The concept of storing human tissue for future use by either the donor or an anonymous person is a concept that arose during the last half of the twentieth century. Organ transplants were the first surgical procedure to be performed that involved the placement of a person’s organs into the body of another to replace a diseased organ. Organs, though, cannot be stored for long periods and thus must be transplanted within hours of removal from the donor (as described in Chapter Nine). Today, sperm and embryos can be frozen and thawed and still be viable for artificial insemination procedures or implantation. The newest type of human tissue storage for future use is the storage of umbilical cord blood.

SPERM, OVUM, AND EMBRYO BANKS

Artificial insemination or donor insemination (DI) is a procedure to achieve conception when natural methods have failed. Sperm may be donated by a woman’s husband or by another donor. The first successful artificial insemination was performed in 1790, and donor insemination was first successfully performed in 1884. Both procedures used fresh semen samples. The concept of storing human sperm for long-term use was not realized until the 1970s when the first commercial sperm banks opened, although the first successful donor insemination using frozen sperm occurred in 1953. It was not until 1985 that frozen sperm became the standard for donor insemination. The public recognition of the dangers of AIDS posed a new threat to the use of fresh semen samples, and several organizations began to discourage the use of fresh semen and recommended that only frozen sperm that had been quarantined for a minimum of six months be used for DI. In 1995, there were more than 280 fertility clinics in the United States and 57,000 assisted reproductive technology (ART) cycles were performed. Most of these cycles used the couple’s own egg and sperm to produce embryos.
A few of the major cryobanks and fertility clinics that store human embryos, sperm, and/or oocytes are described below. A more comprehensive list of cryopreservation facilities and fertility clinics with storage services can be found in Appendix I.

**California Cryobank, Inc.**

California Cryobank, Inc., founded in 1977, is one of the largest full-service sperm banks. The California Cryobank provides physicians and their patients a comprehensive resource for semen cryopreservation and specialized reproductive services. It is accredited by the American Association of Tissue Banks, and licensed by the state departments of health in California, Maryland, Massachusetts, and New York. The California Cryobank offers the following services: the freezing and storing of anonymous human sperm for use in artificial insemination; long-term semen storage for men facing the possibility of sterilization, reduction in fertility potential, or genetic damage due to vasectomy, chemotherapy, radiation therapy, and high-risk occupational exposures; long-term storage of preimplantation embryos; and andrology laboratory services, such as semen analysis, fertility testing, sperm washing, and sex selection. California Cryobank’s staff includes physician medical directors, genetic counselors, donor matching counselors, and technical staff.

The California Cryobank’s donor catalog currently contains more than 200 donors, who agree to leave semen donations at least once per week for nine to 12 months. Donors must complete a donor profile that contains a detailed, three-generation medical and genetic history that includes information about the donor’s parents, siblings, grandparents, aunts, and uncles. This donor profile is provided to the patient. Donor profiles also include personal information, such as the donor’s religion, physical characteristics, favorite sports, favorite pets, SAT scores, educational background, and work experience. All donors undergo genetic testing for sickle-cell anemia, Tay-Sachs disease, and cystic fibrosis carrier status. Donors are also tested for infectious diseases, including hepatitis B and C, CMV, sexually transmitted diseases, and HIV/AIDS. All semen specimens are quarantined for at least six months, during which donors are retested every three months for these infectious diseases. Both donor and patient records are kept indefinitely.

California Cryobank has written standard operating procedures pertaining to the storage and maintenance of reproductive tissue. These procedures require a designated secure area for storage tanks that is locked at all times and has limited access, extensive external and internal security systems, personnel to monitor the liquid nitrogen level of each storage tank daily, and complete records of all tissues stored and all activities pertaining to the stored tissues.
Quality-control measures include racially color-coded donor specimens and an electronic identification system to identify donors prior to each deposit.

**Cryobanks International, Inc.**

Cryobanks International, Inc. (CI), is a “Cryocenter” that unites parallel technologies of freezing autologous blood, semen, and umbilical cord blood within one facility. One of the services of CI is to provide anonymous donor semen to couples and individuals.

**Genetics & IVF Institute**

The Genetics & IVF Institute (GIVF), founded in 1984, is one of the largest, fully integrated providers of infertility treatment and genetics services. The GIVF has a main facility in Fairfax, Virginia, and a second facility in Gaithersburg, Maryland. In the Fairfax facility, the GIVF provides medical diagnosis and treatment; genetic and reproductive laboratory testing, including paternity testing; and cryobank services.

The GIVF’s Cryopreservation Division, established in 1986, produced the first frozen human embryo twins in the United States. The cryobank services include embryo cryopreservation and storage, sperm banking, and human ovarian tissue cryopreservation. The institute’s embryo cryopreservation program currently freezes 2,300 embryos annually and has produced more than 250 pregnancies.

