Large tissue banks and repositories exist in almost every sector of the scientific and medical communities, including the military, the federal government, universities and academic medical centers, commercial enterprises, and nonprofit organizations. In addition, several universities have established core tissue banking facilities to support both their own research and collaborations with other universities. These large tissue banks, repositories, and core facilities are major sources of human tissue for biomedical research.

**MILITARY FACILITIES**

The military maintains two of the largest tissue repositories in the world. The National Pathology Repository and the Department of Defense (DoD) DNA Specimen Repository for Remains Identification are housed within the Armed Forces Institute of Pathology (AFIP). The AFIP is responsible for maintaining a central laboratory of pathology for consultation and diagnosis of pathologic tissue for DoD, other federal agencies, and civilian pathologists. The AFIP also conducts research in pathology, trains enlisted personnel in histopathology and related techniques, and offers more than 50 pathology education courses for medical, dental, and veterinary personnel.

**National Pathology Repository**

The National Pathology Repository, located at the AFIP, is the largest and most comprehensive collection of pathology material in the world. Since 1917, the Pathology Repository has collected more than 2.5 million cases comprising more than 50 million microscopic slides, 30 million paraffin tissue blocks, 12 million preserved wet tissue specimens, and associated written records. The Pathology Repository accessions approximately 50,000 cases annually, with 53,384 cases accessioned in fiscal year (FY) 1996, and 51,908 in 1997. In addition, approximately 40,000 cytology cases are sent for primary diagnosis annu-
ally but are not accessioned (only cytology cases sent for second opinions are accessioned). During 1993, approximately 10,000 of the cases were cancers and 8,000 were benign neoplasms, with the balance representing the entire spectrum of human disease. Material is stored permanently unless a specific request comes from the contributor or other authorized individual to return or release the material.

The AFIP accepts cases from all Army, Navy, and Air Force medical facilities and investigative agencies. The AFIP also serves as the central laboratory of pathology for the DoD and certain other federal agencies, such as the Public Health Service and the Justice Department. In addition, the AFIP serves as a Veterans Affairs Special Reference Laboratory for Pathology and maintains a special registry of former prisoners of war. Civilian and foreign contributions are accepted from pathologists (or clinicians functioning as pathologists) through the Civilian Consultation program. Cases represent both sexes, all races/ethnicities, and all ages and come from contributors worldwide.

Cases are sent to the AFIP for a variety of reasons. The majority of cases are submitted to the AFIP because the contributor wants a second opinion regarding the diagnosis. Some are forwarded as part of established peer-review and quality-assurance programs. DoD regulations require some military cases to be forwarded, such as forensic cases and cases subject to litigation. Other cases are submitted because they are rare and could be used by the AFIP in their research and education missions. In addition, cases have been submitted over the years for specific purposes, such as to study particular diseases or to answer current and future research questions (for example, sera from Gulf War veterans).

All submitted case material is coded by pathological diagnosis and is identified by an AFIP accession number. The source name, Social Security number, date of birth, age, sex, and race are stored if provided by the contributing pathologist. Any medical history provided is stored in the case folder and on an optical disk imaging system. The source address is not routinely provided or stored but is obtained on occasion for follow-up studies. Likewise, the original consent remains a matter between the patient and the clinician and is not routinely provided to AFIP by the contributing pathologist. The submitting pathologist’s name and address and the source’s surgical identification numbers are also stored.

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

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

**DoD DNA Specimen Repository for Remains Identification**

The DoD DNA Specimen Repository for Remains Identification is the world’s largest DNA bank. As of September 1999, the DNA Repository has received more than 2.8 million DNA specimens. Specimens come into the DNA Repository at a rate of 10,000 per day, and the tally (database) is updated every seven seconds. It is estimated that by 2001 the DNA Repository will contain approximately 3.5 million samples. All DNA specimens will be maintained for 50 years before being destroyed. However, donors may request that their specimens be destroyed following the conclusion of their military service obligation or other applicable relationship to DoD.

Since June 1992, DoD has required all military inductees, and all active-duty and reserve personnel to provide blood and saliva samples for its DNA Specimen Repository at the time of enlistment, reenlistment, annual physical, or preparation for operational deployment (McEwen, 1997). The DNA Repository also contains samples from civilians and foreign nationals who work with the U.S. military in arenas of conflict. Three DNA specimens are collected from each person: a blood stain card (stored in a pouch in the service member’s medical record), a second blood stain card, and a buccal swab (stored at the DNA Specimen Repository). The blood is placed on special cards with the service member’s Social Security number, date of birth, and branch of service designated on the front side of the card and a fingerprint, a bar code, and signa-
ture attesting to the validity of the sample on the reverse. The bloodstain card stored at the DNA Repository is placed in a vacuum-sealed bag and frozen at –20°C. The buccal swab is fixed in isopropanol and stored at room temperature. DNA will be extracted from the specimens in the repository only when it is needed for remains identification.

The DNA Repository, along with the Armed Forces DNA Identification Laboratory (AFDIL), make up the DoD DNA Registry. The purpose of the DNA Registry is to identify the remains of soldiers killed in combat or missing in action. High-velocity weapons often destroy any chances of using fingerprints or dental records, but DNA can almost always be used to identify remains. Most times the armed forces can identify the dead based on rosters, but DNA identification provides closure for the family and biological proof of death required by life insurance companies. The military’s policy ensures that specimens can be used only for remains identification and routine quality control, except for cases subpoenaed for the investigation or prosecution of a felony. The specimens cannot be used without consent for any other purpose, such as paternity suits or genetic testing. In addition, the specimens are considered confidential medical information, and military regulations and federal law exist to cover any privacy concerns.

**NATIONAL INSTITUTES OF HEALTH**

The National Institutes of Health (NIH), founded in 1930, consists of 24 separate Institutes, Centers, and Divisions. NIH is the principal health research agency of the federal government. It is one of the eight health agencies of the Public Health Service, which is part of the U.S. Department of Health and Human Services. The mission of NIH is to protect and improve human health. To accomplish its mission, NIH conducts and supports basic, applied, and clinical health services research aimed at understanding the processes underlying human health and acquiring new knowledge to help prevent, diagnose, and treat human diseases and disabilities. In 1999, the NIH budget was more than $15.65 billion. The extramural program, which accounts for approximately 80-85 percent of NIH’s total budget, awards grants to researchers at universities, medical schools, hospitals, small businesses, and research institutions across the country, while the intramural program, which represents approximately 11 percent of the budget, supports research and training of scientists at NIH. NIH is probably the single highest funder of extramural tissue and data resources for basic, applied, and clinical research. Some of the institutes at NIH that support tissue banks include the National Cancer Institute, the National Institute of Allergy and Infectious Disease, the National Heart, Lung, and Blood Institute, the National Institute of Mental Health, the National Institute on Aging, the
National Institute of Environmental Health Sciences, and the National Institute of Diabetes and Digestive and Kidney Diseases.

**National Cancer Institute**

The National Cancer Institute (NCI), the largest of NIH's biomedical research institutes and centers, has coordinated the U.S. government's cancer research program since 1937. Through both its extramural and intramural programs, the NCI supports research on all aspects of cancer prevention, detection, diagnosis, and treatment. In addition, the NCI supports several tissue and data resources for cancer research, including the NCI Cooperative Human Tissue Network, the NCI Clinical Trials Cooperative Group Human Tissue Resources, the NCI Cooperative Breast Cancer Tissue Resource, the NCI Breast Cancer Specimen and Data Information System, the NCI Cooperative Family Registry for Breast Cancer Studies and NCI Cooperative Family Registry for Colorectal Cancer Studies, and the NCI AIDS Malignancy Bank.

The NCI supports a great number of other tissue banks and collection systems. Among the many NCI-funded tissue collections are breast and prostate cancer and HIV/AIDS. These tissue collections may vary in their specific objectives and goals, but, overall, the tissues are collected for the advancement of knowledge and development of clinical applications in a particular field.

**NCI Cooperative Human Tissue Network.** The Cooperative Human Tissue Network (CHTN), supported by the NCI since 1987, provides biomedical researchers access to fresh surgical or biopsy specimens of normal, benign, precancerous, and cancerous human tissues. The CHTN is a tissue collection system and not a tissue bank. Only very rare specimens that are difficult to obtain are stored to anticipate future requests. Except for a collection of frozen tissue from rare pediatric tumors, banked specimens are generally not stored for more than one year. Normally, the specimens are obtained prospectively to fill specific researcher requests. Five member institutions coordinate the collection and distribution of tissues across the United States and Canada.¹ Tissues are provided by the CHTN only for research purposes and cannot be sold or used for commercial purposes. The intent of the CHTN is to encourage research using human tissue for the good of the public rather than for private gain.

During the first nine years of its operation, the CHTN supplied more than 100,000 specimens to approximately 600 investigators. CHTN tissues have been used widely in cancer research for both basic and developmental studies,

¹The five regional divisions are the Eastern Division, the Midwestern Division, the Southern Division, the Western Division, and the Pediatric Division, which provides samples of childhood tumors nationwide through the Children’s Cancer Study Group.
including molecular biology, immunology, and genetics. Researchers have used these tissues to study mutations of protooncogenes in human tumors and the role of growth factors in cancer and to isolate new cancer genes. More than 2,000 publications have resulted from studies using CHTN tissues.

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

Participating CHTN institutions include the University of Alabama at Birmingham, University of Pennsylvania Medical Center, the Ohio State University Medical Center, Case Western Reserve University, and Children’s Hospital of Columbus.

**NCI Clinical Trials Cooperative Group Human Tissue Resources.** The NCI Clinical Trials Cooperative Group (CTCG) is a program of national networks that conduct large-scale, multi-institutional clinical trials supported by the Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis. The primary goal of CTCG is the definitive evaluation of clinical treatment programs. Currently, the groups conduct approximately 400 clinical trials, evaluating approximately 20,000 patients a year. The large amount of patient data collected annually through these trials and the large-scale collection of biologic specimens with clinical and outcome data provide researchers with a rich resource of specimens for correlative studies. The network member groups that maintain tissue banks are briefly described below.

