

## II. HUMAN TISSUE SAMPLE COLLECTIONS IN THE UNITED STATES

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2           *Where are human tissues stored?*  
3           *How many tissue samples are stored at each institution?*  
4           *Who are the sources of stored tissue samples?*  
5           *Why were the tissue samples originally collected?*  
6           *For what purposes have the stored tissues been used?*  
7           *Who has access to the samples?*  
8           *How are the tissue samples stored, and for how long?*  
9           *What identifying information is kept with the tissues?*

10           These are some of the questions NBAC asked as it began its review of the use of collected  
11 and stored human tissues. To date, there has been a paucity of information concerning tissue  
12 acquisition, use, and storage; there is no central database that captures information about stored  
13 tissue samples. To assist in its review, NBAC commissioned a study to assess the magnitude and  
14 characteristics of the existing archives of tissues.<sup>1</sup>

### MAJOR FINDINGS

16           NBAC estimates that there are over 282 million specimens from more than 176.5 million  
17 cases of stored tissue in the United States, accumulating at a rate of over 20 million per year.<sup>2</sup>  
18 The size and detail of tissue collections varies considerably, ranging from formal, highly organized  
19 repositories to the informal storage of blood or tissue specimens in a researcher's laboratory  
20 freezer. Archives of human tissue range in size from less than 200 specimens to more than 92  
21 million.

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<sup>1</sup> These data were collected by RAND's Critical Technologies Institute in response to a request by the NBAC Genetics Subcommittee. The report, *Stored Tissue Samples: An Inventory of Sources in the United States*, is not meant to be a comprehensive inventory, however it does identify the major sources of stored tissue.

<sup>2</sup> This report attempts to count both the number of cases from which stored tissues are derived as well as the number of specimens generated from each case. For example, when a patient enters the hospital for a biopsy, the resulting tissue is accessioned in the pathology department as a single case. However, that single biopsy may generate several specimens including a number of slides, a paraffin block, and a frozen sample.

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1           Large collections include archived pathology samples taken in diagnostic and surgical  
2 procedures, autopsy material, and stored Guthrie cards from newborn screening tests. These  
3 tissue samples are stored at military facilities, forensic and other DNA banks,<sup>3</sup> government  
4 laboratories, diagnostic pathology and cytology laboratories, university- and hospital-based  
5 research laboratories, commercial enterprises, and non-profit organizations.

6           Tissue collections generally fall into the following categories:

- 7       • large tissue banks, repositories and core facilities;
- 8       • longitudinal studies;
- 9       • research requiring unique tissue collections;
- 10      • pathology specimens;
- 11      • newborn screening laboratories;
- 12      • forensic DNA banks;
- 13      • sperm, ovum and embryo banks;
- 14      • umbilical cord blood banks;
- 15      • organ banks; and
- 16      • blood banks.

17           Two of the largest tissue repositories in the world, the National Pathology Repository and  
18 the DNA Specimen Repository for Remains Identification, are housed within a single institution,  
19 the Armed Forces Institute of Pathology (AFIP). These two repositories alone store more than  
20 94 million specimens. State newborn screening laboratories collectively have archives totaling  
21 more than 13 million. Finally, the pathology departments at Graduate Medical Education (GME)  
22 teaching institutions collectively constitute the largest and oldest stores of tissue samples in the  
23 United States, with some specimens over 100 years old.<sup>4</sup> These three sources—the AFIP

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<sup>3</sup> The term “DNA bank” refers to a facility that stores extracted DNA, transformed cell lines, frozen blood or tissue, or biological samples for future DNA analysis. Specimens are usually stored with some form of individual identification for later retrieval. “DNA da ta banks” are repositories of genetic information obtained from the analysis of DNA samples, sometimes referred to as “DNA profiles.”

<sup>4</sup>The genetic information is usually stored in computerized form with individual identifiers. Graduate Medical Education (GME) program s are the primary means of medical education beyond the four year medical school training received by all physicians. Usually ca lled residency programs, they are based in hospitals

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1 National Pathology Repository, GME teaching institution pathology departments, and newborn  
2 screening laboratories—represent more than 265.5 million diagnostic and therapeutic specimens  
3 from over 176 million cases. Although the tissue repositories supported by the National Institutes  
4 of Health (NIH) are not as large as those of AFIP, NIH is the largest funder of tissue repositories,  
5 providing over \$53 million in FY 1996.

6 The vast majority of tissues currently in storage were originally collected for diagnostic or  
7 therapeutic reasons, although a small percentage of them are used for research, educational, and  
8 quality control purposes.

9 Several repositories have been established specifically for use in research. In addition,  
10 several large longitudinal studies collect and bank samples from study participants. Likewise, a  
11 fair amount of research simultaneously creates tissue collections or contributes to tissue banks.  
12 Collectively, these tissue collections contain more than 2.3 million specimens.

13 Other than for diagnostic, therapeutic, or research purposes, tissues are collected and  
14 stored for a variety of other reasons. Blood banks collect approximately 12 million units of blood  
15 a year, but only about 20,000 to 40,000 units are stored at any one time. Also, most of the blood  
16 collected is used for transfusions, and very little is used for other purposes such as research and  
17 quality control. Organ banks do not collect the same volume of tissue as do blood banks, but are  
18 similar in that most of the organs and tissues collected are used for transplants, and very little is  
19 available for research purposes. Forensic DNA banks collect and store tissues for use in criminal  
20 investigations. The Department of Defense (DOD) DNA Specimen Repository and some  
21 commercial DNA banks store DNA samples for remains identification. Sperm, ovum and embryo  
22 banks store specimens for anonymous donation or for later use by the individual storing the  
23 material. Umbilical cord blood banks also store blood for anonymous donation and later use by  
24 families banking their newborn's cord blood.

25 Table 1 summarizes sources of stored tissue samples in the United States. Descriptions of

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or other health care institutions, some of which do and some of which do not have formal relationships with medical schools. GME teaching institutions include medical schools, the Armed Forces hospitals, Veterans Affairs medical centers, the Public Health Service, state, county and city hospitals, non-profit institutions, and health maintenance organizations.

1 representative collections appear below.

## 2 **DEFINITION OF HUMAN TISSUE**

3 In this report, human tissue is defined as including everything from subcellular structures  
4 like DNA, to cells, tissue (bone, muscle, connective tissue and skin), organs (e.g. liver, bladder,  
5 heart, kidney), blood, gametes (sperm and ova), embryos, fetal tissue, and waste (urine, feces,  
6 sweat, hair and nail clippings, shed epithelial cells, placenta). The most common source of tissue  
7 is from patients following diagnostic or therapeutic procedures. Tissue specimens may also be  
8 taken during autopsies that are performed to establish the cause of death. In addition, volunteers  
9 may donate blood or other tissue for transplantation or research, organs for transplantation, or  
10 their bodies for anatomical studies after death. Each specimen of human tissue may be stored in  
11 multiple forms, such as slides, paraffin blocks, formalin fixed, frozen, tissue culture, or extracted  
12 DNA.

