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Ethical and Legal Issues

The collection of tissue from one individual for therapeutic use in another individual involves not only technical and medical issues, but also ethical and legal issues. Donors of cord blood are not merely depositing the leftover by-products of the birth process with interested researchers and physicians; rather, they are making a choice to do something that may potentially benefit either unknown beneficiaries or members of their own families. Pregnant women receive a great deal of information—sometimes conflicting—about the donation process and the consequences of different types of banking. It is crucial to disclose several kinds of information to the potential donor, including who has access to the cord blood once it is donated, where it is stored, how it is stored, and how the donor's privacy is protected.

From the perspective of the recipient, some patients with high-risk diseases known to respond poorly to conventional therapies may consider pursuing experimental HPC interventions. These patients might be willing to take greater risks than less severely ill patients when they are pursuing treatment. As experimental treatments become available, some patients may be willing to undergo them even if the risks and side effects are not fully known. It is crucial to disclose to the potential recipient all available information about risks and probable benefits of experimental interventions, as well as uncertainties, so that he or she can make an informed decision.

Because uses of cells from umbilical cord blood are not yet considered routine medical practice, and because of the need for informed decision-making, this therapy currently falls within the legal framework of an investigational new drug (IND) application with the Food and Drug Administration (FDA). This well-established mechanism allows for the use of experimental drugs or biological products in studies with humans via a registration process.

This chapter focuses on: (1) issues surrounding the procedures used to obtain informed consent from potential cord blood donors, (2) concerns about disclosure to donors of significant clinical information discovered during the donor screening process, (3) and points to consider in the research use of cord blood, including protection of donor confidentiality. In addition, brief mention is given to the potential impact of patent litigation on cord blood banking practices.

INFORMED CONSENT OF DONORS

Until recently, cord blood was considered one of the many biological waste materials discarded after the birth of a baby (Fernandez, 1998; Gluckman, 2000). The possibility of using cord blood as a source of stem cells for transplantation altered this view and introduced different rules and regulations for appropriate decision-making, handling, and use of this biological material. It is ethically important to obtain informed consent for the donation of any cord blood unit, regardless of the timing of collection or the potential use of the unit (see Table 5-1 for descriptions of consent practices among several agencies). Informed consent procedures for the donation of cord blood should follow a consistent set of protocols that educate the donor about the various options for cord blood use. The requirements should be modeled on already established criteria for transfusion of whole blood and other unfrozen blood products (Fernandez, 1998).

TABLE 5-1 Consent practices for agencies currently involved with cord blood.

Consent Parameter	FACT/NetCord	AABB	NMDP
Timing	Before or within 7 days of delivery; consent should be obtained before the collection procedure when the cord blood is collected with the placenta in utero	The consent process should begin before collection and should be completed within 48 hours	Consent should be not be undertaken after the onset of active labor and should be postponed until the mother has sufficiently recovered from the delivery process
Surrogate pregnancy	Consent should be obtained from both the surrogate and the biological mother	Consent should be obtained from the biological birth mother	Not addressed
Minor	Not addressed	Applicable informed-consent requirements and regulations shall be met	Not addressed

Consent Parameter	FACT/NetCord	AABB	NMDP
Specific elements to be included in the consent	<ul style="list-style-type: none"> • If for an allogeneic transplant, the donation will be made available to other individuals and may not necessarily be available to the donor or donor's family at a later date • If intended for a related allogeneic or autologous transplantation, the release of the cord blood will be limited to the specific family recipients or donor • An interview for personal and family history will be undertaken • A review of the medical record of the mother and infant will be performed • A description of the cord collection procedure • Collection of blood from the mother and infectious and genetic testing on the cord blood unit and maternal sample will be performed • Maintenance of linkage for the purpose of notifying donor/family of infectious or genetic diseases • Use of cord blood for research, quality control or validation studies • Disposal of cord blood units not meeting criteria for banking 	<ul style="list-style-type: none"> • Description of cord collection procedure • Sample collection and storage for possible future testing • Testing for infectious diseases and genetic disorders • Notification of abnormal results • Review of medical history and family genetic history • Possible dispositions of cord blood units • Discussion of confidentiality • Ownership 	Specific document currently under development

Note: FACT = Foundation for the Accreditation of Cellular Therapy; AABB = American Association of Blood Banks; NMDP = National Marrow Donor Program.

Who Provides Consent?