**Fairfax Cryobank**

The Fairfax Cryobank, a sperm bank, was established in 1986 to provide patients at GIVF with anonymous frozen donor semen. Fairfax Cryobank was the first sperm bank in the United States to test for genetic carriers of BRCA1, Gaucher’s disease and Canavan’s disease in Jewish donors and cystic fibrosis, alpha-1 antitrypsin, and HIV by polymerase chain reaction (PCR) in all donors. Fairfax Cryobank also tests for Tay-Sachs in Jewish donors, thalassemia in Asian, Middle Eastern, and Mediterranean donors, and sickle-cell anemia and other hemoglobinopathies in African-American donors. Fairfax Cryobank is one of the largest human sperm banks in the country and has provided donor specimens throughout the United States and abroad.
UMBILICAL CORD BLOOD BANKS

Stem cells—progenitor cells, which produce all other blood cells—are used to treat patients with blood diseases, patients with certain genetic disorders, and patients receiving chemotherapy and/or radiation treatment for cancer. Until scientists discovered that umbilical cord blood contained hematopoietic stem cells, the only known source of stem cells was bone marrow. The retrieval of bone marrow, though, is invasive, may be painful, requires general anesthesia, and is expensive. In contrast, retrieval of umbilical cord blood is noninvasive, painless, and generally takes only a few minutes to complete. After a baby is delivered and the umbilical cord is cut, blood is withdrawn from the umbilical cord and placenta with a syringe and then cryogenically stored. In addition, bone marrow is difficult to match between donor and recipient, while cord blood is compatible with more people. Cord blood transplants also have a lower incidence of graft versus host disease (GVHD) and are less likely to transmit infectious diseases.

In 1988, the first successful human cord blood transplant was performed in a child with Fanconi’s anemia using cord blood from a sibling (Gluckman et al., 1989). Since then, over 500 autologous and allogeneic umbilical cord blood transplants have been performed worldwide, with the majority done in the past two to three years (Perdahl-Wallace, 1997). Approximately two-thirds of the cord blood transplants have been performed for malignant conditions, including acute lymphocytic leukemia, acute myelocytic leukemia, chronic myelogenous leukemia, and neuroblastoma (Wagner et al., 1995). The other one-third have been for a variety of genetic disorders, including Hurler’s syndrome and Hunter’s syndrome, adrenoleukodystrophy, osteopetrosis, severe aplastic anemia, severe combined immunodeficiency, and hemoglobinopathies, such as beta thalassemia and sickle-cell anemia (Wagner et al., 1995; Wagner et al., 1996). The majority of transplants have been in children, although a few adults have been transplanted as well.

Under an NIH-sponsored program, cord blood is now being collected and stored at several large banks around the United States, including the New York Blood Center, Duke University, Indiana University, and the University of Minnesota. The International Cord Blood Registry, maintained by the University of Minnesota, matches requests for allogeneic transplants with cord blood banks. In addition, the NHLBI is sponsoring a five-year, $30 million study to show whether cord blood transplantation is a safe and effective alternative to bone marrow transplantation. The collection and storage centers for this study are at Children’s Hospital of Orange County, Duke University, and the University of California at Los Angeles.
In the last few years, privately owned companies have also begun offering umbilical cord blood banking services to individuals and families. When dealing with private storage companies, users pay a one-time fee for the collection, testing, and freezing of the blood. An annual fee is charged for storing the blood in liquid nitrogen. The stored cord blood may be withdrawn if illness occurs later. In contrast, when parents donate their baby's cord blood to a public bank, they generally pay no fees, but they give up all rights to the sample to help build the public supply of cord blood for use in transplantation and research. Even though umbilical cord blood banking has become popular, the Working Group on Ethical Issues in Umbilical Cord Blood recently concluded that “until additional data are obtained regarding safety and efficacy, umbilical cord blood banking and use ought to be considered an investigational technology rather than a proven treatment” (Sugarman et al., 1997).

**Public Donor Umbilical Cord Blood Banks**

**American Cord Blood Program.** The American Cord Blood Program, located at the University of Massachusetts Medical Center, is the first nonprofit umbilical cord blood bank in New England. The American Cord Blood Program, partially funded through a grant from the National Children’s Cancer Society, is only the eighth public donor cord blood bank in the world. To date, the American Cord Blood Program is the only academic health center in the country with a comprehensive program of cord blood collection, banking, transplantation, and research.

The first donation of cord blood was made on January 2, 1997. Since then, the American Cord Blood Program has collected more than 1,000 cord bloods and hopes to get 10,000 cord blood donations by 2007. Expectant mothers are asked to contact the program between 28 and 30 weeks of pregnancy to become donors. The mother is given a kit to bring to the hospital on the day of delivery. However, hospitals keep spare kits on hand. Blood collected from the umbilical cord vein is sent to the University of Massachusetts to be typed, frozen, and stored at the American Cord Blood Bank until a match is found.