## 13 **LARGE TISSUE BANKS, REPOSITORIES, AND CORE FACILITIES**

14 Large tissue banks and repositories exist in almost every sector of the scientific and  
15 medical communities, including the military, the federal government, universities and academic  
16 medical centers, commercial enterprises, and non-profit organizations. In addition, several  
17 universities have established core tissue banking facilities to support both their own research as  
18 well as collaborations with other universities. These large tissue banks, repositories, and core  
19 facilities are a major source of human tissue for biomedical research. Representative collections  
20 are described below.<sup>5</sup>

### 21 **Military Facilities**

22 The military maintains two of the largest tissue repositories in the world. The National  
23 Pathology Repository and the DOD DNA Specimen Repository for Remains Identification are

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<sup>5</sup> The complete text of the inventory appears in the commissioned paper.

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1 housed in the Armed Forces Institute of Pathology (AFIP)<sup>6</sup>. The AFIP is responsible for  
2 maintaining a central laboratory of pathology for consultation and diagnosis of pathologic tissue  
3 for DOD, other federal agencies, and civilian pathologists. AFIP also conducts research in  
4 pathology, trains enlisted personnel in histopathology and related techniques, and offers over 50  
5 pathology education courses for medical, dental, and veterinary personnel.

6 The National Pathology Repository<sup>7</sup>, located at AFIP, is the largest and most  
7 comprehensive collection of pathology material in the world. Since 1917, the Pathology  
8 Repository has collected over 2.5 million cases comprising over 50 million microscopic slides, 30  
9 million paraffin tissue blocks, 12 million preserved wet tissue specimens, and associated written  
10 records. The Pathology Repository logs in approximately 50,000 cases annually, with 53,384  
11 cases accessioned in FY 1996, and 51,908 in FY 1997. In addition, approximately 40,000  
12 cytology cases are sent for primary diagnosis annually, but are not deposited in the repository.  
13 During 1993, approximately 10,000 of the cases were cancers and 8,000 were benign neoplasms,  
14 with the balance representing the entire spectrum of human disease. Material is stored  
15 permanently unless there is a specific request by the contributor or other authorized individual to  
16 return or release the material.

17 Cases are sent to AFIP for a variety of reasons. The majority of cases are submitted  
18 because the contributor wants a second opinion on a diagnosis. Some are forwarded as part of  
19 established peer-review and quality assurance programs. Some military cases are required to be  
20 forwarded by DOD regulation, such as forensic cases and cases subject to litigation. Other cases  
21 are submitted because they are unusual or rare and may be useful to AFIP in its research and  
22 education missions. In addition, cases have been submitted over the years for specific purposes,  
23 such as to study particular diseases, or to answer current and future research questions (for  
24 example, illnesses of Gulf War veterans).

25 All submitted case material is coded by pathological diagnosis, and is identified by an

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<sup>6</sup>Armed Forces Institute of Pathology (AFIP), <http://www.afip.mil/default.html>

<sup>7</sup>National Pathology Repository , <http://www.afip.mil/repository/welcome.html>

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1 AFIP accession number. The source name, social security number, date of birth, age, sex, and  
2 race are stored if provided by the contributing pathologist. Any medical history provided is stored  
3 in the case folder and on an optical disk imaging system. The source address is not routinely  
4 provided or stored but is obtained on occasion for follow-up studies. Likewise, the original  
5 consent is a matter between the patient and the clinician and is not routinely provided to AFIP by  
6 the contributing pathologist. The submitting pathologist's name and address, and the source's  
7 surgical identification numbers are also stored.

8 All research protocols using Pathology Repository stored material or data are reviewed by  
9 the AFIP's Institutional Review Board (IRB). Research involving patient follow-up, and thus  
10 requiring identifying information, is reviewed at a full meeting of the IRB prior to approval.  
11 Other than for research involving follow-up, original sources of material are not notified. If an  
12 unexpected disease or abnormality is discovered, the contributing pathologist is notified, and it is  
13 then up to the pathologist to contact the patient. Otherwise, current AFIP policy requires that  
14 material be anonymized before release to outside investigators.

15 The main functions of the Pathology Repository are consultation, education and research  
16 in pathology. The Pathology Repository also loans pathologic material for patient treatment,  
17 research, or litigation. Requests for loan of material or provision of data for research purposes  
18 requires submission and approval of a research protocol. Requests from individuals or  
19 organizations other than the original contributor must be accompanied by a properly executed  
20 authorization signed by the patient or designated representative. Pathologic specimens stored at  
21 the Pathology Repository can be used to study unusual tumors, or as part of a public health  
22 surveillance system to study emerging infectious diseases or trends in disease progression. For  
23 example, samples in the Repository have been used to identify and date tissues harboring genomic  
24 material of the Human Immunodeficiency Virus (HIV) that were obtained before the availability  
25 of HIV testing and before the spread of the HIV infection.

26 The DOD DNA Specimen Repository for Remains Identification<sup>8</sup> is the world's largest  
27 DNA bank. As of September 1997, the DNA Repository has received approximately 2 million  
28 DNA specimens. Specimens come into the DNA Repository at a rate of 10,000 per day, and the

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<sup>8</sup>Armed Forces DNA Identification Laboratory, <http://www.afip.mil/oafme/dna/afdil.html>

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1 tally is updated every seven seconds. It is estimated that by the year 2001 the DNA Repository  
2 will contain approximately 3.5 million samples. All DNA specimens will be maintained for 50  
3 years before being destroyed. However, donors may request that their specimens be destroyed  
4 following the conclusion of their military service obligation or other applicable relationship to  
5 DoD.

6 Since June 1992, DoD has required all military inductees, and all active duty and reserve  
7 personnel to provide blood and saliva samples for its DNA Specimen Repository at the time of  
8 enlistment, re-enlistment, annual physical, or preparation for operational deployment (McEwen,  
9 1997). The DNA Repository also contains samples from civilians and foreign nationals who work  
10 with the United States military in arenas of conflict. A total of three DNA specimens are  
11 collected from each person: one bloodstain card is stored in a pouch in the service member's  
12 medical record; another bloodstain card and a buccal swab are stored at the DNA Specimen  
13 Repository. The blood is placed on special cards with the service member's Social Security  
14 number, date of birth, and branch of service designated on the front side of the card, and a  
15 fingerprint, a bar code, and signature attesting to the validity of the sample on the reverse side.  
16 DNA will only be extracted from the specimens in the Repository when it is needed for the  
17 purpose of remains identification.

18 The DNA Repository, along with the Armed Forces DNA Identification Laboratory  
19 (AFDIL), make up the DOD DNA Registry. The purpose of the DNA Registry is to identify the  
20 remains of soldiers killed in combat or missing in action. The military's policy ensures that  
21 specimens can only be used for remains identification and routine quality control except where  
22 subpoenaed for the investigation or prosecution of a felony. The specimens cannot be used  
23 without consent for any other purpose, such as paternity suits or genetic testing. In addition, the  
24 specimens are considered confidential medical information, and military regulations and federal  
25 law exist to cover any privacy concerns.

26 **National Institutes of Health**

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1           The National Institutes of Health<sup>9</sup> (NIH), founded in 1930, consists of 24 Institutes,  
2 Centers, and Divisions. It is the principal health research agency of the federal government. It is  
3 one of the eight health agencies of the Public Health Service, which is part of the U.S.  
4 Department of Health and Human Services. The mission of NIH is to protect and improve human  
5 health. To accomplish its mission, NIH conducts and supports basic, applied, and clinical and  
6 health services research aimed at understanding the processes underlying human health and  
7 acquiring new knowledge to help prevent, diagnose, and treat human diseases and disabilities.  
8 NIH is the highest funder of tissue and data resources for basic, applied and clinical research.  
9 Some of the institutes at NIH that support tissue banks include the National Cancer Institute  
10 (NCI), the National Institute of Allergy and Infectious Disease (NIAID), the National Heart,  
11 Lung, and Blood Institute (NHLBI), the National Institute of Mental Health (NIMH), and the  
12 National Institute on Aging (NIA). Examples of tissue banking supported by NIH are described  
13 below.