The need for consent from the mother, father, or both varies according to the individual circumstances of the potential donors. If the cord blood is removed while the placenta is still in the uterus, generally the mother's consent is sufficient because it is an extension of her body. If the cord blood is removed after the placenta has been taken from the mother's uterus, however, an argument could be made that the father's wishes are also relevant—just as both the mother and the father would be decision makers about their child's care. Few cord blood banks or collection centers obtain consent from both parents (Institute of Medicine bank survey; see Table 5-1 and Appendix C). Because the father may not be available at the moment of delivery, it would be difficult for a cord blood bank to obtain the both paternal and maternal consent within the timeframe needed to begin processing. The majority of women polled in a recent study (86 percent) believed that cord blood was a valuable resource and should be collected, since the risks to the mother and fetus were extremely low (Fernandez et al., 2003). When asked who should decide about making the donation, two-thirds believed that the partner should be included in the decision to donate, but in the case of a disagreement, 77 percent held the opinion that the decision should ultimately be left up to the mother (Fernandez et al., 2003). A father informed at some point after collection may have questions or objections. Thus, while the committee does not advocate requiring the father's consent, cord blood collection centers should have a plan in place to address paternal objections to the donation of cord blood.

Recommendation 5.1: Cord blood collection centers should have clear policies about who must provide consent for donation and a plan in place to address paternal objections to the donation of cord blood.

Some have questioned whether minors can appropriately consent to donation. In the committee's site visits, only one bank collected cord blood from mothers who were less than 18 years of age. In those situations where the mother was 16 or 17 years old and was otherwise not exempt from donating for health reasons, the consent was obtained from the baby's maternal grandmother. The committee believes that situations regarding non-adult consent should be dealt with on a case-by-case basis, after review of the policies and procedures for obtaining minority consent have been reviewed and approved by a local Institutional Review Board (IRB). State law regarding age of consent for health services associated with pregnancy should also be taken into account.

When Should Consent be Obtained?

Optimally, to promote and ensure respect for a pregnant woman's autonomous choice, her informed consent for the collection, storage, and use of her cord blood should

be given late in the pregnancy but before labor and delivery and after adequate disclosure of information on the potential uses of the donated cord blood. This is especially important in the realm of public banking, in which the parents often do not initiate the donation process. Almost all the women polled in a recent study expressed the opinion that the information about the collection of cord blood should be presented before the third trimester of pregnancy and could be included in the informational packets that are given to mothers during prenatal visits (Sugarman et al., 2002).

A significant roadblock to donation could develop if women were subjected to the lengthy taking of an extensive family and personal medical history and extensive physical examination, resulting in the signing of multiple consent forms, leading to 1) either failure to collect the cord blood because of lack of staffing, or 2) inability to bank the blood following collection (Sugarman et al., 1998). Historically, a few banks have addressed these concerns issue by approaching women only after the unit has been collected and deemed potentially usable. Thus, women are not asked to engage in an unnecessary decision-making process while they are under the stress of labor, especially if the unit is ultimately deemed unusable after it is collected (or is unable to be collected for a variety of reasons). However, it is important to note that the women interviewed in the previously mentioned study believed that it was important that they be kept informed throughout the process, especially in light of the additional time and testing required of them as donors (Fernandez et al., 2003).

In the course of site visits, the committee learned that a majority of banks require consent prior to labor and delivery, with two variations. One bank obtained consent when the mother enters the hospital, and the other routinely collected cord blood after delivery from mothers who were not registered with private banks and subsequently requested consent for banking units that were bankable. Notably, these two banks also had a great deal of success in banking units from otherwise underrepresented populations. Thus, while informed consent procedures must be designed to protect the interests of the donor family, they may also need to take into account practicality and demographic realities of the donor communities without compromising donor autonomy. Further, banks should consider routinely translating the informed consent document and other information into languages other than English that are common in their collection areas as this will help achieve the goal of a diverse inventory.

Recommendation 5.2: Informed consent for the collection, storage, and use of cord blood should be obtained before labor and delivery, and after the adequate disclosure of information.

Given the realities of labor and delivery, this ideal approach to consent may not always be feasible. At a minimum, the donor's consent for the collection of cord blood should be given prior to delivery, and the donor should be informed that no steps other than the col-

lection of the cord blood and samples for testing of the mother will be taken until the mother (and, if present, the father) can participate in a full informed consent discussion.

Clarifying Potential Options and Outcomes of Donation

In obtaining informed consent it is important to address any assumptions or motivations the donors might have. The attitudes of mothers toward the collection of cord blood units generally reflect their level of knowledge of the process (Sugarman et al., 1998; Fernandez et al., 2003). Misconceptions about the collection process, the associated risks, and the availability and access of units, should they be needed in the future, are common among cord blood donors. In one recent study, women failed to appreciate their alternatives to donating cord blood to a public bank. Almost one-third did not understand that they had the option of discarding their cord blood at delivery, whereas just over half were aware of the option of placing cord blood unit in a private bank (Sugarman et al., 2002).