Pediatric Oncology Group. The Pediatric Oncology Group (POG), established in 1980, is a consortium of 39 full member institutions, 48 affiliate, 12 consortia, and 9 CCOP institutions. This consortium has pooled its patient resources and scientific expertise to study the natural history of childhood cancer, develop and compare effective therapeutic regimens, and investigate the toxicity and efficacy of new anticancer agents in the treatment of childhood cancer. Many of the members are funded through the NCI. Since 1980, nearly 50,000 children have been enrolled in pediatric cancer research studies. Several tissue banks have been established to provide qualified investigators with tissue and cells for studies focused on childhood cancers. For example, the Acute Lymphoblastic Leukemia (ALL) Cell Bank (Stanford University, California) has collected thou-
sands of frozen cell suspensions from bone marrow extractions from ALL patients. The cell bank collects and stores approximately 600 new samples each year. Other POG-maintained tissue banks are listed below:

- Pediatric Oncology Group—Hodgkin's Disease Cell Bank (Wake Forest University, North Carolina)
- Pediatric Oncology Group—Germ Cell Tumor Bank (University of Alabama, Birmingham, Alabama)
- Pediatric Oncology Group—Lymphoid Relapse Cell Bank (MCSD Medical Center, California)
- Pediatric Oncology Group—Neuroblastoma Tumor Bank (Children's Memorial Hospital, Illinois)
- Pediatric Oncology Group—NHL Cell Bank (University of Massachusetts Medical School, Massachusetts)
- Pediatric Oncology Group—Hepatoblastoma Biology Study and Tissue Bank (University of Texas Southwestern Medical Center, Texas)
- Pediatric Oncology Group—AML Cell Bank (St. Jude Children's Research Hospital, Tennessee)
- Pediatric Oncology Group—CNS Tumor Bank (Duke University, North Carolina)
- Pediatric Oncology Group—Sarcoma Cell Bank (Dana-Farber Cancer Institute, Massachusetts)

Gynecologic Oncology Group Tissue Bank. The Gynecologic Oncology Group (GOG) Tissue Bank, supported by the NCI, provides malignant, benign, and normal ovarian and cervical tissue from almost 3,200 patients for molecular biology studies of gynecologic tumors. The specimens are stored as snap-frozen specimens, formalin-fixed sections, OCT embedded primary tumors, touch imprint slides, and patient serum collected prior to surgery. Currently, specimens are stored dating back five years. Each case is given a unique identifier, and a link is kept at the GOG Tissue Bank. The link provides a one-way flow of information for research purposes. Clinical information is provided with each case and may include patient age and race in addition to the institutional pathology and operative reports.

Specimens obtained from patients in clinical trials at approximately 76 participating institutions are stored centrally at the Children's Hospital Research Foundation in Columbus, Ohio. The GOG Tissue Bank is ideal for clinical correlative studies to identify those factors that place patients with ovarian carcinoma at high risk for treatment failure independent of such traditional vari-
ables as stage, grade and cell type. A total of 52 projects, focusing mainly on the molecular genetics underlying gynecologic malignancies, have utilized this resource.

Intergroup Rhabdomyosarcoma Tissue Bank. The Intergroup Rhabdomyosarcoma Study (IRS) was initiated in 1972 and is a collaborative multi-disciplinary study carried out by the Children’s Cancer Group (CCG) and the POG. The IRS was designed to answer therapeutic, clinical, and laboratory questions about rhabdomyosarcoma. Eligible patients in CCG and POG institutions are enrolled in IRS protocols. Four major study protocols have taken place, and between 600 and 1,000 patients have been enrolled in each protocol. Tissue samples from patients in many of these protocols have been collected and stored in the Intergroup Rhabdomyosarcoma Tissue Bank for future study.

Cancer and Leukemia Group B. The Cancer and Leukemia Group B (CALGB) was founded in 1955 and is a national clinical research group sponsored by the NCI. CALGB consists of 31 university medical centers, more than 185 community hospitals, and more than 3,000 physicians. CALGB seeks to conduct clinical research studies aimed at reducing the morbidity and mortality from cancer, to relate the biological characteristics of cancer to clinical outcomes, and to develop new strategies for the early detection and prevention of cancer. CALGB research focuses on six diseases: leukemia, lymphoma, breast cancer, lung cancer, gastrointestinal malignancies, and prostate cancer.

The CALGB maintains a leukemia tissue bank at the Arthur G. James Cancer Hospital and Research Institute in Columbus, Ohio. Tissue specimens from study participants are collected from newly diagnosed patients with acute or chronic leukemia or myelodysplastic syndrome who are entered into a CALGB protocol for previously untreated patients. The specimens are archived for future investigations. Bone marrow, blood, and buccal swabs are collected from patients. Requests for tissue will be reviewed for scientific merit, strength of the analytical techniques, and track record of the investigator, among other criteria.

Children’s Cancer Group. The Children’s Cancer Group (CCG) was founded in 1955 and is a national cooperative research organization devoted to the development of new treatments and cures for childhood cancers. CCG conducts research on the biology of these cancers, their etiology, and long-term follow-up of cured patients into adult life. In 1990, the National Childhood Cancer Foundation was established as the fiscal agent of CCG. More than 2,500 pediatric cancer specialists are CCG members at more than 115 pediatric medical centers in the United States, Canada, and Australia. CCG’s main priority is to facilitate the transition of new biological findings into clinical trials for treatments of childhood cancer.
Tissue specimens are collected from study participants and stored for future investigations. The CCG maintains a solid tumor tissue bank, an AML tissue bank, and an ALL tissue bank.

National Wilms Tumor Study Group. The National Wilms Tumor Study Group (NWTSG) was established in 1969, and POG and CCG member institutions participate as part of their study groups. The NWTSG seeks to increase the survival rate of children with Wilms tumor and other renal tumors, to study the long-term outcome of children who have been treated successfully for Wilms tumor, to identify adverse effects of treatment for Wilms tumor, to conduct epidemiological and biological studies of Wilms tumor, and to disseminate information regarding successful treatment strategies of Wilms tumor.

More than 100 pediatric oncology treatment centers are involved in NWTSG therapeutic studies. Approximately 440 patients are enrolled annually into NWTSG studies. A tissue bank is maintained for tissue specimens collected from NWTSG study participants for future research.

Radiation Therapy Oncology Group. The Radiation Therapy Oncology Group (RTOG), established in 1968, has received funding from the NCI since 1971. RTOG is a national cooperative cancer study group that conducts multicenter clinical trials that integrate surgical, radiotherapeutic, and chemotherapeutic treatments. Since its inception, the RTOG has activated 271 protocols and accrued almost 56,000 patients in its cooperative group studies. Close to 300 radiation oncology departments in North America are members of the RTOG, which has its headquarters at the American College of Radiology in Philadelphia, Pennsylvania. In 1996, RTOG created the Translational Research Program (TRP), which coordinates RTOG’s basic science committees, including the Tumor Repository.

In 1993, a frozen tumor tissue repository was established at Fox Chase Cancer Center to provide access to frozen tissue for use in correlative and translational studies. The frozen tumor repository collects 3–5 frozen tissue fragments per case from phase III protocols of cervical, lung, head and neck, esophageal, and anal cancers. Currently, the frozen tumor repository contains more than 290 specimens from approximately 70 different tumors (cases). About two-thirds of the specimens are from cervical cancer, and the next most abundant specimens are from head and neck tumors.

Because of technological advances allowing the analysis of tumor markers in paraffinized tissue removed from tumors, the RTOG began archiving paraffin blocks and tissues from all RTOG phase III trials in 1995. Phase III protocols for cancer of the prostate, bladder, lung, head and neck, esophagus, and malignant glioma were modified to contain a request for blocks or unstained slides on each patient. The patient consent form was modified to allow tissues to be
stored and used for future research. These tissues are used for population-based studies but not for patient-related issues. Investigators performing research on RTOG specimens lack access to clinical information that might allow patient identification or linkage to treatment and demographics. A central processing site for all blocks and unstained slides was established in February 1996 and funded by the NCI in November 1996. The fixed tissue repository was moved to Latter-Day Saints Hospital in March 1997. Currently, the RTOG has approximately 4,400 cases stored at a central repository in Salt Lake City, Utah, and is accruing about 1,500 cases per year.

Eastern Cooperative Oncology Group. The Eastern Cooperative Oncology Group (ECOG), established in 1955, is supported by the NCI. ECOG is an international organization with more than 365 university and community-based hospitals and practices and more than 5,000 participating scientists and health-care professionals, including physicians, statisticians, nurses, clinical research associates, and pharmacists. ECOG’s primary functions include conducting clinical trials that compare new therapeutic approaches to standard therapies, assessing dose and toxicity levels, and determining response rates of experimental therapies. In addition to clinical trials, ECOG conducts studies in cancer control and prevention and performs translational research. ECOG’s overall goal is to improve the care of patients with cancer.