The research component of this program is conducted at the University of Massachusetts. Research continues in several areas, including investigating the ways cord blood cells divide, studying engraftment of transplanted cord blood cells in mice, and developing other applications of cord blood transplantation, such as for gene therapy.

**Chicago Community Cord Blood Bank.** The goal of the Chicago Community Cord Blood Bank (CCCB) is to collect units of cord blood, test them for infectious diseases, identify the protein markers (HLA molecules) required for matching the cord blood to patients, and store them for future transplantation
into patients with cancer or other life-threatening diseases. The CCCBB, at University of Chicago Children’s Hospital, is a community resource dedicated to providing units of cord blood for stem cell transplantation and medical research. The CCCBB is currently supported by grants and private donations, which cover the cost of collection, testing, and storage (approximately $1,000 per cord blood unit).

The CCCBB has been in operation for about two years and has collected approximately 300 cord blood units. The majority of cord blood is donated for use in unrelated allogeneic transplants. However, less than 10 percent of cord bloods stored at CCCBB are family donations for use in related transplants for family members at risk or in need of stem cell transplants. There is no charge to donors for the processing and storage of cord blood units.

Expectant mothers who donate their baby’s cord blood are asked to consent to providing medical, ethnic, and related information, donating the cord blood to the cord blood bank for transplantation and/or research, allowing blood to be drawn from the mother for tests, including HIV testing, and granting permission to track the newborn’s medical history for up to one year. No blood is drawn from the baby for the cord blood bank. A minimum of 50 cc of cord blood is necessary for use in transplantation. However, approximately 10 percent of cord blood collections yield less than 50 cc and are used for research or quality-control purposes.

International Cord Blood Foundation. The International Cord Blood Foundation, established in 1995, is a nonprofit, public bank that stores umbilical cord blood for use in unrelated, anonymous transplants. The foundation holds the policy that before prospective donors decide to donate, they must be fully educated about the importance of cord blood, its potential uses, and the options available (family banking versus donation to a public bank versus disposal). Donors are required to supply a variety of personal information to ensure the safety of the donated cord blood. The foundation keeps all information confidential and does not provide it in a form allowing personal identification unless compelled to by legal order or other lawful authority.

The International Cord Blood Foundation does supply cord blood for research purposes to universities and other institutions. Cord blood is normally used for research when it is not suitable for transplantation, such as when not enough blood is collected from the placenta or not enough nucleated cells are in the specimen. The possibility that the donated cord blood may be used for research is mentioned in the informed consent that donors sign.

New York Blood Center. The New York Blood Center’s (NYBC) placental blood program, established in 1993, was the nation’s first program for storing umbilical cord blood for allogeneic transplantation. The NYBC placental blood pro-
gram currently has an inventory of approximately 7,000 units of frozen umbilical cord blood (Torloni, 1997). The NYBC placental blood program is a nonprofit storage program funded by the NHLBI.

**St. Louis Cord Blood Bank.** The St. Louis Cord Blood Bank at Cardinal Glennon Children’s Hospital/St. Louis University is a public donor bank, not a private storage bank. In cooperation with other cord blood banks, the St. Louis Cord Blood Bank serves as a worldwide resource for children in need of stem cell transplants. The banking program includes community and donor education, cord blood collection, processing in the cord blood laboratory, release of the cord blood product, and evaluation of transplant outcomes. As of April 1997, more than 1,800 banked and fully characterized cord blood units were available at the St. Louis Cord Blood Bank.

**Puget Sound Blood Center Cord Blood Bank.** The Puget Sound Blood Center has recently established the Cord Blood Bank program. It is the only cord blood bank in the state of Washington and will be used by patients around the world. The Cord Blood Bank will seek 400 donations this year from donor mothers who deliver at Swedish Medical Center in Seattle and Kapiolani Medical Center for Women and Children in Honolulu.

**Related Umbilical Cord Blood Bank for Hemoglobinopathy Patients.** The Related Umbilical Cord Blood Bank for Hemoglobinopathy Patients at Children’s Hospital Oakland in California is supported by the NHLBI. Umbilical cord blood has been recognized as a source of hematopoietic stem cells and has been used in transplants in patients with hemoglobinopathies. The purpose of this project is to store umbilical cord blood for genetically related patients with hemoglobinopathies for transplants. The bank will serve as a resource to hemoglobinopathy centers. The bank will also serve as a research resource for evaluation of the role of umbilical cord blood transplantation in patients with hemoglobinopathies.