Some donors reportedly view public banking as a less expensive way to preserve and gain access to their children's cord blood in the future rather than contracting with a private bank. In one survey, almost one-half of the respondents indicated that the reason they chose to donate their cord blood to a public bank was to protect their child's future health (Sugarman et al., 2002). Sugarman et al. assert that potential donors should be informed that they will not have a property claim to the unit after donation and that if the family were to have a need for the unit in the future it would not necessarily be available.

Recommendation 5.3: The information provided to a donor must include a balanced perspective on the different options for banking. The information disclosed for allogeneic donation should not include language that gives the donor an impression that the unit will be available to the family after donation.

In addition to meeting the major informational concerns discussed above, collectors of cord blood may elect to provide donors with the option to restrict the use of the cells to clinical transplantation. These collectors, who are themselves health care providers, have an obligation to convey in clear and unequivocal language to potential donors that no matter what their decision about donation, their care will not be affected.

Standards for Obtaining Informed Consent of Donors

Because cord blood transplantation is considered an experimental procedure, review and approval of the design and implementation of the informed consent process is the

responsibility of the IRB¹ designated by the collection center. Cord blood collectors must be able to tailor the informed consent process to accommodate the local population, which may have specific cultural, religious, and historical attitudes toward the donation of the body or any of its parts. They should present to IRBs an informed-consent process that engenders confidence that use of the donated cord blood will not conflict with personal beliefs or practices. Further, the IRB must adequately assess the methods proposed to maximize the collection of cord blood to be certain they do not conflict with the steps needed to protect the donor's rights and welfare.

DISCLOSURE OF INFORMATION REGARDING SCREENING AND OTHER RISKS

One of the major responsibilities of the collection staff and the storage facility is to screen the donated cord blood units in order to provide units that are safe for the transplant recipient. (A more extensive discussion of safety and quality issues can be found in Chapter 4). The extensive screening and testing of the donor's mother is similar to that required of blood donors and is required by the FDA regulations addressing human cells, tissues, and products (21 CFR 1271, effective in May 2005). Because no screening or testing program can eliminate all risks, donors should be informed that they will be notified if abnormal conditions are detected when the cord blood itself is tested.

Screening includes the process of obtaining the donor's extensive social, medical, and genetic history. This information may or may not be linked to the unit for future reference. Health questionnaires designed to determine certain characteristics of the donor's history often include questions about sexual and other behaviors and risk factors that then become part of the record. The questionnaires currently in use in allogeneic banks are designed to solicit this information. However, the record may be incomplete because volunteers for allogeneic cord blood donation are not generally motivated by the threat of the immediate loss of a family member and may therefore be less inclined to provide intimate personal information to anyone beyond their personal physician (Zilberstein et al., 1997)

The additional testing of the cord blood unit could reveal unanticipated information about the mother or her child's health that would have otherwise gone unnoticed. These new revelations could result in future emotional, social, and physical hardship to the donor, the donor's child, or the donor's family. For example, the discovery of a genetic predisposition to a disease such as cancer could make health insurance difficult for the family to obtain. Or, to take another example, the discovery of carrier status for certain recessive diseases could lead to stigmatization.

¹IRB review of research protocols, unless otherwise exempt, is required for all human subjects research conducted or supported by the Department of Health and Human Services, 16 other federal agencies, or subject to FDA regulations (see 45 CFR part 46 and 21 CFR parts 50 and 56).

Banks that provide blood for transfusion have been guided by principles of beneficence and autonomy in the testing and notification of their donors of abnormal conditions (Haley, 1999). Extensive disclosure and discussions, both before and after donation, are ways to implement these principles by ensuring that the donor fully comprehends the medical, legal, and ethical issues that arise from the donation of the cord blood units. Test results carry information not only about the child's health, but also about the genetic health of both parents and the infectious disease status of the mother. Although cord blood banks have the duty to notify a donor of abnormal test results, especially in light of the regulations regarding reportable infectious diseases, the information must be kept confidential and also be delivered to the donor in a manner that is not only appropriate relative to the severity of the abnormality, but that is also sensitive to the possible social and economic repercussions of the disclosure.

Hirschhorn et al. (1999) suggest that the patient's general practitioner, if he or she is available, may often be the best person to contact the donor after abnormal genetic testing results. Health care providers unfamiliar with the donor could be perceived as more distant and may not understand the cultural and familial needs of the patient as well as a primary physician who has had a long-standing relationship with the donor and her family (Burgess et al., 1998; Hirschhorn et al., 1999). If this is to become the normal practice, however, primary care physicians may need additional education or training on appropriate methods of genetic counseling.