Tissue banking is an integral part of the laboratory science effort of ECOG. ECOG maintains four tissue banking facilities, a solid tumor tissue bank, a myeloma tissue bank, a leukemia cell bank, and an immunologic tumor repository. In January 1997, ECOG moved the solid tumor tissue bank and disbursement facility from the ECOG Operations Office in Boston, Massachusetts, to the Pathology Coordinating Office (PCO) in Evanston, Illinois. The new facility consists of 750 square feet of space—a 500-square-foot laboratory, a specially designed 250-square-foot walk-in cold room for storage of paraffin-embedded tissue blocks and slides, and a –80°C freezer for storage of bone marrow and DNA. The ECOG-PCO is responsible for acquisition, storage, data entry, tissue processing, and quality assurance of solid tumors and lymphomas. The ECOG-PCO stores both retrospective, archived fixed tissues (blocks and slides) and prospectively collected tissues (blocks, slides, frozen tissues, etc.). Tissue samples will never be discarded from the bank, and great efforts will be made to maintain at least a portion of all samples indefinitely. Tissues will be returned to their home institutions for storage if the ECOG-PCO bank ever closes. In 1995, the solid tumor bank contained 3,000 paraffin-embedded blocks and 15,000 slides with an estimated accrual rate of 3,000 blocks per year. The ECOG-PCO bank also stores specimens for three other Cancer Cooperative Groups—the Southwest Oncology Group (SWOG), the Cancer and Leukemia Group B (CALGB), and the Radiation Therapy Oncology Group (RTOG).
Southwest Oncology Group. The Southwest Oncology Group (SWOG) was first organized as a pediatric oncology group in 1956 but has evolved into an adult multidisease, multimodality, clinical research organization. SWOG is primarily funded by the NCI and includes 34 full member institutions; 26 Community Clinical Oncology Programs (CCOP) institutions, including seven minority-based CCOPs; 23 urologic cancer outreach programs; 25 high-priority program members; and a network of approximately 1,000 Cooperative Group Outreach Programs (CGOPs) investigators at 291 affiliate hospitals. Approximately 3,500 oncologists are members of SWOG and actively participate in the enrollment of patients to oncology protocols. Participants in SWOG study protocols are in excess of 8,000 per year. Tissue samples collected from participants are stored in the SWOG National Tissue Repository for future use by approved investigators in the field of oncology. For example, the Intergroup Breast Tissue Bank has more than 4,000 breast tissue specimens and estimates that more than 8,000 additional specimens from nine study protocols will be collected.

National Surgical Adjuvant Breast and Bowel Project. The National Surgical Adjuvant Breast and Bowel Project (NSABP) was established in 1971 and is primarily supported by the NCI. The NSABP is a cooperative group that conducts clinical trials in breast and colorectal cancer research. Currently, almost 300 participating medical centers in the United States and more than 6,000 physicians, nurses, and other medical professionals conduct NSABP research. In 1997, NSABP treatment trial members enrolled more than 3,000 breast and colorectal patients in seven treatment trials. The NSABP has collected malignant breast tissue samples from 10,000 patients enrolled in NSABP trials. These specimens are available for confirmatory studies for potential therapeutic response variables and limited nongenetic studies.

NCI Breast Cancer Specimen and Data Information System. The NCI has developed a national information database of breast cancer resources to help investigators studying breast cancer identify sources of biological specimens for use in their research. The NCI Breast Cancer Specimen and Data Information System contains information about 14 breast tissue banks. This database does not represent an exhaustive national listing of all facilities holding breast cancer tissue. However, by centralizing information on biological specimens, this database promotes access to breast tissue specimens and facilitates collaboration among basic, clinical and epidemiologic researchers. Table 3.1 summarizes the information contained in the NCI Breast Cancer Specimen and Data Information System.

Cumulatively, the 14 breast tissue banks in the NCI database contain more than 130,000 cases of breast cancer–related specimens and data, with banks ranging in size from 48 cases to approximately 101,000 cases (see Table 3.1). Three of
### Table 3.1

NCI Breast Cancer Specimen and Data Information System

<table>
<thead>
<tr>
<th>Resource</th>
<th>Number of Specimens/ Tissue Type(s)</th>
<th>Other Data</th>
<th>Limitations</th>
<th>Consent</th>
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</thead>
<tbody>
<tr>
<td>Baylor SPORE—Familial Breast Cancer Registry and Gene Bank</td>
<td>6 frozen and 42 paraffin-embedded malignant breast cancer specimens</td>
<td>Demographic Clinical Outcome</td>
<td>Proposals reviewed and approved by Baylor SPORE Executive Committee, and collaboration is required</td>
<td>Specific patient consent form for research use of breast cancer-related specimens</td>
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<tr>
<td>Alkek N550, MS 600</td>
<td>Blood or blood products Frozen and paraffin-embedded malignant tissue</td>
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<td>One Baylor Plaza</td>
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<td>Houston, TX 77030</td>
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<td>Ph. 713-798-1600</td>
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<td>Fax: 713-198-1642</td>
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<td>Baylor SPORE—National Breast Cancer Tissue Resource</td>
<td>151,320 biopsy specimens from about 101,000 cases of breast cancer</td>
<td>Demographic Clinical Outcome</td>
<td>Proposals reviewed and approved by Baylor SPORE Executive Committee, and collaboration is required</td>
<td>Standard hospital consent</td>
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<tr>
<td>Alkek N550, MS 600</td>
<td>Frozen malignant tissue</td>
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<td>One Baylor Plaza</td>
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<td>Fax: 713-198-1642</td>
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<tr>
<td>Dana Farber Cancer Institute</td>
<td>225 invasive breast cancer cases aged 32 and under</td>
<td>Demographic Clinical Other</td>
<td>Outside advisory committee prioritizes requests for specimens and risk factor data; no identifying information provided. Tissue samples are available for detection of p53, BRCA1, and additional inherited breast cancer susceptibility genes and studies of gene-environmental interactions Costs associated with generating and delivering all specimens requested</td>
<td>Not applicable since data provided is unidentified</td>
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<tr>
<td>44 Binney St.</td>
<td>Cell lines Genomic DNA Plasma Viable frozen cells</td>
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<td>Boston, MA 02115</td>
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<td>Resource</td>
<td>Number of Specimens/ Tissue Type(s)</td>
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<tr>
<td>Duke University</td>
<td>&gt;1,400 blood and tissue samples in inventory (50 fresh and 100 frozen tissues per year) Blood or blood products Fresh and frozen malignant, benign, and normal tissue</td>
<td>Demographic Clinical Outcome</td>
<td>Use by Duke researchers is high and has priority, otherwise collaboration is required</td>
<td>Standard hospital consent</td>
</tr>
<tr>
<td>Georgetown University Medical Center and Lombardi Cancer Center and SPORE 3900 Reservoir Rd., N.W. Washington, D.C. 20007 Ph. 202-687-2904 Fax: 202-687-8935</td>
<td>~200 cases per year of paraffin-embedded tissue since the mid-1970s (each case has from 3–30 tissue blocks) Blood or blood products Frozen and paraffin-embedded malignant, benign, and normal tissue</td>
<td>Demographic Clinical Outcome</td>
<td>Use of some samples restricted for use by Lombardi Cancer Center investigators, otherwise collaboration is required</td>
<td>Standard hospital consent</td>
</tr>
<tr>
<td>National Cancer Institute of Canada—Manitoba Breast Tumor Bank 100 Olivia St. Winnipeg Manitoba R3E OV9 Canada Ph. 204-787-1446 Fax: 204-783-6875</td>
<td>Malignant: &gt;2,000 frozen and &gt;2,000 paraffin-embedded Normal: 100 frozen and 100 paraffin-embedded</td>
<td>Demographic Clinical Other</td>
<td>Acknowledgment of bank in publication required Use of material restricted to studies proposed Data limited to information requested at outset of study Fees restricted to cost recovery only</td>
<td>Standard hospital consent</td>
</tr>
<tr>
<td>Resource</td>
<td>Number of Specimens/ Tissue Type(s)</td>
<td>Other Data</td>
<td>Limitations</td>
<td>Consent</td>
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<tr>
<td>National Surgical Adjuvant Breast and Bowel Project (NSABP)</td>
<td>10,000 specimens of malignant tissue from breast cancer patients enrolled in NSABP clinical trials</td>
<td>Demographic</td>
<td>Available only for confirmatory studies for potential therapeutic response variables; use limited to nongenetic studies only, otherwise collaboration is required</td>
<td>Old tissue banks have no research-related consent. Newer protocols have consent regarding research</td>
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<tr>
<td></td>
<td>Paraffin-embedded malignant tissue</td>
<td>Clinical</td>
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<td>Outcome</td>
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<tr>
<td>NCI Cooperative Breast Cancer Tissue Resource (CBCTR)</td>
<td>8,289 primary breast cancer tissues</td>
<td>Demographic</td>
<td>Must document IRB approval for use of human subjects; scientific merit will be determined by Research Evaluation Panel. Charge for preparation of section and shipping costs</td>
<td>Standard hospital consent</td>
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<tr>
<td></td>
<td>Formalin-fixed, paraffin-embedded primary breast cancer tissues</td>
<td>Clinical</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Outcome</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCI Cooperative Human Tissue Network (CHTN)</td>
<td>Specimens collected to meet researcher requests; only rare specimens banked to meet future requests</td>
<td>Demographic</td>
<td>Cannot be used to produce commercial products. Must have evidence of IRB approval, and nominal processing fee for each specimen and shipping and handling fees</td>
<td>Standard hospital consent</td>
</tr>
<tr>
<td></td>
<td>Neoplastic and associated normal tissue, blood, and body fluids from routine resections and autopsies</td>
<td>Clinical</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Outcome</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resource</td>
<td>Number of Specimens/ Tissue Type(s)</td>
<td>Other Data</td>
<td>Limitations</td>
<td>Consent</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>NCI Surveillance, Epidemiology, and End Results Program (SEER)</td>
<td>Not applicable; this is a source of breast cancer-related data, not actual specimens. Database contains information on 1.7 million cancers diagnosed between 1973 and 1991; ~12,000 new cases per year</td>
<td>Demographic Clinical Outcome</td>
<td>Must not make primary data available to anyone who has not signed a confidentiality statement</td>
<td>Not applicable—data are unidentified and collected under state regulations</td>
</tr>
<tr>
<td>New York University Medical Center, NYU Medical Center</td>
<td>300 malignant samples 500 benign and precancerous samples (10 slides per case) 500 serum and blood samples Blood or blood products Frozen and paraffin-embedded malignant, benign, and normal tissue</td>
<td>Demographic Clinical</td>
<td>Fees will be levied</td>
<td>Standard hospital consent</td>
</tr>
<tr>
<td>North Central Cancer Treatment Group Research Base at Mayo Clinic</td>
<td>800 specimens from breast cancer patients entered in clinical trials over the past 10 years Paraffin-embedded malignant tissue</td>
<td>Demographic Clinical Outcome</td>
<td>Peer reviewed, scientifically meritorious uses only, and collaboration is required</td>
<td>Specific patient consent form is signed</td>
</tr>
</tbody>
</table>
Table 3.1—continued