#### 14           **National Cancer Institute**

15           NCI<sup>10</sup> is the largest of NIH's biomedical research institutes and centers. It supports  
16 several tissue and data resources for cancer research. The Cooperative Human Tissue Network  
17 (CHTN), in existence since 1987, provides biomedical researchers with access to fresh surgical or  
18 biopsy specimens of normal, benign, pre-cancerous and cancerous human tissues. CHTN is a  
19 tissue collection system and not a tissue bank. Only rare specimens that are difficult to obtain are  
20 stored to anticipate future requests. Except for a collection of frozen tissue from rare pediatric  
21 tumors, banked specimens are generally not stored for more than one year. Normally, the  
22 specimens are obtained prospectively to fill specific researcher requests. Five member institutions  
23 coordinate the collection and distribution of tissues across the United States and Canada. Tissues  
24 are provided by the CHTN only for research purposes, and can not be sold or used for  
25 commercial purposes.

26           During the first nine years of operation, the CHTN supplied over 100,000 specimens to

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<sup>9</sup> National Institutes of Health (NIH), <http://www.nih.gov/index.html>

<sup>10</sup> National Cancer Institute (NCI), <http://www.nci.nih.gov>



1 approximately 600 investigators. CHTN tissues have been used in many areas of cancer research  
2 including molecular biology, immunology, and genetics. Researchers have used these tissues to  
3 study mutations of proto-oncogenes in human tumors, the role of growth factors in cancer, and to  
4 isolate new cancer genes. Over 2,000 publications have resulted from studies using CHTN  
5 tissues.

6 CHTN obtains tissues from routine surgical resections and autopsies of adult and  
7 pediatric patients, representing all organ systems, as well as blood and other body fluids.  
8 Specimens are collected according to the individual investigator's protocol, and may be preserved  
9 as fresh, fixed or frozen tissue, slides, or paraffin blocks. CHTN was designed for basic research  
10 studies not requiring clinical follow-up information. Each specimen is given a unique identifier. A  
11 link is kept by the parent institution for quality control purposes. Only minimal demographic data  
12 is provided with the specimen. Other information routinely provided with the specimens includes  
13 pathology reports and histological characterization.

14 The NCI-National Action Plan on Breast Cancer (NAPBC) Specimen and Data  
15 Information System<sup>11</sup> contains information from 14 breast tissue banks. This database does not  
16 represent an exhaustive national listing of all facilities holding breast cancer tissue. However, by  
17 centralizing information on biological specimens, it provides access to breast tissue specimens and  
18 facilitates collaboration among basic, clinical, and epidemiologic researchers.

19 Cumulatively, the 14 breast tissue banks in the NCI-NAPBC database contain more than  
20 130,000 cases of breast cancer-related specimens and data, with banks ranging in size from 48  
21 cases to approximately 101,000 cases. Three of the 14 banks are accruing as many as 200 new  
22 cases per year. A specimen from a single case may generate several samples. For example, a  
23 specimen from a single case may be split into 3 to 30 paraffin-embedded blocks, 10 slides, or  
24 matched frozen and paraffin-embedded tissue blocks (i.e. one frozen and one paraffin-embedded  
25 sample from the same case). A conservative estimate is there are approximately 240,000 samples  
26 in the database. Samples available to the research and clinical communities include breast tissue,  
27 serum, urine, cells, and DNA from patients diagnosed with breast cancer, those at high risk, and

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<sup>11</sup> NCI-NAPBC Breast Cancer Specimen and Data Information System,  
<http://cancernet.nci.nih.gov/breastdata/contents.htm>

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1 unaffected individuals. Information on demographics (age, sex, race, ethnicity, family history of  
2 cancer), clinical findings (pathologic diagnosis, stage, initial therapy), and outcome (subsequent  
3 breast cancer, vital status) are also available from some institutions.

4 The NIH AIDS Research and Reference Reagent Program (Repository), established by the  
5 National Institute of Allergy and Infectious Disease<sup>12</sup> (NIAID) in 1988, acquires critically needed  
6 reagents for AIDS-related research, and provides these reagents free of charge to qualified  
7 investigators world wide. The Repository contains samples of cell lines, HIV and related viruses,  
8 opportunistic infectious agents associated with HIV infections, DNA libraries, DNA clones,  
9 antibodies, purified proteins, synthetic peptides, body fluids, and reference standards.

10 The Repository encourages collaborative research aimed at standardizing reagents and  
11 laboratory techniques. Most of the reagents in the Repository are used by and donated by  
12 scientists from NIH, academic and non-profit institutions, and the private sector. Any commercial  
13 use of reagents requires written permission and compensation of reagent donor(s) and notification  
14 of the Repository. Currently, the Repository has 500 registered users of its services. During the  
15 past five years the Repository has provided more than 17,000 reagents to AIDS investigators  
16 worldwide.

17 The Transfusion Medicine Branch of the National Heart, Lung, and Blood Institute  
18 (NHLBI)<sup>13</sup> maintains a contractor-operated Blood Specimen Repository available for use by the  
19 scientific community for research related to transfusion-transmitted diseases, other blood  
20 disorders, or diseases of the cardiovascular system. The repository, established in 1974, contains  
21 approximately 1.5 million well characterized specimens of serum, plasma, and cells from NHLBI-  
22 sponsored studies. Since 1991, the Blood Specimen Repository has been storing an average of  
23 approximately 300,000 samples per year (National Heart, Lung, and Blood Institute, 1996).  
24 From 1991 to 1993, approximately 1,000 specimens per year were distributed to researchers, in  
25 1994 approximately 4,000 specimens were distributed, and in 1995, approximately 20,000  
26 specimens were distributed (National Heart, Lung, and Blood Institute, 1996).

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<sup>12</sup> National Institute of Allergy and Infectious Disease (NIAID), <http://www.niaid.nih.gov>

<sup>13</sup> National Heart, Lung, and Blood Institute (NHLBI), <http://www.nhlbi.nih.gov/nhlbi/nhlbi.htm>

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1           The National Institute of Mental Health<sup>14</sup> (NIMH) has awarded funds to three universities  
2 to establish a national resource to study both early and late-onset Alzheimer's Disease. A  
3 collection of 400 pairs of relatives, primarily pairs of siblings, are available for finding  
4 susceptibility genes linked to Alzheimer's Disease. This resource provides a large enough sample  
5 of families, obtained through a common protocol and diagnosed by a consensus procedure, to be  
6 useful for identifying clinical and genetic subtypes of Alzheimer's Disease.

7           Two other agencies within the federal government have tissue banks, the National  
8 Institute of Standards and Technology (NIST) and the United States Environmental Protection  
9 Agency (EPA). These tissue banks were established primarily to determine human exposure to  
10 pollutants and pesticides, and to follow long-term health trends.