Additional testing of the mother might also result in the detection of a disease that laboratories have a legal obligation to report to state health departments, and the informed consent materials need to include this possibility. FDA has declared that records that link the donors and the donated human cells, tissues, and cellular and tissue-based products must be secure to ensure the safety of the transplantable products as well as the safety of the patients receiving transplants. It has also declared that the records must be retained for 10 years to ensure the prevention of communicable disease transmission (FDA, 2004). Given that cord blood units can be stored for long periods, this record retention period might need to be extended.

Sugarman et al. suggest that women who have volunteered to donate cord blood should be given materials that allow them to easily contact the cord blood bank if the child's health or their personal contact information changes. The follow-up assessment of cord blood donation needs to be bidirectional. However, in a recent study almost 25 percent of 170 women reported that they did not know how to contact the bank if their child developed an illness that would render the donated cord blood unusable (Sugarman et al., 2002).

This risk is extremely low because of the screening for genetic and infectious diseases that takes place prior to storage. However, there is a chance that the child may develop a malignancy or be affected by a metabolic or genetic disease that is undetected at the time of storage. Anecdotal evidence offered the committee suggested that such a unit was likely to be identified as a 6/6 match at the time the child-donor needed a transplant, and DNA testing would reveal the unit to be the one donated by the child, at which point it would be removed from the inventory.

MAINTENANCE OF DONOR RECORDS/PATIENT PRIVACY

Patient care and research rely on the efficient acquisition, analysis, and transfer of data that are accurate, readily accessible, and maintained with integrity. Protecting the privacy of individual patients and the confidentiality of the data is the responsibility of all data users, and is necessary to protect individual rights and public expectations. Many groups have focused on privacy concerns related to medical information and medical research and recently enacted regulations aim to improve privacy protections.

Korn (2000) identifies two different types of public concern over the field of bioinformatics: (1) pragmatic (e.g., loss of health insurance or discrimination), and (2) ideological (e.g., strong, deeply held beliefs regarding privacy). Pragmatic concerns about the information gained about the donor's health status can be mitigated—at least in part—by a set of statutes or regulations outlining the appropriate uses of personal data as well as methods to prevent inequity. Ideological concerns, however, are not so effectively mitigated (Korn, 2000).

The privacy of donor medical records is a major concern in cord blood banking. Because most units are frozen for future use and, in order to be cost effective, the required tests are done sequentially, the most expensive tests are done only on units that have otherwise met the bank's requirements. Thus, there is need to maintain a linkage between the cord blood unit and the donor's social and medical histories for the benefit of the donor, the donor's child, and the donor's family (in the case of genetically inherited diseases), as well as for the safety of the recipient and his or her family.

The Privacy Rule of the recent Health Insurance Portability and Accountability Act (HIPAA) legislation was an attempt by legislators to create a set of standards to protect patients' privacy and alleviate some pragmatic concerns. Specially, it set limits on who can look at and receive patients' medical records and other health information. The standards are intended to provide patients with more control over how their health information is used. The regulation covers health plans, health care clearinghouses, and health care providers that conduct financial and administrative transactions electronically. (HHS, 2002; HHS, 2003a; HHS, 2003b). This has specific applications to cord blood banks as they will be collecting identifiable health information to ensure the safety of the cord blood unit and ultimately transmitting some of that information to transplant centers and/or researchers. The Privacy Rule generally requires authorization from individuals to use their protected health information in research, unless an exception applies. This authorization is distinct from informed consent, which is a separate process.

When cord blood units are collected for research, even future unspecified research use, donors must be informed of risks that might ensue, including violations of confidentiality. In its 1999 report *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance* (NBAC, 1999), the National Bioethics Advisory Commission noted that a great deal of the research that is conducted with human biological materials should be considered minimal risk research. Even so, risks to privacy and confidentiality must

always be considered in research involving specimens and/or the associated data. Donors need to be informed of the potential uses of their cord blood samples and should be aware of the implications of their use in research, even after the removal of identifiers linking the sample to the donor's medical record (Clayton, 1995; Meslin and Quaid, 2004).

Several models exist for protecting individuals whose biological material and associated health data are collected by repositories and used for research. The Office for Human Research Protections (OHRP) has included a model and additional guidance for repositories on its website.² In this model the repository's IRB reviews and approves the repository's operating procedures and policies for protecting donor, including the informed consent process. IRB review and informed consent is required at the collection site, unless the IRB has approved a waiver of informed consent. In this model, investigators who are not receiving identifiable data need not obtain IRB review and approval if they sign a human use agreement form documenting that they will abide by the human subjects regulations and not to try to identify donor subjects. Thus, OHRP does allow the research use of coded samples if an agreement exists between the researcher and the bank that the source of the samples will remain inaccessible to the researchers.³ That is, the cord blood bank will not provide the identities of the donors to the researcher. A complete description of the limits of deidentification should be included in the informed-consent process.