<table>
<thead>
<tr>
<th>Resource</th>
<th>Number of Specimens/ Tissue Type(s)</th>
<th>Other Data</th>
<th>Limitations</th>
<th>Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Michigan Breast Cell/Tissue Bank Data and Data Base Dept. of Radiation Oncology University of Michigan Medical School 1331 East Ann St. Ann Arbor, MI 48109 Ph. 313-647-1008 Fax: 313-763-1581</td>
<td>Malignant: 5–10 fresh/month, &gt;100 frozen, several hundred paraffin-embedded Normal: 1–2 fresh/month, ~20 frozen, &gt;100 paraffin-embedded Fresh, frozen, and paraffin-embedded normal and malignant tissue Blood or blood products Cells and cell lines</td>
<td>Demographic Clinical Outcome</td>
<td>None specified</td>
<td>Standard hospital consent</td>
</tr>
<tr>
<td>University of Pennsylvania 1009 BRBI, 422 Currie Blvd. University of Pennsylvania Philadelphia, PA 19104 Ph. 215-898-0247 Fax: 215-662-7617</td>
<td>Frozen: 200 malignant, 30 benign, and 100 normal Paraffin-embedded: &gt;1,000 malignant, &gt;1,000 benign, &gt;1,000 normal &gt;500 lymphoblastoid cell lines Fresh, frozen, and paraffin-embedded normal, benign and malignant tissue Blood or blood products Lymphoblastoid cell lines</td>
<td>Demographic Clinical Outcome</td>
<td>Results reported back for inclusion in University of Pennsylvania database, and collaboration is required</td>
<td>Standard hospital consent for tumor tissue. Specific patient consent for immortalized cells</td>
</tr>
</tbody>
</table>
the 14 banks accrue as many as 200 new cases per year. A specimen from a single case can generate several samples. For example, a specimen from a single case might be split into 3–30 paraffin-embedded blocks, 10 slides, or matched frozen and paraffin-embedded tissue blocks (i.e., one frozen and one paraffin-embedded sample from the same case). Conservatively, a total of approximately 240,000 samples are included in the repositories listed in the database. Samples available to the research and clinical communities include breast tissue, serum, urine, cells, and DNA from patients diagnosed with breast cancer, those at high risk, and unaffected individuals. Information on demographics (age, sex, race, ethnicity, family history of cancer), clinical findings (pathologic diagnosis, stage, initial therapy), and outcome (subsequent breast cancer, vital status) is also available from some institutions.

**NCI Cooperative Breast Cancer Tissue Resource.** The Cooperative Breast Cancer Tissue Resource (CBCTR), supported by the NCI, provides access to more than 8,200 cases of formalin-fixed, paraffin-embedded primary breast cancer tissues. The current specimens represent cases accessioned from 1974 through the present. Each case receives a unique identifier. Since the block is currently part of the pathology archives, a link is kept at the collecting institution. The link provides a one-way flow of information for research purposes but is not part of the research database. Associated pathology and clinical data, such as demographic data, diagnosis, extent of disease, treatment, follow-up, recurrence, survival, and vital status, are available. However, patient identification or information about other family members will not be provided. Cases representing all stages of disease from both sexes, all ages, and all races/ethnicities are available for study. Four collaborating institutions contribute tissue and data from patients treated at their hospitals: Fox Chase Cancer Center (Fox Chase Breast Cancer Tissue Registry), Philadelphia, Pennsylvania; Kaiser Foundation Research Institute, Portland, Oregon; University of Miami, Miami, Florida; and Washington University, St. Louis, Missouri. The resource was designed for large studies to validate promising diagnostic and prognostic markers for breast cancer.

**Cooperative Central Nervous System Consortium Tissue Bank.** The Central Nervous System Consortium (CNSC) is funded by the Cancer Therapy Evaluation Program and the Radiation Research Program of the Division of Cancer Treatment Diagnosis and Centers at the NCI. The CNSC conducts laboratory and clinical phase I and phase II research trials to study central nervous system (CNS) tumor biology and to discover new treatments for adult patients with malignant brain tumors. The Cooperative CNSC Tissue Bank provides the consortium with a mechanism for sharing human brain tumor specimens among investigators conducting research on the biology, clinical behavior, or therapy of CNS tumors.
Biologic Specimen Bank for Early Lung Cancer Markers in Chinese Tin Miners. The Biologic Specimen Bank for Early Lung Cancer Markers in Chinese Tin Miners is maintained by the Division of Cancer Prevention and Control. The specimen bank aims to collect specimens and data that can be used for validation and refinement of potential early markers of lung cancer and to establish a cohort for the study of environmental and genetic risk factors for lung cancer. Early detection and identification and alteration of etiologic factors may reduce the incidence and mortality of lung cancer. More than 7,000 miners in the Yunnan Tin Corporation (40 years of age with 10-plus years of underground and/or smelting experience) have been enrolled in an annual lung cancer screening program for the past 20 years. Since 1992, sputum samples have been collected and stored annually for future projects on early marker identification.

NCI AIDS Malignancy Bank. The NCI AIDS Malignancy Bank (AMB), established by the NCI in 1994, consists of five “banks” located in San Francisco, Washington, D.C., Ohio, New York, and Los Angeles. Each “bank” is actually a multi-institutional consortium. The San Francisco consortium is centered at the University of California at San Francisco, coordinated by the AIDS Immunobiology Research Laboratory at San Francisco General Hospital, and consists of investigators at the major hospitals in San Francisco, New England Deaconess Medical Center in Boston, Memorial Sloan-Kettering Hospital in New York, and the Duke University Oncology Consortium of eight hospitals in the southeastern United States. The Washington, D.C., bank is a consortium operated by the Department of Pathology at George Washington University Medical Center with participation by Children’s National Medical Center, Fairfax Hospital, Howard University Hospital, University of Miami, Veterans Affairs Medical Center, and Washington Hospital Center. The Ohio State AIDS Malignancy Bank is in consortium with the University of Texas Southwestern Medical Center in Dallas, Texas. The participating institutions in New York are the State University of New York Health Science Center at Brooklyn, King’s County Hospital Center, and Woodhull Medical and Mental Health Center. The University of California at Los Angeles AIDS Malignancy Bank consortium includes the University of Southern California.

The AMB is a collection of tissues and biological fluids with an associated clinical database from patients with HIV-related malignancies. Currently, the AMB contains more than 18,000 samples from 2,002 cases of HIV-related malignancies. The AMB contains formalin-fixed paraffin-embedded tissues, fresh frozen tissues, malignant cell suspensions, fine needle aspirates, and cell lines from patients with HIV-related malignancies. The bank also contains serum, plasma, urine, bone marrow, cervical and anal specimens, saliva, semen, and multisite autopsy tissues from patients with HIV-related malignancies, includ-
ing those who have participated in clinical trials. The bank has an associated
database that contains prognostic, staging, outcome, and treatment data on
patients from whom tissues were obtained. Follow-up clinical information will
be requested every six months. The specimens and clinical data are available to
qualified investigators in the United States for research studies, particularly
those that translate basic research findings to clinical applications. Access to
these specimens should encourage and facilitate research in HIV-related
malignancies.

**National Institute of Allergy and Infectious Disease**

The National Institute of Allergy and Infectious Disease (NIAID) provides major
support for scientists conducting research on improving diagnosis, prevention,
and treatment of many infectious, immunologic, and allergic diseases affecting
people worldwide. NIAID is composed of four extramural divisions: the Divi-
sion of AIDS; the Division of Allergy, Immunology, and Transplantation; the
Division of Microbiology and Infectious Disease; and the Division of Extramural
Activities. Major areas of investigation include AIDS, asthma and allergic dis-
eases, enteric diseases, malaria and other tropical diseases, and vaccine devel-
opment.

The NIH AIDS Research and Reference Reagent Program (AIDS Reagent Pro-
gram), established by the NIAID in 1988, is a unique resource. The AIDS
Reagent Program is an AIDS Collaborating Center of the World Health Organi-
zation. It acquires critically needed reagents for AIDS-related research and
provides these reagents free of charge to qualified investigators worldwide. The
program contains samples of cell lines, HIV and related viruses, opportunistic
infectious agents associated with HIV infections, DNA libraries, DNA clones,
antibodies, purified proteins, synthetic peptides, body fluids, and reference
standards.

The AIDS Reagent Program encourages collaborative research aimed at stan-
ardizing reagents and laboratory techniques. Most of the reagents are used by
and donated by scientists from the NIH, academic and nonprofit institutions,
and the private sector. Any commercial use of reagents requires written per-
mission and compensation of reagent donor(s) and notification of the AIDS
Reagent Program. Currently, the program has 500 registered users of its ser-
vices. During the past five years the AIDS Reagent Program has provided more
than 17,000 reagents to AIDS investigators worldwide.