## 11 **Research Universities and Academic Medical Centers**

12           Research universities and academic medical centers maintain both formal tissue banks for  
13 distribution throughout the research community as well as core facilities to support both their own  
14 research. For example, the Harvard Brain Tissue Resource Center<sup>15</sup> (The Brain Bank) is a  
15 centralized repository for the collection and distribution of post-mortem human brain specimens  
16 from both diseased and normal donors for use in research on the brain and nervous system.  
17 Research on brain tissue has contributed to the understanding of severe mental illness, the  
18 development of a genetic test for Huntington's disease, and a treatment for Parkinson's disease.  
19 Since the majority of research only requires very small amounts of tissue, each donated brain  
20 provides a large number of samples for many researchers. Brain tissue donations are accepted by  
21 the Brain Bank from individuals or the parents, siblings and offspring of individuals with severe  
22 neurological disorders such as Huntington's, Parkinson's, and Alzheimer's disease, serious  
23 psychiatric diagnoses, and various other disorders. The Brain Bank also accepts brain tissue from  
24 individuals with no neurological or neuropsychiatric disorders for comparative research.  
25 Prospective brain tissue donors must be 18 years of age or older and are encouraged to discuss  
26 their wishes with their families, and register with the Brain Bank by completing a "Brain Donation

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<sup>14</sup> National Institute of Mental Health (NIMH), <http://www.nimh.nih.gov/>

<sup>15</sup> Harvard Brain Tissue Resource Center, <http://www.brainbank.mclean.org:8080/into.html>

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1 Questionnaire".

2 Another example, the University of California-San Francisco (UCSF) AIDS Specimen  
3 Bank, in existence since 1982, has banked over 76,000 specimens and sent out over 82,000  
4 specimens to researchers worldwide. Specimens include serum, tissue, saliva, cells, and  
5 cerebrospinal fluid from HIV infected individuals. Specimen data are archived on a computerized  
6 database. The Bank provides investigators with specimens for basic, epidemiological, and clinical  
7 research.

## 8 **Commercial Enterprises**

9 Some commercial enterprises maintain tissue banks for their own proprietary use, while  
10 others establish banks for storage and distribution purposes. OncorMed and LifeSpan  
11 Biosciences, Inc. are examples of companies that maintain proprietary tissue banks, while  
12 PathServe collects human tissues and organs for marketing to the research community.

13 OncorMed<sup>16</sup> is a medical services company that provides genetic testing and information  
14 services for the early detection and management of cancer. It offers cancer predisposition  
15 counseling, genetic susceptibility testing, early diagnosis, and analysis of tumors. OncorMed's  
16 Hereditary Cancer Consulting Service, offered at sites around the country, determines a patient's  
17 risk for developing cancer by analyzing family history information. OncorMed also offers genetic  
18 testing for cancer susceptibility genes, including BRCA1 and BRCA2 for breast and ovarian  
19 cancer, Hereditary Non-polyposis Colorectal Cancer (HNPCC), inherited melanoma, and  
20 hereditary thyroid cancer. The company has an IRB for review and approval of protocols, and  
21 has developed physician guidelines that closely parallel the American Society of Clinical Oncology  
22 (ASCO) guidelines. In addition to genetic testing, OncorMed has established a proprietary  
23 biorepository.

24 LifeSpan BioSciences, Inc.<sup>17</sup>, founded in 1995, is a genomics company focused on the

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<sup>16</sup> OncorMed, <http://www.oncormed.com>

<sup>17</sup> LifeSpan BioSciences, Inc., <http://www.lsbio.com>

1 discovery and licensing of genes that play a role in the aging process and identifying disease-  
2 associated genes for use as therapeutic or diagnostic targets. Because highly characterized  
3 samples of normal and diseased tissues are critical in localizing disease-associated genes,  
4 LifeSpan has an on-site tissue bank. LifeSpan's Tissue and Disease Bank contains 250,000  
5 normal and diseased human samples. The tissue bank has over 175 different types of tissues from  
6 virtually every organ in the body, covering all ages. The tissue bank also includes over 500  
7 different pathologic disease categories such as autoimmune diseases, infectious diseases,  
8 degenerative diseases, cancer and benign proliferative diseases, and genetic diseases.

9 PathServe Human Tissue Bank<sup>18</sup>, established in 1990 and commercial since 1996, is a  
10 major supplier of human tissue to biotechnology and neuropathological research institutions.  
11 PathServe also serves as a main training facility of autopsy technicians for private pathologists and  
12 local hospitals. PathServe collects all types of organs and tissues including specimens from  
13 placental and fetal origin. Tissues are obtained through post-mortem examinations, referrals from  
14 transplant banks of nontransplantable organs, and donations by next of kin. PathServe collects  
15 specimens from approximately 300 autopsies per year, and each autopsy yields approximately 100  
16 specimens. PathServe has approximately 300 specimens stored at any one time, and has  
17 distributed approximately 30,000 specimens in the last year. Consent for donation is obtained  
18 from the family. PathServe does not maintain a centralized storage facility. Instead, specimens  
19 are stored in the morgues of different hospitals.

## 20 **Non-Profit, Non-Educational Organizations**

21 There are a variety of non-profit institutions that bank tissues for purposes of storage and  
22 distribution. Non-profit institutions such as the American Type Culture Collection, Coriell  
23 Institute for Medical Research, the Research Foundation for Mental Hygiene, the Rocky  
24 Mountain Multiple Sclerosis Center, the National Psoriasis Tissue Bank, the Kaiser Permanente  
25 Center for Health Research, and the Hereditary Disease Foundation receive millions of dollars in  
26 federal funding.

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<sup>18</sup> PathServe, <http://www.tissuebank.com/>

1           An example is the American Type Culture Collection (ATCC).<sup>19</sup> Since its establishment in  
2 1925, ATCC has served as an archive of living cultures and genetic materials for researchers in  
3 the biological sciences. The mission of the ATCC is to acquire, authenticate, and maintain  
4 reference cultures, related biological materials, and associated data, and to distribute these to  
5 qualified scientists in government, industry, and education. The ATCC has approximately 2,300  
6 human cell lines. However, all of the human cell lines are immortalized cultures, and the genetic  
7 material is mainly the product of recombinant DNA research.

8           Another example is the Coriell Institute for Medical Research,<sup>20</sup> a basic biomedical  
9 research institution that conducts research on the causes of genetic diseases, including cancer.  
10 The Coriell Institute's three missions are research, cell banking, and public education. The largest  
11 collection of human cells for research is maintained at the Coriell Institute, and these cells are  
12 available to the general scientific community. Seminal research on the genes associated with  
13 Huntington's disease, cystic fibrosis, Alzheimer's disease, ataxia telangiectasia and manic  
14 depression have utilized cells from the Coriell collection. The Coriell Cell Repositories also  
15 support the human genome project. Over 35,000 cell lines are currently stored representing  
16 approximately 1,000 of the 4,000 known genetic diseases, and more than 60,000 cell lines have  
17 been distributed to over 40 nations, resulting in over 8,000 research publications. Cultures are  
18 established from both blood and skin, and the cells are stored frozen at the Institute. There are  
19 three quarters of a million vials of cells in 37 giant tanks containing liquid nitrogen.

## 20   **LONGITUDINAL STUDIES**

21           Longitudinal studies, in which the same group of individuals is studied at intervals over a  
22 period of time, often collect large numbers of specimens that can be used for both retrospective  
23 and prospective research. Several well-known longitudinal studies have been conducted over the  
24 years including the Physician's Health Study, the Nurses' Health Study, and the Framingham  
25 Heart Study. Other large longitudinal studies include the Health Professionals Follow-up Study,

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<sup>19</sup> American Type Culture Collection (ATCC), <http://www.atcc.org/>

<sup>20</sup> Coriell Institute for Medical Research, <http://arginine.umdj.edu/info.html>

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1 Mr. Fit, the Family Heart Study, and the National Health and Nutrition Examination Surveys.