The use of a number that cannot be traced without going into the cord blood bank records is considered sufficient. Public banks operating under an IND can request a statement of confidentiality from the FDA for research subjects. This is good practice for cord blood banks aiming to protect the confidentiality assure privacy of their donors.

Often, however, it will be critical to research goals to retain identifiers to materials so investigators can continue to gather clinical information about the donors (e.g., diagnoses, outcomes). These secondary data (i.e., data gleaned from sources that were originally collected for another purpose) are critical to advancing the understanding of health and health care practices (Black, 2003). Cord blood units could provide useful data—especially as genetic testing becomes more practicable—on the correlation of early development and health issues later in life. Because, theoretically, cord blood units can be stored indefinitely, the data obtained from tests performed at the time of the initial collection might be useful if the donor later develops a disease. Retrospective analyses can often answer many questions about health conditions, as long as test results are still linkable to the patient-donor. Thus, for the most part, cord blood units will retain identifiers, primarily for transplant safety. It is likely that future research use will increasingly rely on the availability of some clinical information. If that information can be retained in a manner that protects the identity of the donor (e.g., through a coding scheme or use of an honest broker), then it likely that risks can be minimized, and in most cases the need for informed consent to research can be waived.

²<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/reposit.htm>

³See *Guidance on Research Involving Coded Private Information or Biological Specimens*, OHRP/DHHS, Aug. 10, 2004.)

Recommendation 5.4: Secure links between the medical records of the donor and the banked cord blood unit must be established to ensure the safety of transplantable products and the patients receiving the transplants. These records must be kept confidential and afforded the full protection of the law. If an abnormality is discovered during testing, the results must be delivered to the donor in a manner that is appropriate in relation to the severity of the abnormality.

CORD BLOOD RESEARCH

Cord blood units are banked primarily for use for transplantation, but, as the previous section notes, some are used as a source of stem cells for research purposes. Throughout this report, the committee has used the term “research” in reference to laboratory research and “clinical use” in reference to the transplantation of the cord blood product into a patient. However, as noted above, as of the writing of this report, most cord blood collection and banking is performed under an FDA IND application, even though the unit is being transplanted into human patients in a clinical setting. Significant laboratory research is also being conducted with cord blood units but not necessarily under an IND.

Although the harvesting of embryonic stem cells from surplus embryos obtained from infertility clinics is controversial, cord blood units offer a relatively noncontroversial source of stem cells, although the versatility of cord blood cannot match that of embryonic stem cells (see Chapter 1). Research uses trigger the need for an ethics review of the research protocols by an IRB (if identifiers are maintained), the need to protect the confidentiality of the associated medical information, and the requirements that donors be informed of and consent to the possible use of the material for research. In addition, the commercial development of stem cell lines could generate significant income for the research facility, a possibility that should be disclosed to donors and that relates to broader debates about ownership of the cord blood and its associated medical information. Identifiers or labeling of cord blood units provides yet another set of legal and ethical challenges. The units are initially linked to the donor’s medical and social histories for the purposes of identifying the usability of the unit for transplantation. For cost reasons, human leukocyte antigen testing of cord blood units is generally performed as the final test before listing the unit for search. The removal of donor identification will not be possible under the FDA regulations that will become effective on May 25, 2005 (21 CFR 1271). In addition, the current rules and regulations for DNA banking stipulate that any unidentifiable material may be used for research purposes without obtaining specific consent from the donor.⁴ Similarly, HIPAA legislation, while imposing stricter rules for de-

⁴45 CFR 46.102(f).

identification, allows for the such de-identified material to be exempted from its coverage (Clayton et al., 1995; Clayton, 1995; Bradburn, 2001; OHRP, 2004; Clayton, 2004).

While the de-identification may clear the institution of any obligations under HIPAA or the need for an IRB-approved informed consent procedure, Clayton (2004) explains that public opinion is different, and that most patients still believe they should be informed of all potential research uses of their biological materials and retain some autonomy over their use. Thus, she concludes that research institutions would be best served by working with patients collectively and individually to ensure appropriate oversight.

Recommendation 5.5: Those who collect cord blood for public banks should disclose to potential donors all possible clinical and research uses of the cord blood and, furthermore, that donation will terminate a prospective donor's ability to direct the use of the cells.

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