**DAIDS Specimen Repositories.** The Division of the Acquired Immunodefi-
ciency Syndrome (DAIDS) within the NIAID was established in 1986 to
address the national research needs created by the HIV/AIDS epidemic. The
mission of DAIDS is to increase basic knowledge of the pathogenesis, natural
history, and transmission of HIV disease and to promote progress in its detection, treatment, and prevention. DAIDS supports several multi-institutional programs in epidemiologic, therapeutic, and vaccine/prevention research. Collectively, these studies have amassed a large amount of clinical data and biological specimens. The specific fluids and tissues collected vary according to study group but include peripheral blood mononuclear cells, serum, plasma, semen, saliva, vaginal washings, urine, placenta, and autopsy samples. The clinical trial studies are described below and the longitudinal studies are described in Chapter Four.

HIV Network for Prevention Trials. The HIVNET efficacy trials network is a network of clinical programs established in 1994. The mission of the HIVNET network is to conduct HIV vaccine efficacy trials and prevention trials in higher-risk populations. One of the objectives of HIVNET is to determine the incidence of HIV in higher-risk populations who may serve as good study groups for future trials.

HIVNET consists of five contracts supported by DAIDS:

1. The domestic HIV/AIDS vaccine efficacy trials master contract, which evaluates the efficacy of candidate vaccines in U.S. population.
2. The international HIV/AIDS vaccine efficacy trials master contract, which supports HIV vaccine trials in international populations.
3. The statistical and data coordinating center contract, which provides statistical and data management service for both U.S. and international trials.
4. The laboratory contract for HIV/AIDS vaccine efficacy trials, which provides specialized laboratory testing.
5. The specimen repository, which collects and archives specimens from U.S. and international trials.

The HIVNET specimen repository includes serum, plasma, peripheral mononuclear cells, genital tract secretions, and saliva. HIV strains isolated from these specimens are also available. Specimens collected from individual clinical trials are routinely sent to a central laboratory for testing. The availability of specimens depends on the type requested. Peripheral mononuclear cells are potentially available for use by collaborating investigators. Fresh specimens, such as blood or mucosal specimens, are potentially available, provided that the research offers a unique or immunological/virological assessment.

Pediatric AIDS Clinical Trials Group. The Pediatric AIDS Clinical Trials Group (PACTG) is a multicenter national clinical trials network. It supports the development and implementation of phase I, II, and III studies designed to test and
optimize therapies to prevent and treat HIV infection in infants, children, and adolescents; conducts studies throughout the United States; and collaborates closely with the adult clinical trials groups, the FDA, pharmaceutical and biotechnology companies, and community constituencies to promote HIV/AIDS research.

Specimens collected from the PACTG trials include serum, plasma, peripheral mononuclear cells, culture supernatants, lymph node biopsies, tissues, urine, and other body fluids. Specimens are normally collected several times during a clinical trial. Specimens are usually sent to a specific laboratory for processing, testing, and storing. Stored specimens fall into one of two categories: protocol-specified batch testing and unspecified future studies. Specimens collected for protocol-specified batch testing are stored pending collection of all protocol specimens, at which time they undergo a protocol-specified test. Batch testing is more economical and feasible compared to "real-time" testing. Batch testing specimens are rarely available for other purposes. Specimens collected for unspecified future studies are additional specimens drawn and stored for future research.

Adult AIDS Clinical Trials Group. The Adult AIDS Clinical Trials Group (ACTG) is a consortium of 30 clinical research institutions. It conducts all phases of clinical trials designed to assess the safety and efficacy of new and improved therapies for HIV/AIDS and its associated illnesses. To date, ACTG has implemented more than 280 clinical investigations, enrolling more than 35,000 adult volunteers who are at all stages of the disease.

The goals of the ACTG are to evaluate innovative therapeutic strategies and interventions to control HIV infection; to facilitate rapid translation of basic research into clinical research and practice; and to provide a flexible resource for multidisciplinary, multicenter, clinical trials.

ACTG specimens are collected and stored several times during a clinical trial. Specimens are usually forwarded to a specific laboratory for testing. Specimens collected include serum, plasma, peripheral blood mononuclear cells, culture supernatants, lymph node biopsies, tissues, urine, and other body fluids. Specimens fall into two categories: protocol-specified batch testing and unspecified future studies, as described above for PACTG specimens.

AIDS Vaccine Evaluation Group. The AIDS Vaccine Evaluation Group (AVEG) evaluates candidate AIDS vaccines in phase I and II clinical trials for safety and immunogenicity. AVEG consists of six AIDS Vaccine Evaluation Units (AVEUs), a Statistical Coordinating Center, and a Central Immunology Laboratory. Specimens collected from AVEG studies include serum, plasma, peripheral mononuclear cells, genital tract secretions, saliva, and tears. Specimens are routinely sent to two laboratories for testing. The availability of specimens
depends on the type requested. Serum specimens are usually available from all volunteers and trials. Peripheral blood mononuclear cells are potentially available for use by collaborating investigators.

Division of AIDS Treatment Research Initiative. The Division of AIDS Treatment Research Initiative (DATRI) was established to conduct phase I and II studies for HIV and associated diseases. DATRI performs small focused studies and substudies of protocols conducted by other extramural programs. DATRI clinical specimens vary according to the study under which they were collected. Many studies intentionally set aside specimens for future investigations. Samples include serum, plasma, cells and cultured cells, and supernatant from peripheral blood mononuclear cells and plasma HIV cultures.

**National Heart, Lung, and Blood Institute**

The Transfusion Medicine Branch of the National Heart, Lung, and Blood Institute (NHLBI) has a Blood Specimen Repository available for use by researchers for studies related to transfusion-transmitted diseases, other blood disorders, or diseases of the cardiovascular system. The repository is operated by McKesson BioServices Corp. in Maryland through an extramural contract with NHLBI. The repository, established in 1974, contains approximately 1.5 million well-characterized specimens of serum, plasma, and cells from NHLBI-sponsored studies. Since 1991, the Blood Specimen Repository has been storing an average of approximately 300,000 samples per year (see Figure 3.1) (National Heart, Lung, and Blood Institute, 1996). In 1995, the demand for specimens greatly increased. From 1991 to 1993, approximately 1,000 specimens per year were distributed to researchers, and in 1994 approximately 4,000 specimens were distributed, while in 1995, approximately 20,000 specimens were distributed (see Figure 3.2) (National Heart, Lung, and Blood Institute, 1996).

**National Institute of Mental Health**

The National Institute of Mental Health was originally established in 1949, left NIH and became a separate bureau with the Public Health Service in 1967, and rejoined NIH in 1992, where it is currently located. NIMH has established four major research priorities: (1) fundamental research on brain, behavior, and genetics, (2) rapid turnover of basic discoveries into research on mental disorders, (3) research that directly impacts the "real world" settings, and (4) research on child development and childhood mental disorders.

NIMH has awarded funds to three universities, the University of Alabama at Birmingham, Harvard Medical School, and Johns Hopkins University, to estab-
lish a national resource to study both early and late-onset Alzheimer’s disease. A collection of samples from 400 pairs of relatives, primarily sibling pairs, are available for finding susceptibility genes linked to Alzheimer’s disease. This resource provides a large enough sample of families, obtained through a common protocol and diagnosed by a consensus procedure, to be useful for identifying clinical and genetic subtypes of Alzheimer’s disease.

NIMH maintains a brain collection of more than 1,200 frozen or formalin-fixed brain specimens. Brain specimens are collected from cases of schizophrenia, bipolar disorder, depression, alcoholism, drug addiction, suicides, and other cases, including AIDS, Alzheimer’s, and Parkinson’s disease.

**National NeuroAIDS Tissue Consortium.** The National NeuroAIDS Tissue Consortium (NNTC) was established in 1998 and is jointly supported by three institutes: the National Institute on Drug Abuse (NIDA), NIMH, and the National Institute of Neurological Disorders and Stroke (NINDS). The goal of the NNTC is to provide high-quality, well-characterized tissue samples to increase research efforts on HIV infection in the human brain. Four centers currently participate in the NNTC and are described below. Tissue samples will be collected from a diverse population of HIV-infected individuals and will be
available for multiple studies. Detailed data at autopsy will be collected with all specimens, including drug use history, psychological evaluations, and clinical tests and treatment.

Mount Sinai Medical Center, New York. The Manhattan HIV Brain Bank located at the Mount Sinai Medical Center (MSSM) collects patient tissues from MSSM, Beth Israel Medical Center, and St. Luke’s-Roosevelt Hospital Center in New York City. The objectives of the Manhattan HIV Brain Bank will be to identify and follow a cohort of advanced HIV patients, establish a multi-institutional clinical database, and obtain CNS, peripheral nervous system (PNS), and systemic tissues from autopsies of HIV patients; dissect, store, catalog, and distribute tissue specimens to approved investigators; and utilize pathology specimens and clinical databases in correlational studies to elucidate the pathogenesis and natural history of HIV-related neurologic diseases.

National Neurological AIDS Bank, California. The National Neurological AIDS Bank (NNAB) at UCLA will collect and store pre- and postmortem clinical data and neural tissues from autopsies for future distribution to investigators. The NNAB will also set up an electronic database and an Internet-based applications process so investigators may gain access to the bank’s resources. There
is no cost for the use of tissue specimens for approved investigators. The bank currently has three brains/spinal cords and 25 CSF samples.

California NeuroAIDS Tissue Network. The objective of the California NeuroAIDS Tissue Network (CNTN) is to establish a tissue bank of CNS autopsy specimens from HIV-infected individuals who have been well-characterized neuropsychologically and neuromedically within six months of death. The CNTN represents a collaborative effort between the NIMH-funded HIV Neurobehavioral Research Center in San Diego and four California HIV network sites: University of Southern California, Cedars-Sinai/UCLA, University of California, Irvine, and the University of California, San Diego. Collectively, these sites follow more than 4,300 patients. The CNTN seeks to identify and characterize HIV-infected persons neuromedically and neurobehaviorally following a standardized protocol, to characterize neuropathologic changes associated with HIV, to establish a tissue registry, repository, and database that can support current and future studies integrating ante- and postmortem data, and to obtain control tissue specimens. By 2003, the CNTN proposes to collect 209 sets of brain and other tissues from HIV-infected individuals with detailed ante-mortem clinical data. Seventy-five control brains from immunosuppressed patients dying after transplantation or from trauma will also be collected and stored.

