining the donor’s health is appropriate for discharge. | Added to be consistent with U.S. CC Participation Criteria. |
| **2.b.** | **9.** | A licensed physician qualified by training and experience must place and monitor removal of any required central venous catheters. | Added to be consistent with U.S. AC Participation Criteria. Moved from #2 to #9. |
| **2.b.** | **10.** | For HPC(M) collections, ~~when required,~~ ~~center must~~ ~~administer~~ anesthesia must be administered under supervision of a licensed, certified or accredited anesthesiologist, in accordance with its country’s requirements. | Minor re-wording. Moved from #2 to #10. |
|  | **11.a****11.b** | 1. Center shall have an experienced team who has performed at least three HPC(M) collections in the past three years at the center;b. Center shall have an experienced team who has performed at least three collections of mononuclear cells by apheresis in the past year.
 | 11a and 11b added to be consistent with U.S. CC Participation Criteria. These criteria define the experience of the “center/team”, as opposed to the required experience of the physician. |
|  | **14.** | Center must be able to ship donor blood samples to the U.S. for timely arrival. Per. U.S. FDA regulations, workup infectious disease marker testing must be performed at a CLIA certified lab in the U.S. for all U.S. patient requests.  | Added to clarify that the IDMs performed at this stage must currently be performed at a U.S. CLIA-certified lab. This is not a new practice; it clarifies the need to be able to ship donor blood samples promptly *in cases where the product collection center is coordinating the sample collections.* |
| **6.** |  | ~~Collection facility must provide written documentation of the characteristics of the collected product (including cell counts) with the product, according to applicable guidelines.~~ | Incorporated into #20 in revision 2. |
| **7.** | **15.** | Collection ~~facility~~ center must ensure the identity, safety, and privacy of the donor. | Changed for consistency in terminology. Moved from #7 to #15. |
|  | **16.b** | Have irradiated and leukoreduced blood components available in the event that the use of allogeneic blood cannot be avoided. | Added for consistency with U.S. CC Participation Criteria. |
|  | **16.c** | Verify that if autologous units have been collected, the units are available prior to the HPC(M) collection. Autologous blood must be collected at a center that fulfills national guidelines in that country. | Added per WMDA Standards. |
|  | **16.d** | Have the ability to store autologous units prior to HPC(M) collection. | Added to be consistent with U.S. CC Participation Criteria and Standards. |
| **9.** | **17.** | Center must maintain a system of strict confidentiality of records that meets NMDP requirements to protect the privacy of potential donors (registry members), donors, patients, and recipients. This must include a designated site for the management of collection activities. ~~and a secure environment for confidential record storage.~~ | The deleted phrase is already mentioned in criterion #4. Moved from #9 to #17. |
| **10.** | **18.** | Quality Assurance criteria and sub-points | Moved from #10 to #18. |
| **10.** | **18.c** | Product ~~C~~complaints | Updated per change to 11.3000 of NMDP Standards. |
| **12.** | **20.** | Collection ~~facility~~ center must have written policies and procedures in place to ensure the identity, quality and quantity of the collected cells. These must include policies for ~~communication between the requesting registry, collection facility, and cell processing unit regarding the number of cells required and the number of cells able to be obtained~~ prompt transmission of results and completion of NMDP data forms regarding characteristics of the collected product. | Two modifications:1) Deleted the communication reference, as this was derived from a WMDA Standard on communication that applies to registries, not individual collection facilities.2) added the requirement for International facilities to submit the NMDP/CIBMTR data form(s) that provide characteristics of the product.Moved from #12 to #20. |
| **13.** | **21.** | Center must promptly report to the NMDP any significant changes in personnel (including but not limited to medical director or coordinator), facilities, accreditation status, FDA registration (for HPC(A) collections only), or support services. | Clarified that FDA registration applies only to the collection of HPC(A) products. Moved from #13 to #21.  |
| **14.** | **22.** | Cellular product complaints or Serious Adverse Events (SAE) impacting the donor and hence potentially the patient’s health must be identified, documented, investigated, and remedial and/or corrective action taken by the collection ~~facility~~ center. The event must be reported to the ~~WMDA’s SEAR/SPEAR Centralized database~~ NMDP. ~~via the donor/s managing registry.~~ | Changed from WMDA to NMDP. This reference was previously derived from a WMDA Standards that applied to a registry, not an individual collection facility. Moved from #14 to #22. |
| **15.** | **23.** | Collection ~~facility~~ center must cooperate with any product or adverse event investigation conducted by the NMDP. | Terminology change. Moved from #15 to #23. |
| **16.** | **24** | ~~Cells must be transported in a timely and reliable fashion to meet transplant center requirements for the quality and quantity of the cell produce.~~ Product packaging and labeling must comply with national and international regulations. ~~Policies and procedures documenting the transport process must be stipulated.~~ | Product transport is not the responsibility of the product collection center, so this portion of the criterion was deleted. Moved from #16 to #24. |
| **17.** | **25.** | Collection ~~facility~~ center must have appropriate policies and procedures to protect the health and safety of the donor ~~and of the recipient~~ if a donor is subjected to a medical intervention (e.g. administration of GCSF) as part of the product collection process.  | Recipient health and safety are addressed in other criteria. Moved from #17 to #25. |
| **20.** |  | ~~For centers performing HPC(A) collections:~~~~These policies should include the procedure to be followed in case of failed mobilization.~~ | This is a WMDA standard that refers to the registry’s responsibility. |
|  | **30.** | Center must maintain adequate professional and general liability insurance coverage. | Added to be consistent with other NMDP Participation Criteria. |
|  | **31.** | Center must provide documentation that it continues to meet NMDP Participation Requirements on an annual basis. | Added to be consistent with other NMDP Participation Criteria. This refers to the annual network membership survey. |