**Private Umbilical Cord Blood Banks**

**Cord Blood Registry.** Cord Blood Registry, in partnership with the University of Arizona School of Medicine, provides state-of-the-art facilities for the collection, processing, and long-term cryogenic storage of umbilical cord blood for parents who wish to store their newborns’ cord blood. Cord Blood Registry also established the Designated Transplant Program to allow qualified families in imminent need of stem cell transplants to store their newborns’ cord blood free of charge. Umbilical cord blood stem cells banked at the Cord Blood Registry have been used for both related and unrelated transplants.
Families not in imminent need of stem cell transplants store umbilical cord blood with Cord Blood Registry on the remote chances that the child it came from or another family member may need a stem cell transplant in the future. Cord Blood Registry requires mothers to sign an informed consent at least 30 days prior to collection of the cord blood. Each client who privately stores cord blood receives a certificate of legal ownership for their deposit. When samples are not suitable for transplantation due to small sample size or shortage of nucleated cells in the sample, the family is given a refund and recontacted as to the disposition of the sample. Families are given the choice to donate the cord blood for use in research or to request that the sample be disposed of.

Cord Blood Registry also has programs in education and research. In 1996, more than a million pieces of educational material were distributed to the public and medical communities through Cord Blood Registry’s national network of Medical Education Specialists and Cord Blood Educators outreach programs. Cord Blood Registry also sponsors continuing medical education programs led by cord blood experts in major institutions across the country. As a founding member of the International Cord Blood Foundation (see “Public Donor Umbilical Cord Blood Banks”), Cord Blood Registry provides substantial support to help fund the foundation’s educational and public health initiatives and assists with the National Marrow Donor Program to educate the transplant and research communities. In addition, Cord Blood Registry makes a $200 donation from each privately banked cord blood to the foundation to help in the collection and processing of cord blood. Combined, the Cord Blood Registry and the International Cord Blood Foundation have collected more than 8,000 umbilical cord blood units.

**New England Cord Blood Bank.** The New England Cord Blood Bank, Inc., is part of the New England Cryogenic Center, Inc., a private cryogenic laboratory. Since its establishment in June 1997, New England Cord Blood Bank has stored more than 200 units of umbilical cord blood for use in autologous transplants or for related transplants in family members. New England Cord Blood Bank does not store cord blood for unrelated allogeneic transplants. If a family decides to terminate their storage agreement at New England Cord Blood Bank, the sample can be donated to a public bank to help others in need of stem cell transplants.

**Cryobanks International, Inc.** Cryobanks International, Inc. (CI), also cryogenically stores human umbilical cord blood in its multiservice complex. The purpose of CI’s bank is to develop a registry of donated umbilical cord blood for transplantation, to provide affordable personal umbilical cord blood storage, to provide storage for vital blood tissues, and to provide anonymous donor semen to couples and individuals.
Reproductive Genetics Institute. For almost a decade, the Reproductive Genetics Institute (RGI) has provided state-of-the-art genetics services, including genetic counseling, prenatal diagnosis, DNA diagnosis, forensic identification, paternity testing, IVF, and preimplantation genetic diagnosis. Established in 1990, RGI is a private enterprise and was one of the first to provide chorionic villus sampling in the United States. Scientists at RGI are involved in basic research in human genomics, experimental embryology, and cell genetics. The Cell and Tissue Bank, including an umbilical Cord Blood Bank, contains living biological samples available for research and practical application. Types of the cells/tissues available include 107 diploid cell strains from embryos of different gestational ages, chromosomally abnormal cell strains obtained from spontaneously aborted embryos and abnormal embryos, cell strains from skin fibroblasts of patients with single gene disorders, more than 100 human umbilical cord blood samples, hundreds of sperm samples, and dozens of donor oocytes.

Viacord. Viacord, Inc., is a medical service company that provides private family cord blood banking. Physicians refer expectant families to Viacord to have their newborn’s cord blood processed and banked for another immediate family member in need or at risk of needing a stem cell transplant arising from a known malignancy, genetic blood disorder, or other relevant disease. In addition, families with no apparent need or risk also bank cord blood at Viacord, although the chances of needing it within the family are relatively small.

Viacord’s comprehensive cord blood banking services include everything from training of the obstetrician and labor and delivery staff on proper collection procedures to testing and typing, cryopreservation, and storage of umbilical cord blood. Expectant mothers and their physicians complete an extensive health questionnaire and appropriate informed consents. The expectant mother is tested for infectious diseases once during the third trimester and again at delivery. The cord blood is tested for the number of stem cells (CD34-positive cells) and bacterial and fungal contamination and typed for blood type (ABO and Rh) and histocompatibility (HLA-A and HLA-B). The testing and typing results are provided to the referring physician.

A number of insurance companies have begun to pay for Viacord’s services when the newborn’s sibling or parent is in need of or has significant risk of needing a stem cell transplant. Blue Cross Blue Shield, Aetna Health Plan, Prucare, and even some state Medicaid providers have paid in full for collection, processing and storage of cord blood for these families.