Texas Repository for AIDS Neuropathogenesis Research. The Texas Repository for AIDS Neuropathogenesis Research will be based at the University of Texas Medical Branch in Galveston. The goal of the research is to establish a Texas regional brain repository to elucidate the mechanisms underlying neuropsychological problems in AIDS patients. Frozen human brain specimens will be collected from community-based clinics in Galveston, Dallas, and Houston. Clinics in these three cities are collectively following more than 10,000 HIV-infected subjects. The brain repository will build on a prior AIDS brain repository that has almost 500 brain specimens already stored. A secure database will be established containing neuropsychiatric data, substance abuse histories, and other clinical and laboratory information.

National Institute on Aging

The National Institute on Aging (NIA) supports research on the general biology of aging and age-associated diseases and disabilities. The specific areas of research on the general biology of aging include the characterization of normal aging, cell cycle regulation and programmed cell death, stress response, and DNA damage and repair. Age-associated disease and disabilities research include the study of Alzheimer’s disease, cancer, cardiovascular disease and hypertension, diabetes, and osteoporosis, osteoarthritis, and frailty. The NIA
also supports the development of different intervention strategies to treat many of these age-associated diseases, such as pharmacotherapy, gene therapy, and behavioral or lifestyle changes. To provide appropriate tissue for neuropathological studies in Alzheimer's disease, the NIA maintains a Brain Bank.

As part of the NIA Research Resources Branch, the Central Laboratory Services Section (CLSS) collects, analyzes, and prepares for long-term storage blood and tissue samples. Other services provided by CLSS include phlebotomy, tissue handling and preservation, DNA extraction, cell transformations to create renewable cell lines, and inventory management of stored samples.

**Alzheimer's Disease Research Centers.** NIA funds 27 national Alzheimer's Disease Research Centers (ADRC), some of which maintain brain tissue banks described below. The ADRCs are designed to serve as shared resources to facilitate research in Alzheimer's disease. There are 14 ADRCs and 13 Alzheimer's Disease Core Centers (ADCCs). These centers provide core resources that enhance ongoing research by bringing together biomedical, behavioral, and clinical science investigators in a single center. Many of the centers provide well-characterized patients, patient and family information, and tissue and other biological samples from persons with Alzheimer's disease and from age-matched control subjects for research projects.

**Kathleen Price Bryan Brain Bank.** The Kathleen Price Bryan Brain Bank (Brain Bank), sponsored by NIA since 1985, is within the Alzheimer's Disease Research Center at Duke University. The major function of the Brain Bank is to retrieve and evaluate tissue for the presence of Alzheimer's neuropathologic changes and to select and retrieve human brain tissue, which will be used for further scientific investigations. The Brain Bank currently stores about 600 brains from Alzheimer's patients or related causes of dementia and 150 brains from patients with other neurological disorders, such as amyotrophic lateral sclerosis (ALS), Huntington's disease, and muscular dystrophy. The Brain Bank also has 150 brains donated from normal individuals. Fixed or frozen hemispheres, paraffin blocks, and histological slides are distributed for research, and clinical information is available.

**The Taub Center for Alzheimer's Disease Research Tissue Bank.** The Taub Center for Alzheimer's Disease Research Tissue Bank at Columbia-Presbyterian Medical Center is operated by the Neuropathology Core and funded by the NIA. The Tissue Bank contains flash frozen and fixed brain tissue with neurodegenerative disorders as well as normal specimens. The bank has about 300 brains stored, including those with Alzheimer's disease, Parkinson's disease, diffuse Lewy body diseases, progressive supranuclear palsy, cortico-basal ganglionic degeneration, ALS, and Creutzfeldt-Jakob disease (CJD). The bank also has peripheral blood cells and DNA stored from patients with these disorders.
Washington University Alzheimer Disease Research Center. The Washington University Alzheimer Disease Research Center (funded by NIA) has a tissue bank that is operated by the Neuropathology Core. The tissue bank collects, stores and distributes human brains, cerebrospinal fluid (CSF), and blood samples to investigators. CSF samples, heart blood samples, brain slices, and dissected anatomical regions are obtained from autopsies and stored at –80°C.

Boston University's Alzheimer's Disease Core Center. Boston University's Alzheimer's Disease Core Center operates a Brain Tissue Resource Center that supplies tissue for ongoing research projects whose focus is on any aspect of neurodegenerative diseases, especially Alzheimer's disease. The center is supported by NIA. Flash frozen and PLP immersion-fixed tissue is available from all areas of the cerebral cortex and brainstem. Brain endothelium cell cultures created from rapid postmortem samples are also available.

Michigan's Alzheimer's Disease Research Center Brain Bank. The University of Michigan Alzheimer's Disease Research Center Brain Bank was established in 1989 and its goal is to further research on Alzheimer’s disease and related disorders. It is supported by NIA. The Neuropathology Core is responsible for the collection of postmortem material, part of which is frozen and part of which is used for diagnosis. Currently, more than 300 brains are stored in the Brain Bank and are available to qualified investigators nationwide.

Alzheimer's Disease Research Center at Baylor College of Medicine. The Alzheimer's Disease Research Center (ADRC) at Baylor College of Medicine was established to conduct clinical and basic science research and to diagnose and treat patients with Alzheimer's disease and related disorders. The ADRC is funded by NIA. The goal of the ADRC is to help patients, family members, and professionals cope with Alzheimer’s disease through research, patient care, and education. The ADRC’s research efforts target progressive deterioration of nerve cells in Alzheimer’s, exploration of the potential involvement of the immune system in Alzheimer’s, and mechanisms by which the beta-amyloid protein contributes to brain cell death. The ADRC maintains a serum bank of stored blood samples donated by patients who have Alzheimer's disease as well as by spouses and normal control subjects. A Brain Donation Program for Alzheimer's Disease has also been established for the collection of brain specimens for research.

The University of Kansas Medical Center Alzheimer's Disease Center. The University of Kansas Medical Center Alzheimer's Disease Center (ADC) mission is to broaden research and understanding of Alzheimer’s disease and other memory disorders. The main focus of the University of Kansas Medical Center’s ADC is on Alzheimer’s disease and Parkinson’s disease, and it is supported by NIA. The ADC has four main areas of focus: a clinical program, a brain bank,
an educational program, and a research program. The clinical program has
developed and maintains a large database registry of Alzheimer’s disease,
Parkinson’s disease, and normal control subjects for research studies. The
neuropathology core has established a brain bank to collect brain tissue from
normal control subjects and persons with Alzheimer’s and Parkinson’s disease
for research studies. The brain bank serves as a repository of nervous system
tissue that allows for the correlation of clinical and neuropathological findings.
The education program provides information about Alzheimer’s and Parkin-
son’s disease to professionals, patients, families, and the general public. A
major goal of the ADC research program is the development of effective phar-
macotherapy for Alzheimer’s and Parkinson’s disease.

University of California, Los Angeles (UCLA), Alzheimer’s Disease Center. The
UCLA Alzheimer’s Disease Center (ADC) consists of five cores: administrative,
clinical (including six clinical sites), imaging, pathology, and educa-
tion/information transfer. The center is supported by NIA. The UCLA ADC has
also established a brain bank. More than 800 patients and controls have been
evaluated by the Clinical Core or are linked into the Clinical Core database, 639
structural and functional images have been obtained through the Imaging Core,
and more than 100 brains have been examined in the Pathology Core.

Rush Alzheimer’s Disease Center. The Alzheimer’s Disease Center at Rush-
Presbyterian–St. Luke’s Medical Center focuses on four main areas of research:
identifying risk factors for Alzheimer’s disease, understanding the presentation
and course of Alzheimer’s disease, investigating underlying neurobiologic
causes of Alzheimer’s disease, and developing treatments for Alzheimer’s dis-
ease. The Rush Center is supported by NIA. The Rush Alzheimer’s Disease
Center Brain Bank has two objectives: to provide neuropathological diagnosis
of Alzheimer’s disease by postmortem evaluation and to facilitate research of
the etiology of Alzheimer’s disease. More than 1,000 brain autopsies have been
conducted by the brain bank since 1987. Cerebrospinal fluid samples, serum,
DNA, and white blood cells are also collected by the brain bank. All tissue
specimens are available to outside investigators throughout the United States.

Indiana Alzheimer Disease Center. The Indiana Alzheimer Disease Center
(ADC) comprises six cores and is supported by NIA. The Indiana ADC has
focused its studies on AD patients within the African-American community, on
clinical and neuropathologic studies of familial forms of AD and other heredi-
tary degenerative adult onset dementias, on trials for new drug therapies for
AD, and on educational activities.

The Indiana ADC maintains a National Cell Repository that has collected
genetic material from more than 2,200 individuals from 440 families with histo-
ries of AD. Both lymphocytes and DNA are available from most participants.
Family pedigrees are available for participating AD families. Tissues from various types of AD families are stored in the repository, including families with autopsy-confirmed cases of AD, families with multiple affected siblings, two-generation affected families, and early and late-onset AD families. Cell lines and DNA are available to approved investigators at no cost.

Northwestern University's Alzheimer's Disease Core Center. The goal of the Alzheimer's Disease Core Center (ADCC) at Northwestern University is to establish a clinical registry of well-characterized patients with Alzheimer's disease and other dementias and healthy elderly subjects. The center is supported by NIA. The ADCC will focus on basic mechanisms of the disease, clinical symptoms, treatments, and caregiving aspects. A brain endowment program has been established to collect normal and diseased brain tissue for research.

