

	Combined Private and Public Banking of Cord Blood and Other Related Products			
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INTRODUCTION

The World Marrow Donor Association (WMDA) has taken note of the emergence of public cord blood banks that also collect cord blood units for private use. A number of models for combined banking have been developed in this area including joint marketing of separate banking operations, opportunities to split units for private and public use, and the offer to bank units as either public or private units initially, but with the potential of converting the units' status at a later date or event. In addition, new banking options are emerging including the opportunity to bank cells derived from the cord, placenta or amniotic fluid. Though the WMDA has issued a position statement regarding private banking, the WMDA has not taken any position on whether a public banking entity should pursue private banking or whether cells that originally were banked for private use could ever be placed in the public inventory.

By adopting the following guidelines, the WMDA is providing guidance for units collected by a bank that the bank intends to put into the public inventory. It does not take a position on whether a public banking entity should engage in private banking. For those organisations that pursue both public and private banking, it adopts these guidelines regarding public use of stored materials. For the purpose of this document, the term "Banked Cells" means *cells or products collected from the umbilical cord, placenta or amniotic fluid that are to be cryopreserved for later human use.*

GUIDING PRINCIPLES

Where the operation of a public cord blood bank also has a private banking operation or where it affiliates with a private bank for purposes of joint marketing, operational economies or other reasons, the following guidelines should be followed:

1. Banked Cells intended for public use must meet all regulatory and accreditation standards as applicable to publicly Banked Cells, including those applicable to informed consent, at the time of collection.
2. Banked Cells collected solely for private use should not be stored with Banked Cells that may enter the public inventory unless they meet all regulatory and accreditation standards at the time of processing and storage.
3. Joint marketing must clearly identify the current scientific understanding of the use of the Banked Cells in both public and private use and any statement concerning potential future use that lacks available supporting scientific data should be clearly labelled as such. A use that is under current clinical study should never be represented as an established use.
4. Any claims of accreditation should clearly identify to which parts of the operation the accreditation applies and whether the bank is accredited for public banking.
5. Informed consent should fully disclose the timing and circumstances upon which the Banked Cells would convert to public use.
6. Banked Cells listed for public use should be fully consented for public use and not be subject to further consent from the donating family once they are placed in the public inventory. Banked Cells should only be placed in the public inventory after all testing and consents have been obtained by the listing cord blood bank.
7. Banked Cells not consented for eventual public use at the time of collection should never be placed into the public inventory.

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DISCUSSION

Compliance with regulatory requirements. Any Banked Cells that would qualify for public banking use must meet all regulatory guidelines for public banking in existence at the time the Banked Cells were collected and banked.

Some countries may adopt a less rigorous regulatory scheme for private banking than public banking. It would be difficult to retroactively qualify Banked Cells for public use and may raise concerns about the associated public inventory. Therefore, Banked Cells that may or will be put into the public inventory must meet all public banking standards both at the time of collection and listing.

Exceptions to this rule may be appropriate under certain circumstances. For instance, HLA testing on Banked Cells that may initially be intended for private use may be unnecessary at the time of collection provided the testing can be done reliably at a later date consistent with test manufacturer's validated test parameters. However, it is not acceptable to rely on risk screening questionnaires that were not completed contemporaneously with the time of collection.

Disclosure of potential public use. The potential of Banked Cells going into the public inventory must be disclosed to the family at the time of collection.

The cord blood bank must fully disclose its interests in the Banked Cells that could be converted into public use as a part of the initial consenting process. This includes the potential that the bank will acquire rights in the Banked Cells when the family decides to donate it to the public inventory.

Information intended to inform potential donors about banking should provide a clear description of current potential uses of Banked Cells in both a private and public use setting. If the information contains reference to potential uses in the future, this should be done in a separate section and be qualified by language that clearly states that there is no proof that the Banked Cells could have therapeutic potential.

Consent. A consent that meets the standards of a public banking consent must be completed contemporaneously with the collection of the Banked Cells.

The concept of informed consent is well developed in the public banking setting. The appropriate legally responsible person must acknowledge in writing the intention to make an unequivocal donation of the Banked Cells upon the occurrence of specific and objective criteria concerning when the Banked Cells go into the public inventory, which is fully described as a part of the informed consent.