## 2 **The National Institutes of Health Women's Health Initiative**

3 The NIH Women's Health Initiative<sup>21</sup> (WHI), established in 1991, is the largest preventive  
4 study of women's health in the United States. The WHI is a 15- year research program,  
5 concluding in the year 2005, that focuses on the major causes of death, disability and impaired  
6 quality of life in postmenopausal women. The overall goal of WHI is to reduce coronary heart  
7 disease, breast and colorectal cancer, and osteoporosis in postmenopausal women through  
8 prevention, intervention, and risk factor identification.

9 The WHI will involve over 164,500 women of all races and socioeconomic backgrounds  
10 ages 50 to 79. Approximately 64,500 women will be enrolled in a randomized clinical trial with  
11 three study groups: hormone replacement therapy, dietary modification, and calcium and vitamin  
12 D supplementation. The observational study will track the medical history and health habits of  
13 approximately 100,000 women to examine the relationship between lifestyle, health and risk  
14 factors and disease. The clinical trial and observational study are being conducted at 40 clinical  
15 centers nationwide.

16 The 164,500 women enrolled in both the clinical trial and the observational study will be  
17 followed for eight to 12 years and will provide multiple blood samples throughout the course of  
18 the study. Participants sign a consent form that states that the collection of blood samples is for  
19 use in future research, which may include genetic research, and participants will not be informed  
20 of any test results. Participants may opt out of having their samples used for genetic research, if  
21 they so desire. The clinical trial participants provide a blood sample at their initial visit and at  
22 their one year visit, and a subset of participants have samples drawn at three, six, and nine years.  
23 Blood samples are also collected from participants in the observational trial at their initial visit,  
24 and then again at their three year visit. Blood samples are divided into serum, plasma and buffy  
25 coat, and stored at a central facility in Rockville, Maryland. Participants' charts contain  
26 identifying information including name, social security number, address and telephone number,

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<sup>21</sup> NIH Women's Health Initiative (WHI), <http://odp.ld.nih.gov/whi/>

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1 and are bar-coded. Blood samples are labeled with matching barcodes to link them back to the  
2 charts. Approximately 27,000 women will be enrolled in the hormone replacement therapy trial,  
3 some of whom will also undergo an endometrial biopsy to rule out endometrial hyperplasia or  
4 cancer. These biopsies are stored at the individual clinical centers within the pathology  
5 departments and are labeled with a pathology accession number. In cases where abnormalities are  
6 detected, slides of the biopsy are bar-coded and sent to a central laboratory at NIH. Participants  
7 and their physicians are informed of any abnormalities found in the endometrial biopsy. All study  
8 records are kept indefinitely for analysis and follow-up.

### 9 **Baltimore Longitudinal Study of Aging**

10 The Baltimore Longitudinal Study of NIA was initiated in 1958, enrolling only men until  
11 1978 when women were included. Storage of samples of blood or blood fractions began in 1963  
12 and has been systematically continued since that time. Serum, plasma, lyophilized erythrocytes  
13 and whole blood plasma (including leukocytes), and aliquots of 24-hour urine collections have all  
14 been stored. Over the years, samples have been used for various approved protocols. For  
15 example, recently a longitudinal study of prostate-specific antigen (PSA) was retrospectively  
16 performed and showed that following PSA levels over time could detect prostatic cancer many  
17 years early than usual clinical measures.

### 18 **Bogalusa Heart Study**

19 The Bogalusa Heart Study<sup>22</sup>, ongoing since 1972, is the longest and most detailed study of  
20 children in the world. The Bogalusa Heart Study is NIH-sponsored at Louisiana State University  
21 Medical Center, and run by a multidisciplinary team of anthropologists, biochemists, cardiologists,  
22 epidemiologists, geneticists, nurses, nutritionists, psychologists, sociologists, and statisticians.  
23 The purpose of the study is to understand the environmental and hereditary aspects of early  
24 coronary artery disease, essential hypertension and cardiovascular risk factors in a African  
25 American and Caucasian children in the semi-rural community of Bogalusa, Louisiana. In  
26 addition, over 160 substudies have been conducted including special studies on socioeconomic

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<sup>22</sup> Bogalusa Heart Study, <http://www.mcl.tulane.edu/cardiohealth/bog.htm>



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1 evaluations, blood pressure, lipid levels, genetics, exercise, heart murmurs, and pathology.  
2 Knowledge gained in the Bogalusa Heart Study has been applied to develop, test and evaluate  
3 methods for cardiovascular risk intervention.

4 The Bogalusa Heart Study has cross-sectional and longitudinal observations on more than  
5 14,000 children and young adults. For example, there is currently a post high school study which  
6 follows children until 38 years of age. More than 632 publications, three textbooks and numerous  
7 monographs have been produced using samples and data from the Bogalusa Heart Study.

### 8 **National Health and Nutrition Examination Survey**

9 Since 1960, the National Center for Health Statistics (NCHS) of CDC has conducted  
10 seven health examination surveys of the population of the United States, the National Health  
11 Examination Surveys (NHES) Cycles 1, 2 and 3, the National Health and Nutrition Examination  
12 Surveys (NHANES) I, II and III, and the Hispanic Health and Nutrition Examination Survey  
13 (HHANES). The surveys are designed to periodically assess the health and nutritional status of  
14 children and adults in the United States through interviews and direct physical examinations. The  
15 surveys employ interviews to answer questions about demographics, socioeconomic status,  
16 dietary habits and health-related issues, and physical and dental examinations which include  
17 physiologic assessments and laboratory tests. Blood samples are collected as part of the  
18 physiologic assessments, and placed in storage banks after laboratory tests are completed.

19 Cumulatively, all of the health examination surveys have analyzed and banked samples  
20 from more than 85,000 participants. The most recent survey, NHANES III<sup>23</sup>, conducted between  
21 1988 and 1994, performed laboratory test on approximately 29,314 people of all races aged 2  
22 months and older from 81 counties in 26 states. Some of the 30 topics investigated in the  
23 NHANES III included high blood pressure, high cholesterol, obesity, second-hand smoking, lung  
24 disease, osteoporosis, HIV/AIDS, hepatitis, helicobacter pylori, immunization status, diabetes,  
25 allergies, growth and development, anemia, dietary intake (including fats), antioxidants, and  
26 nutritional blood measures. The NHANES I analyzed blood and urine samples from 23,808 study

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<sup>23</sup> National Health and Nutrition Examination Survey (NHANES),  
<http://www.cdc.gov/nchswww/about/major/nhanes/nhanes.htm>

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1 participants, and NHANES II analyzed 20,322 samples. The HHANES was a one-time survey  
2 conducted from 1982 to 1984 that provided data on 11,653 people of Hispanic origin.

### 3 **RESEARCH REQUIRING UNIQUE TISSUE COLLECTIONS**

4 Most research that uses human tissue obtain specimens from pathology laboratories or  
5 existing tissue banks. However, some research studies require unique samples and must collect  
6 specialized tissue, thereby developing small tissue collections and ultimately contributing the  
7 samples to an established tissue bank for storage.