University of Rochester Alzheimer's Disease Center. The Alzheimer's Disease Center (ADC) at the University of Rochester consists of four cores: administrative, clinical (including two satellite diagnostic centers), neuropathology (brain bank), and education and information transfer. The center is supported by NIA. The ADC is designed to serve a broad range of studies, particularly in the area of clinical studies and trials of therapeutic interventions. Neuropathologic examination of brains has been expanded to distinguish Lewy bodies and plaque subtypes.

Emory University's Alzheimer's Disease Center. The Alzheimer's Disease Center (ADC) was established in 1991 at Emory University and is supported by NIA. The ADC consists of five cores: administrative and data management, clinical, neuropathology, molecular biology, and education and transfer. The Clinical Core examines a high proportion of African-American subjects and provides research, clinical, and educational opportunities to the African-American community. The Neuropathology Core supplies brain and other tissues from its brain bank of cases of well-characterized dementia and control cases to investigators.

University of Washington Alzheimer's Disease Research Center. The Alzheimer's Disease Research Center (ADRC) at the University of Washington focuses on understanding the basic mechanisms underlying the development of adult dementing disorders, specifically on susceptibility factors underlying Alzheimer's disease. The ADRC consists of five major research projects and seven supporting core units, including a cell tissue and fluid bank. The center is supported by NIA. A Clinical Registry Core has been established at a satellite site devoted to underserved populations in the region.

The ADRC Core, Cell, Tissue and Fluid Bank Cell Culture and Cytogenetics is one of the oldest repositories for familial AD pedigrees. The core maintains AD and control lymphoblastoid cell lines, fibroblasts, lymphocytes, and plasma.
Tissue specimens are available to ADRC investigators and approved investigators at the University of Washington and other institutions.

University of California, Davis, Alzheimer’s Disease Center. The objectives of the Alzheimer’s Disease Center (ADC) at the University of California, Davis, are to educate health professionals and the public about Alzheimer’s disease and related dementias, to conduct research in clinical and community populations into the causes and potential treatments for dementia, and to advocate changes in health policy and practice that will enhance the recognition, treatment, and management of dementia. The center is supported by NIA. Research studies are focused on the behavioral and mental changes of dementing disorders, genetics of Alzheimer’s disease, and strategies to prevent mental loss.

The Neuropathology Core at the UC Davis ADC has three major goals: to obtain brain autopsies on ADC patients and controls, to accurately diagnose brain lesions encountered at autopsy, and to preserve and distribute autopsy brain tissues to research collaborators. Brains are removed within 24 hours of death and half the brain is formalin-fixed and the other half is coronally sectioned and frozen. Twenty-five blocks of the formalin-fixed tissue are obtained for paraffin embedding from multiple neocortical, limbic, diencephalic, basal ganglia, and brainstem regions. A standard gross and microscopic neuropathology examination is performed on each new brain specimen. An inventory of all tissue specimens, the mode of processing and storage, pathological diagnosis, and autolysis interval are maintained in a neuropathology laboratory database.

Case Western Reserve Alzheimer Center. The Alzheimer Center at Case Western Reserve University consists of seven departments and is supported by NIA. Research projects include studies on apolipoprotein E, brain electrical studies of attention in Alzheimer’s disease, clinical studies to design effective treatments for Alzheimer’s disease, life history studies, changes in emotional responsivity studies, and visual spatial studies. The Neuropathology Core provides adequately preserved and well-characterized human brain tissue samples for biochemical and morphometric studies. The core has examined and stored 183 brains, 123 of which were diagnosed with pure Alzheimer’s disease or in combination with other processes. The core has also examined and stored 554 brains, 397 of which with prion diseases.

National Institute on Deafness and Other Communication Disorders

The National Institute on Deafness and Other Communication Disorders (NIDCD) was established in 1988, splitting off from the National Institute of Neurological and Communicative Disorders and Stroke. NIDCD conducts and supports biomedical and behavioral research and research training in the normal and disordered processes of hearing, balance, smell, taste, voice, speech,
and language. NIDCD also conducts and supports research and research training related to disease prevention and health promotion and addresses special biomedical and behavioral problems associated with people who have communication impairments or disorders.

NIDCD established the National Temporal Bone, Hearing and Balance Pathology Resource Registry in 1992. The registry was originally founded as the National Temporal Bone Banks Program (NTBB) in 1960 by the Deafness Research Foundation (DRF) to encourage individuals with ear disorders to donate their temporal bones at death for scientific research. The NTBB, however, became virtually inactive in the 1980s due to rising costs, dwindling funds, and a decrease of investigations in the area of temporal bone research. In 1988, a workshop cosponsored by NIDCD and DRF reaffirmed the importance of temporal bone research and NIDCD established the new registry in 1992, which would assume the responsibilities of the NTBB.

The contract of the registry was awarded to the Massachusetts Eye and Ear Infirmary and DRF. The services and functions of the registry include establishing a computerized database of human temporal bone collections, dissemination of information about the temporal bone collections, the implementation of professional educational activities in the study of human temporal bones and auditory brain stems and the development and implementation of a national acquisition network to increase the yield of human temporal bone and brain tissue from donors.

The registry's temporal bone database contains information from more than 6,300 cases (12,000 specimens) from 18 U.S. temporal bone collections. It provides basic information on the specimens and catalogues all known processed human temporal bones and related brain tissue specimens in the United States and the data associated with these specimens, such as clinical and histopathological diagnoses.

There are 26 temporal bone laboratories in the United States that possess temporal bone collections, though only 15 actively collect, process, and study temporal bone specimens. The active laboratories are listed below and their collections are described in detail in Appendix C:

- Baylor College of Medicine, Houston, Texas
- Bowman-Gray School of Medicine, Winston-Salem, North Carolina
- Eye and Ear Institute of Pittsburgh, Pittsburgh, Pennsylvania
- Goodhill Ear Center (UCLA), Los Angeles, California
- Johns Hopkins University, Baltimore, Maryland
National Institute of Environmental Health Sciences

The mission of the National Institute of Environmental Health Sciences (NIEHS) is to reduce the burden of human illness and dysfunction from environmental causes by understanding each of these elements and their interactions. NIEHS achieves its mission through multidisciplinary biomedical research programs and prevention and intervention efforts. One way NIEHS achieves its mission by funding environmental health centers throughout the United States. The mission of these centers is multifold and includes strengthening the research focus and accomplishments of the host institution in environmental health science; supporting core facilities, which provide access to technology that enhances the research productivity of the center; and stimulating multidisciplinary research. Institutions that have NIEHS-sponsored centers include Harvard, Oregon State, Vanderbilt, University of California at Berkeley, and MIT. Several of the centers collect and store human samples for use by the center’s investigators. Four NIEHS Centers that collect and store human samples for research are described below.

Kresge Center for Environmental Health Studies. The Kresge Center for Environmental Health Studies at Harvard University was established in 1958 to promote interactions among biological scientists, physical scientists, and engineers working on environmental problems concerning human health. Six scientific cores and four facility cores provide equipment and technicians for services for center investigators. One of the facility cores is the Human Cell Bank, Genotyping, and Tissue Culture Facility. The mission of the Human Cell Bank, Genotyping, and Tissue Culture Facility is to provide resources and services for Center investigators, including the acquisition, storage, and characterization of human cells and tissues. The primary focus of the cell bank has been on diploid fibroblasts isolated from three different populations: individuals with defined
syndromes, exhibiting an enhanced predisposition to cancer; families presenting with either multiple cancers, early onset cancers, or rarer types of cancers; and cells from individuals showing unusual clinical responses to radiation or chemotherapy. Cell lines banked in the facility include human diploid fibroblast strains, including normal cells and cells from individuals with cancer susceptibility syndromes and DNA repair defects; 16 human tumor cell lines; six engineered cell lines expressing transfected genes; strains from five hereditary retinoblastoma families; 10 colorectal cancer cell lines; six glioblastoma cell lines; and 15 head and neck cancer cell lines.

Environmental Health Sciences Center. The Environmental Health Sciences Center at the University of Southern California (USC) was established in 1996. The center is a consortium of almost 50 investigators from USC, UCLA, and Caltech. The center seeks to create an interdisciplinary approach to the study and advancement of research in environmental health. The center consists of an administrative core, five research cores, and four service cores. One of the four service cores is the Biological Sampling Processing Facility Core. The mission of the Biological Sampling Processing Facility Core is to provide a single center to assist researchers from about 150 clinical facilities. Services provided by the facility include development of samples handling protocols, receipt of newly collected samples, and the monitoring of the quality of incoming samples. Biological samples stored at the facility include blood, tissue, urine, other body fluids, smears, and scrapings (e.g., buccal cells). Several different research studies have contributed tissue samples to the Facility Core. The Genotyping and Risk of Asthma study has collected more than 1,000 buccal scrapings from school children from various communities. The Gene-Diet/Tobacco Interactions in Breast Cancer in Asians has collected 500 out of an anticipated 800 frozen buffy coats (white blood cells) for study of variant alleles in detoxifying enzymes. The Determinants of Childhood Susceptibility to Air Pollution study has collected 1,000 buccal smears from school children for genotype analysis.

Center for Ecogenetics and Environmental Health. The Center for Ecogenetics and Environmental Health at the University of Washington includes seven major research cores, six facility cores, and an administration core. The objectives of the center are to foster interdisciplinary collaborations among researchers working in the fields of toxicology, molecular biology, genetics, and environmental epidemiology and to stimulate the transition of basic mechanistic research on molecular biomarkers of disease susceptibility to studies in the human population. The Human Studies Facilities Core's objectives are to facilitate collaborations between investigators with expertise in human population-based studies and novel or complicated methodologies. The core has a −80°C freezer and access to a fully equipped lab for preserving tissue samples. The Human Studies Resources Facility Core has worked on establishing and
promoting the use of the Registry for the Study of Genetic and Environmental Risk Factors. This registry consists of demographic data, medical history information, and DNA from blood or buccal cells. Registrants are study subjects participating in projects conducted by Center investigators.

