

Current NCBI Specifications

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Introduction & Mission



Contracts with cord blood banks (CBBs) to continue to build the National Cord Blood Inventory (NCBI) by adding new, high-quality, genetically diverse cord blood units (CBUs).



Mission: NCBI supports HRSA's mission to improve access to quality healthcare and services by contracting services to achieve the statutory goal of adding at least 150,000 new, high-quality, genetically diverse CBUs to the NCBI and making these CBUs available through the CWBYCTP.

Purpose

1. Operate a public CBB that complies with the requirements of the CWBYCTP and:
 - its program contractors,
 - NCBI,
 - HRSA-recognized NCBI CBB Accrediting Organizations Standards (for accreditations it has achieved), and
 - U.S. Food and Drug Administration (FDA) biologics license application (BLA), Section 351 of the Public Health Service Act, for the biological product, Hematopoietic Progenitor Cell (HPC), Cord Blood, for use in unrelated donor hematopoietic progenitor cell transplantation procedures.
2. Collect and store CBUs from a genetically diverse group of donors.
3. Make CBUs available through the CWBYCTP.
4. Make some CBUs, not suitable for clinical transplantation, available for peer-reviewed research.
5. Submit data in a standardized format to the Government and CWBYCTP contractors.
6. Maintain a contingency plan for transferring and receiving NCBI CBUs.
7. Demonstrate self-sufficiency by financial and operational sustainability.



Task 4 Interrelated Contract Requirements

4.1 Comply with CWBYCTP and NCBI Requirements



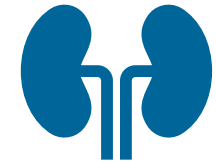
Participate in the CWBYCTP Program through the period of performance– at least, 10 years from the last date Federal funds are obligated to the contract-- of the contract.



Make data available in the standardized format required by SPA-CC contractors.



Make NCBI CBU available through the CWBYCTP SPA-CC contractors until the CBU are released for therapy to a designated patient through an FDA BLA or IND, no longer eligible per contract requirements, or transferred to another NCBI CBB contract.



Submit NCBI CBU pre-transplant data in compliance with the requirements of the CWBYCTP's Stem Cell Therapeutic Outcomes Data Base (SCTOD).

4.3.1 Operate a Cord Blood Bank

Have and maintain its CBB in compliance with:

- U.S. FDA BLA, Section 351 of the Public Health Service Act, for the biological product, Hematopoietic Progenitor Cell (HPC), Cord Blood, for use in unrelated donor hematopoietic progenitor cell transplantation procedures.
- Accreditation Standards for all NCBI accrediting organizations that it has achieved accreditation.



4.3.6 Specify NCBI CBU Characteristics and Specifications

Have and maintain specified CBU characteristics and specifications for NCBI CBUs.

Have a minimum total nucleated cell (TNC) count for NCBI CBUs that shall not be higher than the Contractor's established minimum TNC count for non-contracted public CBUs, by race and ethnicity.

4.3.12 Achieve Self Sufficiency

Achieve self-sufficiency of its CBU collections and CBB operations within 3-years of the entry date of the contract.

Self-sufficiency plan shall have a date for the achievement of self-sufficiency.

Annually evaluate progress towards self-sufficiency.