8 For example, the University of Southern California AIDS-Malignancy Clinical Trials  
9 Consortium (AM-CTC) helps design, develop and conduct collaborative, innovative phase I and  
10 II clinical trials, employing novel agents and approaches in patients with various AIDS-related  
11 malignancies. In addition, the AM-CTC provides tumor tissue and other relevant biologic  
12 materials, derived from patients accrued onto trials. Since 1987, the AIDS Clinical Trials Group  
13 has accrued more than 470 patients onto various AIDS-malignancy protocols.

14 Stanford University is investigating the role of environmental toxicants and genetic  
15 susceptibility factors in the etiology of Amyotrophic Lateral Sclerosis (ALS) by conducting a  
16 case-control study of 175 incident ALS and 550 age- and gender- comparable control subjects. It  
17 is hoped that the proposed study will advance knowledge of neurotoxic and endogenous  
18 susceptibility factors that are important in the etiology of ALS.

### 19 **PATHOLOGY SPECIMENS**

20 A large number of tissues are collected for diagnostic or therapeutic reasons. These  
21 tissues are usually sent to a clinical, diagnostic or pathology laboratory for examination. These  
22 laboratories may be located at GME teaching institutions, physicians offices, community hospitals,  
23 or independent laboratories. Tissues are used for research, educational, and quality control  
24 purposes, however the vast majority are not used for these purposes. Most patients sign a general  
25 consent stating that after completion of any diagnostic tests, some of the sample may be saved for  
26 research purposes.

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1 To be accredited, laboratories are required to keep pathological specimens for a minimum  
2 amount of time. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) set forth the  
3 conditions that laboratories must meet to be certified to perform testing on human specimens.  
4 CLIA stipulates that laboratories must retain cytology slides for a minimum of 5 years,  
5 histopathology slides for a minimum of 10 years, and paraffin blocks for a minimum of 2 years  
6 (Clinical Laboratory Improvement Amendments, 1996). In addition, some states have regulations  
7 that require retention of pathology specimens for longer periods of time. Once the regulated  
8 length of time for storage is met, institutions continue to store pathology specimens based on the  
9 room they have for storage, the philosophy of the institution, and several other variables.

### 10 **Pathology Departments at Graduate Medical Education Teaching Institutions**

11 Medical education in the United States can be divided into three major phases. The first  
12 phase, medical school, provides instruction in the sciences that underlie medical practice and in  
13 the application of those sciences to health care. In 1997, there were 125 medical schools in the  
14 United States (American Medical Association, 1997). The second phase, graduate medical  
15 education (GME), prepares physicians for independent practice in a medical specialty. GME  
16 teaching institutions include medical schools, Armed Forces hospitals, Veterans Affairs medical  
17 centers, the Public Health Service, state, county and city hospitals, non-profit institutions, and  
18 health maintenance organizations. In 1997, there were 1,687 accredited GME teaching  
19 institutions in the United States (American Medical Association, 1997). Continuing medical  
20 education (CME), the third phase of medical education, continues medical professionals'  
21 education throughout their careers. Collectively, pathology departments at GME teaching  
22 institutions constitute the largest and oldest stores of tissue samples in the United States, due to  
23 the requirement that residents examine specific numbers and types of cases/specimens during their  
24 training.

25  
26 Of the pathologic specialties, anatomic and clinical pathology, cytopathology and  
27 hematology specimens probably account for the largest collection of tissues. For the academic  
28 year 1996-1997, there were 180 anatomic and clinical pathology programs with 2,675 residents.  
29 To have enough cases to fulfill the educational needs of their residents, institutions would have  
30 had to accession over 5 million total cases/specimens which is an average of 28,050  
31 cases/specimens per program. In comparison, in 1997-1998 the 180 anatomic and clinical

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1 pathology programs with 2,656 residency positions would have to accession over 5 million total  
2 cases/specimens which is an average of 27,851 cases/specimens per program. Forensic pathology  
3 cases are accessioned separate from the other specialties. It is recommended that forensic  
4 pathology programs conduct approximately 500 medicolegal autopsies per year and  
5 approximately 300 additional autopsies for each additional residency position. Therefore, forensic  
6 pathology programs would have to conducted 21,900 autopsies<sup>24</sup> in 1996-1997, and 29,700 in  
7 1997-1998 to provide enough cases for resident training. To support 28 pediatric pathology  
8 resident positions in 1997-1998, a total of 58,520 specimens and autopsy cases would have to be  
9 accessioned.

10 A conservative estimate is that an average of approximately 30,000 anatomic and clinical,  
11 forensic and pediatric pathology and autopsy cases are seen per GME teaching institution each  
12 year. Cytopathology programs accession an average of approximately 50,000 cytology specimens  
13 per year (range of 14,000 to 100,000 cases/specimens). Hematopathology programs accession an  
14 average of 750 bone marrow aspirations, and biopsies and resections of lymph nodes and related  
15 tissue.

16 Most medical school pathology departments store tissue samples indefinitely, with the  
17 oldest tissues archived anywhere from 20 years old to over 100 years old. Stored specimens are  
18 labeled with either a pathology accession number that is linked to the patient's medical record, or  
19 directly with the patient's name and medical record number. People who have access to the  
20 specimens include the pathologists, researchers, other physicians, and others who have a court  
21 order. Each institution accessions an average of approximately 30,000 cases per year, with  
22 approximately 3.8 million total cases accessioned per year at all 125 medical schools in the United  
23 States.

## 24 **DNA Diagnostic Laboratories**

25 HELIX<sup>25</sup> is a national directory of DNA diagnostic laboratories. It includes a  
26 comprehensive listing of clinical service and research laboratories performing disease-specific

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<sup>24</sup> A single autopsy case may generate several slides and paraffin blocks.

<sup>25</sup> HELIX, <http://healthlinks.washington.edu/helix>

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1 clinical molecular genetic testing for single-gene and contiguous-gene disorders. HELIX is  
2 funded by the National Library of Medicine and administered through the National Network of  
3 Libraries of Medicine. In January 1994, there were 148 laboratories listed in HELIX, 131 were  
4 located in the United States, 16 were located in Canada, and one was in Mexico (McEwen and  
5 Reilly, 1995). One hundred and thirty seven of the labs were academically based or within  
6 government agencies, and 11 were commercial laboratories (McEwen and Reilly, 1995).

7 In a 1994 survey of HELIX DNA diagnostic laboratories, 90 percent of the respondents  
8 stated that they banked DNA (McEwen and Reilly, 1995). DNA banks ranged in size from  
9 having less than 100 to more than 1,000 samples in storage (McEwen and Reilly, 1995). Most  
10 laboratories banked DNA as a service to referring physicians or for individuals and families at risk  
11 for a particular genetic disorder, for research purposes such as gene mapping, and as a service to  
12 clinical, forensic or research laboratories (McEwen and Reilly, 1995). Over 50 percent of the  
13 respondents stated that their laboratories had released samples to researchers after stripping them  
14 of identifiers (McEwen and Reilly, 1995).

### 15 **Clinical Service and Diagnostic Laboratories**

16 The majority of clinical service and diagnostic laboratories are not associated with GME  
17 teaching institutions. These include laboratories within physicians offices or community hospitals,  
18 and independent laboratories. In 1991, there were approximately 640,000 clinical laboratories  
19 and other facilities that perform laboratory tests on human specimens (Department of Health and  
20 Human Services, 1991). The number of tissues stored at these laboratories varies greatly, but the  
21 minimum storage time is determined by CLIA and state regulations.

