NATIONAL MARROW DONOR PROGRAM®

MEMORANDUM

To: U.S. Transplant Centers and U.S. Transplant Center IRBs

From: John Miller, MD, PhD
Vice President and Sr. Medical Director
National Marrow Donor Program (NMDP)

Principal Investigator: *A multicenter access and distribution protocol for unlicensed cryopreserved cord blood units (CBUs) for transplantation in pediatric and adult patients with hematologic malignancies and other indications*

Subject: Accessing Unlicensed Cord Blood Units as of October 20, 2011

The primary objective of this protocol is to comply with the FDA regulations that become effective on October 20, 2011, requiring all unlicensed cord blood units (CBUs) to be accessed only through an FDA-accepted IND. At that time, we anticipate that the majorityof U.S., and virtually all international, cord blood units will not be licensed. This protocol is designed to meet the FDA regulations and ensure that transplant centers have access to the unlicensed cord blood units for their patients. A few key points relating to the rationale for this IND protocol:

- This is an observational study to allow pediatric and adult patients access to CBUs that are not licensed.
- Patients will only have access to unlicensed U.S. or international units by participating in an IND protocol.
- Under this protocol unlicensed units may only be accessed for those disease indications specified in the FDA guidance document. Disease indications not specified in the FDA guidance document will require a transplant center sponsored IND protocol or a transplant center sponsored single patient IND.