### 22 **Centers for Disease Control and Prevention Institutes**

23 The Centers for Disease Control and Prevention<sup>26</sup> (CDC), located in Atlanta, Georgia, is  
24 an agency of the Department of Health and Human Services. CDC's mission is to promote health  
25 and quality of life by preventing and controlling disease, injury, and disability. Several of CDC's

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<sup>26</sup>Centers for Disease Control and Prevention (CDC), <http://www.cdc.gov/>

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1 eight centers have stored tissue samples, including the National Center for Environmental Health  
2 (NCEH) and the National Center for Infectious Disease (NCID). NCEH<sup>27</sup> is involved in several  
3 areas of research, including biomonitoring, breast-cancer related projects, and genetic research. It  
4 has prepared DNA specimens from approximately 8,000 NHANES participants to be used by  
5 researchers around the country. NCID<sup>28</sup> plans, directs, and coordinates a national program to  
6 improve the identification, investigation, diagnosis, prevention, and control of infectious diseases.  
7 It maintains a bank of serum specimens of epidemiological and special significance to CDC's  
8 research and diagnostic activities. The NCID is also responsible for the integrity, security, and  
9 maintenance of a computer inventoried serum bank consisting of 250,000 aliquots of serum from  
10 100,000 Alaskan Natives.

## 11 NEWBORN SCREENING LABORATORIES

12 Archives of newborn screening cards for inborn errors of metabolism (Guthrie Cards)  
13 represent an enormous source of banked DNA. Guthrie cards are used to test newborns for  
14 several different diseases, including congenital hypothyroidism, phenylketonuria, galactosemia,  
15 hemoglobinopathies (e.g. sickle cell anemia), biotinidase deficiency, homocystinuria, Maple Syrup  
16 Urine disease, and cystic fibrosis. These newborn screening tests utilize bacterial inhibition assays  
17 and automated enzymatic methods. However, as new genetic screening tests are developed, and  
18 the Human Genome Project discovers new disease related genes, it is likely that newborn  
19 screening tests may become DNA-based. In addition, interest in using Guthrie cards for  
20 population-wide genetic epidemiological studies has grown, given the stability of DNA in dried  
21 blood, and the ability to analyze the DNA in these samples (McEwen and Reilly, 1994).

22 A 1994 survey of all newborn-screening programs in all 50 states, the District of  
23 Columbia, Puerto Rico, and the Virgin Islands revealed that the majority of laboratories have  
24 accumulated less than 500,000 Guthrie Cards over the years, 7 have amassed more than 500,000,  
25 4 reported collections of between 1 and 5 million cards, and one reported a collection of 6 million  
26 (McEwen and Reilly, 1994). The number of cards collected over a 1-year period ranged from less  
27 than 10,000 in 4 labs to more than 500,000 in 2 populous states (McEwen and Reilly, 1994). For

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<sup>27</sup> National Center for Environmental Health (NCEH), <http://www.cdc.gov/nceh/ncehome.htm>

<sup>28</sup> National Center for Infectious Diseases (NCID), <http://www.cdc.gov/ncidod/ncid.htm>

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1 example, over 99 percent of the 550,000 children born each year in California are tested for 3  
2 genetic conditions (Reilly, 1992).

3  
4 The trend in most states is to save Guthrie cards for longer and longer periods of time.  
5 Eleven laboratories indicated that their state departments of public health have issued written  
6 regulations on the retention of Guthrie cards, while 29 stated that their laboratories have internal  
7 written policies on this matter (McEwen and Reilly, 1994). Forty of the state newborn screening  
8 laboratories retain all the Guthrie cards that they receive through their newborn-screening  
9 programs, including those cards that test negative, at least for a short period of time (McEwen  
10 and Reilly, 1994). Twenty three laboratories indicated that they keep their cards for a year or  
11 less, 10 plan to keep their cards for 1 to 5 years, 13 will keep them for longer than 5 years, three  
12 save all their cards for 20 to 25 years, and four plan to keep their cards indefinitely (McEwen and  
13 Reilly, 1994). Thirteen other respondents discard their cards within several weeks or months  
14 (McEwen and Reilly, 1994).

15 Guthrie cards contain identifying information, such as mother's name and address, hospital  
16 of birth, baby's medical records number, baby's doctor's name and address. The conditions under  
17 which Guthrie cards are stored vary from state to state. Some store the cards in boxes at room  
18 temperature, some keep them in boxes or folders in a freezer, refrigerator, or climate-controlled  
19 room, some keep them in boxes or folders in a basement or warehouse, and some keep them in a  
20 cabinet either in folders or biohazard bags (McEwen and Reilly, 1994). Fourteen state  
21 laboratories periodically check the condition of their stored cards (McEwen and Reilly, 1994).

22 All states participate in some form of newborn screening, but few have issued regulations  
23 that explicitly define the scope of permissible use of Guthrie card samples (Andrews, 1995).  
24 Seven state departments of public health have issued written regulations on third-party access to  
25 Guthrie cards, and 10 of the laboratories have internal written policies on this matter (McEwen  
26 and Reilly, 1994).

## 27 **FORENSIC DNA BANKS**

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1           In 1989, the Virginia Division of Forensic Science<sup>29</sup> was the first state laboratory to offer  
2 DNA analyses to law enforcement agencies, and the first to create a DNA databank of previously  
3 convicted sex offenders. By November 1997, 48 states had established forensic DNA data banks  
4 from convicted criminals, especially violent sex offenders and other violent felons (Finn, 1997).  
5 The two states without Forensic DNA banks, Vermont and Rhode Island, are planning legislation  
6 to create them (Finn, 1997). In addition, the Federal Bureau of Investigation<sup>30</sup> (FBI) exploring  
7 ways to create a Forensic DNA bank for the District of Columbia (Finn, 1997).

8           The DNA Identification Act of 1994 (Pub. L. No. 103-322, 1994 HR 3355, 108 Stat.  
9 1796, §210304), a federal law enacted in the fall of 1994 as part of the Omnibus Crime Control  
10 Law, created a national oversight committee to develop guidelines for DNA forensics and  
11 established a five-year, \$40 million grant program to assist state and local crime laboratories in  
12 developing or improving forensic DNA testing capabilities. The DNA Identification Act also  
13 formally authorized the FBI to establish Combined DNA Index System<sup>31</sup> (CODIS) for law  
14 enforcement identification purposes (TWGDAM, 1989). CODIS is a national computer network  
15 containing DNA profiles of convicted offenders, unknown suspects, and population samples  
16 (which are used for statistical purposes only). Using CODIS, federal, state, and local law  
17 enforcement agencies are able to compare DNA profiles from crime scenes to DNA profiles of  
18 felons in the CODIS database.

19           In addition to collecting specimens from sex offenders and violent felons, a number of  
20 states also require samples from juvenile offenders, non-violent felons, such as drug or white  
21 collar offenders, and those convicted of misdemeanors (McEwen, 1997). South Dakota requires  
22 samples from people merely arrested (not convicted) of a sex offense (Finn, 1997), with several  
23 other states considering similar bills (McEwen, 1997). There is also a proposal to establish a  
24 federal DNA data bank that would include profiles from people convicted in federal or military  
25 courts of offenses similar to those covered by most state laws (McEwen, 1997).

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<sup>29</sup>Virginia Division of Forensic Science, <http://www.state.va.us/~dcjs/forensic/>

<sup>30</sup>Federal Bureau of Investigations (FBI), <http://www.fbi.gov/>

<sup>31</sup>Forensic Science Research and Training Center, <http://www.fbi.gov/lab/report/research.htm>



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1 Convicted offenders are required to provide blood, or in some cases saliva, either at  
2 sentencing or before release from prison (McEwen, 1997). Some states also require samples from  
3 people already incarcerated before laws' effective dates (McEwen, 1997). The DNA from these  
4 samples is analyzed for its unique identification characteristics. Nationwide, samples from about  
5 380,000 offenders have been collected, mostly in Virginia and California, and about 116,000  
6 samples (30 percent) have been analyzed (McEwen, 1997). These DNA identification profiles are  
7 stored, along with the samples themselves, to help identify suspects by matching biological  
8 evidence found at crime scenes to state DNA databases.

### 9 **SPERM, OVUM AND EMBRYO BANKS**

10 In 1995, there were more than 280 fertility clinics in the United States. In 1995, 57,000  
11 assisted reproductive technology (ART) cycles were carried out in the United States. Most of  
12 these cycles used fresh embryos using the couple's own egg and sperm. A smaller number of  
13 ART cycles used frozen, non-donated embryos that had been thawed and then transferred into the  
14 women's uterus, and fewer still used donated eggs. Most of these cycles did not produce a  
15 clinical pregnancy. Sperm, ovum and embryo banks provide physicians and their patients a  
16 comprehensive resource for semen cryopreservation and specialized reproductive services,  
17 including: 1) freezing and storing of anonymous human sperm for the use in artificial insemination;  
18 2) long-term semen storage for men facing the possibility of sterilization, reduction in fertility  
19 potential or genetic damage due to vasectomy, chemotherapy, radiation therapy and high risk  
20 occupational exposures; 3) long-term storage of pre-implantation embryos; and 4) andrology  
21 laboratory services, such as semen analysis, fertility testing, sperm washing, and male sex  
22 selection.

### 23 **UMBILICAL CORD BLOOD BANKS**

24 Stem cells (progenitor cells that produce all other blood cells) are used to treat patients  
25 with blood diseases, certain genetic disorders, and patients receiving chemotherapy and/or  
26 radiation treatment for cancer. Until scientists discovered that umbilical cord blood contained  
27 hematopoietic stem cells, the only known source of stem cells was from bone marrow. However,  
28 retrieval of bone marrow is invasive, may be painful, requires general anesthesia, and is expensive

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1 to harvest. In contrast, retrieval of umbilical cord blood is non-invasive, painless, and generally  
2 only takes a few minutes to complete. After a baby is delivered and the umbilical cord is cut,  
3 blood is withdrawn from the umbilical cord and placenta with a syringe and then cryogenically  
4 stored. In addition, bone marrow is difficult to match between donor and recipient, while cord  
5 blood is compatible with more people. Cord blood transplants also have a lower incidence of  
6 graft versus host disease and are less likely to transmit infectious diseases.

7 In 1988, the first successful human cord blood transplant was performed in a child with  
8 Fanconi Anemia using cord blood from a sibling (Gluckman et al., 1989). Since then, over 500  
9 autologous and allogeneic umbilical cord blood transplants have been performed worldwide, with  
10 the majority done in the past two to three years (Perdahl-Wallace, 1997). Approximately two-  
11 thirds of the cord blood transplants have been performed for malignant conditions including acute  
12 lymphocytic leukemia, acute myelocytic leukemia, chronic myelogenous leukemia, and  
13 neuroblastoma (Wagner et al., 1995). The other one-third have been for a variety of genetic  
14 disorders including Hurler and Hunter syndromes, adrenoleukodystrophy, osteopetrosis, severe  
15 aplastic anemia, severe combined immunodeficiency, and hemoglobinopathies such as beta  
16 thalassemia and sickle cell anemia (Wagner et al., 1995; Wagner et al., 1996). The majority of  
17 transplants have been in children, although a small number of adults have been transplanted as  
18 well. The Working Group on Ethical Issues in Umbilical Cord Blood recently concluded that  
19 "until additional data are obtained regarding safety and efficacy, umbilical cord blood banking and  
20 use ought to be considered an investigational technology rather than a proven treatment"  
21 (Sugarman et al., 1997). Cord blood is now being stored at public and private banks.

22 In the last few years, privately owned companies have also begun offering umbilical cord  
23 blood banking services to individuals and families. When dealing with private storage companies,  
24 users pay a one-time fee for the collection, testing and freezing of the blood. An annual fee is  
25 charged for storing the blood in liquid nitrogen. The stored cord blood may be withdrawn if illness  
26 occurs later in life. In contrast, when parents choose to donate their baby's cord blood to a public  
27 bank, they generally pay no fees, but they give up all rights to the sample to help build the public  
28 supply of cord blood for use in transplantation and research. In general, expectant mothers who  
29 choose to donate their baby's cord blood are asked to consent to providing medical, ethnic and  
30 related information, donating the cord blood to the cord blood bank for transplantation and/or  
31 research, allowing blood to be drawn from the mother for tests including HIV testing, and

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1 granting permission to track the newborn's medical history for up to one year. Some registries  
2 distribute samples for education and research.

### 3 **ORGAN BANKS**

4 Organ and tissue banks recover, process, store and distribute human organs, bone and  
5 tissue for transplantation. Donations are made from people who agree to donate upon their death.  
6 Some organ and tissue banks may also have tissue available for use educational and research  
7 purposes. However, the demand for organs, bone and tissue usually exceeds the current supply.  
8 Therefore, usually only organs and tissues not suitable for transplantation are available for  
9 research.

### 10 **BLOOD BANKS**

11 The American Red Cross<sup>32</sup> collected approximately 5.8 million blood donations in 1996.  
12 However, the Red Cross represents about half of all United States blood donations, so annually,  
13 about 12 million units of blood are donated in the United States. The American Red Cross  
14 usually maintains about a three day supply of fresh blood as well as approximately 20,000 units of  
15 frozen blood at any one time. The American Red Cross also maintains the world's largest registry  
16 of frozen rare blood. Approximately 1000 units of rare blood a year are supplied to recipients  
17 around the globe.

18 The Food and Drug Administration (FDA) requires the tracking of blood from "arm to  
19 arm," however this information is confidential and coded. Donors who test positive for HIV are  
20 notified and counseled. The consent form signed by donors asks donors if excess or expired  
21 blood may be used for research.

22 Fresh red blood cells have a shelf-life of 21 to 42 days depending on the preservative used,  
23 and platelets have a shelf-life of 5 days. Plasma can be stored frozen for 1 to 5 years, and frozen

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<sup>32</sup> American Red Cross, [http:// www.redcross.blood](http://www.redcross.blood)

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1 whole blood can be stored for at least 10 years. Platelets and red cells that expire are sold for  
2 research purposes. Researchers are informed that the samples have been found negative for all  
3 FDA required tests, and only by special request, may be provided with the donor's age and  
4 gender. Plasma that can not be transfused is used for making blood derivatives such as Factor  
5 VIII for hemophiliacs, or for making diagnostic reagents. Nothing goes to waste.

6 **CONCLUSIONS**

7 *to be written*

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