Institute of Toxicology and Environmental Health. The Institute of Toxicology and Environmental Health at the University of California, Davis, is composed of five research cores and seven facility cores. The focus of the center’s research is on agricultural chemicals and related xenobiotics. The Field Studies Facility Core provides services and consulting expertise related to agricultural epidemiologic investigations, field exposure assessments, and biostatistics. Human tissues and fluids are collected from the center’s epidemiologic studies of subjects in agriculture. The Field Studies Service Core provides resources for the application of laboratory methods on agricultural workers and the collection of specimens for laboratory analysis. Specimens are analyzed for exposure and toxicological effects of agrochemicals. Specimens from workers include blood and urine samples.

National Institute of Diabetes and Digestive and Kidney Diseases

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) split from the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases in 1988. NIDDK’s Division of Intramural Research conducts studies on diabetes, inborn errors of metabolism, endocrine disorders, mineral metabolism, digestive diseases, nutrition, urology and kidney diseases, and hematology. Extramural research at NIDDK is separated into five divisions: Diabetes, Endocrinology and Metabolic Diseases; Digestive Diseases and Nutrition; Kidney, Urologic, and Hematologic Diseases; Extramural Activities; and Nutrition Research Coordination.

The Liver Tissue Procurement and Distribution System (LTPADS) is sponsored by NIDDK to provide human liver tissues from three regional centers in the United States for NIH investigators. These regional centers have active liver transplant programs to provide portions of resected pathologic liver. Frozen or fresh tissue is available for common forms of childhood and adult cirrhosis, fulminant liver failure, chronic rejection, and inborn errors of metabolism. Normal liver specimens may be requested, but the supply is much more limited and it usually takes much longer to fulfill requests.
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY AND THE U.S. ENVIRONMENTAL PROTECTION AGENCY

Two other agencies within the federal government have tissue banks: the National Institute of Standards and Technology (NIST) and the U.S. Environmental Protection Agency (EPA). These tissue banks were established primarily to determine human exposure to pollutants and pesticides and to follow long-term trends.

National Biomonitoring Specimen Bank

The National Biomonitoring Specimen Bank (NBSB) at the NIST was established in 1979 in conjunction with the EPA to determine the feasibility of long-term storage of environmental samples (Wise and Koster, 1995). In addition to the specimens contained in the human liver specimen bank supported by the EPA, the NBSB also archives specimens from three other projects supported by various government agencies, such as marine specimens and total human diet specimens. The EPA human liver specimen bank collected and archived 661 human liver specimens from 1980 through 1994 from individuals in Seattle, Baltimore, and Minneapolis. The goals of the EPA human liver project were to develop procedures for the collection, processing, and long-term storage of biologic specimens; to improve analytical methods for the determination of inorganic and organic contaminants in human tissue; to evaluate the long-term storage stability of biologic specimens; and to provide an archive of well-documented specimens of human liver for retrospective studies to determine long-term pollution trends and document the appearance of new pollutants (Wise and Koster, 1995). This archive of human liver specimens is an invaluable resource for the investigation of environmental pollution trends in human population.

National Human Monitoring Program

The National Human Monitoring Program (NHMP) was established in 1967 and continued through 1993. The NHMP was designed to study changes in pesticide residues in the population of the United States. Originally part of the U.S. Public Health Service, the NHMP was transferred to the EPA in 1970. One of the primary activities of the NHMP was the National Human Adipose Tissue Survey (NHATS), a program developed to measure residues of chemicals in human adipose tissue. Through 1991, the NHATS had collected approximately 12,000 samples of adipose tissue from autopsied cadavers and surgical patients. The NHATS documented widespread exposure to pesticides in the United States and showed that reduced use of polychlorinated biphenyls (PCBs), DDT, and
dieldrin resulted in lower tissue concentrations of these compounds (Bailar, 1995).

RESEARCH UNIVERSITIES AND ACADEMIC MEDICAL CENTERS

Research universities and academic medical centers maintain formal tissue banks for distribution throughout the research community as well as core facilities to support their own research. Examples of both types of tissue collections are described below.

AIDS Specimen Bank at the University of California at San Francisco

The University of California at San Francisco (UCSF) AIDS Specimen Bank has been in existence since 1982 and has banked more than 76,000 samples and distributed more than 82,000 specimens to researchers worldwide. Specimens include serum, tissue, saliva, cells, and cerebrospinal fluid from HIV infected individuals. Specimen data are archived in a computerized database. The bank provides investigators with specimens for basic, epidemiological, and clinical research.

The Brain Bank

The Brain Bank is one of two core facilities at the Alzheimer's Research Center (ARC) at the Medical College of Georgia. The ARC was established in 1989 with start-up funds provided by the Calloway Foundation of Georgia. The goal of the ARC is to continue to help investigators, technical scientists, and graduate trainees to better understand the causes of Alzheimer's disease and to develop new treatment strategies through research. Ongoing research at the ARC primarily involves basic science aspects of Alzheimer's disease. The Brain Bank currently stores 24 brains, mostly from Alzheimer's disease patients.

Brain Bank Core

The Brain Bank Core at the Mount Sinai School of Medicine of the City University of New York will obtain, characterize, describe, dissect, preserve, and distribute brain tissues from normal controls and Alzheimer's disease subjects to different investigators involved in Alzheimer's disease research. The Brain Bank Core is supported by the NIA. The right half of the brain will be preserved in paraformaldehyde for neuropathological and neuroanatomical studies, and the left half will be dissected into coronal slabs and snap-frozen. The Brain Bank Core will serve five projects in the Department of Psychiatry: Neuropathology, Neuropsychology, Family History, Acute Phase Reactants, and Neurochemistry.
projects. Tissues from the Brain Bank Core will also be available for projects funded by other grants.

**Brain and Tissue Bank for Developmental Disorders at the University of Maryland, Baltimore, the University of Miami, and Children's Hospital of Orange County**

The Brain and Tissue Banks for Developmental Disorders at the University of Maryland, Baltimore, the University of Miami, and the Children's Hospital of Orange County, supported by the National Institute of Child Health and Human Development (NICHD), were established to advance the research of developmental and childhood disorders. The tissue banks systematically collect, store, and distribute brain and other tissues for research dedicated to improving understanding, care, and treatment of individuals with developmental disorders. The Brain and Tissue Banks store tissues, either frozen or formalin-fixed, of almost all tissue types from both normal and diseased donors. A smaller Ataxia Telangiectasia Patient Brain Tissue Bank exists as a subset of the Brain and Tissue Banks.

**Breast Cancer Database and Biologic Resource Bank**

The University of Washington's Breast Cancer Database and Biologic Resource Bank was established to facilitate the development of a national resource of biologic materials linked to a substantial database. A comprehensive database, tumor tissue bank, and serum/lymphocyte bank was developed from breast cancer patients at the University of Washington Medical Center. Other biologic specimens may be collected from these patients, such as bone marrow, skin biopsies, lymph node biopsies, metastatic tumor samples, and benign breast tissue.

**Breast Tissue Repository**

The Breast Tissue Repository (BTR), at the Hamon Center for Therapeutic Oncology Research in the University of Texas Southwestern's Medical Center, was initiated in the early 1990s and is supported by a U.S. Army grant and funds from the Susan Komen Foundation. The goal of BTR is to create a comprehensive breast tissue/cell repository as a research source for investigators. The repository contains cell lines generated from breast tumor tissues and cryopreserved epithelial and stromal cell lines. Detailed information on the cellular, biochemical, and molecular analysis of these cell lines along with a comprehensive record of clinical and pathological data are available for the breast tumor cell lines.
Breast Tumor Bank

The Breast Tumor Bank at the University of California, Los Angeles, was established for use in basic molecular, biochemical, and epidemiologic studies of human breast cancer. The tumor bank collects and archives malignant breast tissue, premalignant breast tissue, and bone marrow and peripheral blood samples from breast cancer patients. Relevant clinical, demographic, epidemiological, and pathologic data is collected along with each specimen. If sufficient tissue is available, it is processed for DNA, RNA, tissue powder, and tissue fragments (both frozen and paraffin-embedded). Tissue specimens are available for approved studies.

Cancer Center Tissue Core at University of California, San Francisco (UCSF)

The UCSF Cancer Center is an interdisciplinary group that combines basic scientific study, clinical research, epidemiology/cancer control, and patient care services into one program. The Cancer Center’s mission is the discovery and evolution of new ideas and information about cancer. The UCSF Cancer Center Tissue Core is a centralized facility that identifies and stores patient tissue. The goal of the Tissue Core is to provide specimens to approved investigators. The Tissue Core collects fresh, frozen, and formalin-fixed, paraffin-embedded tissue from a variety of organs, including breast, prostate, and bladder.

Cancer Tissue Bank

The VA Medical Center in Minneapolis, Minnesota, maintains a bank of frozen cancer tissue and paired normal tissue sections for future research in oncogenesis and outcome studies. The tissue bank is supported by the Department of Veterans Affairs. Samples will be collected from neoplasms along with noncancerous samples adjacent to tumors. Clinical information, such as type of treatment, exposure to cancer risk factors, and outcome data, can be obtained from the Minneapolis VA Medical Center Tumor Registry or chart review. Currently, more than 2,000 tumor samples have been collected.

Cell and Tissue Bank for Marker Studies of Diseases of the Bladder, Prostate, Kidney, Lung, and Breast

The Cell and Tissue Bank for Marker Studies of Diseases of the Bladder, Prostate, Kidney, Lung, and Breast is located at the Veterans Affairs Medical Center in Oklahoma City, Oklahoma. The Cell and Tissue Bank is supported by the Department of Veterans Affairs. The bank stores blood cells and bladder
washes and tissue samples from patients with diseases, including cancer of the bladder, prostate, or kidney, and blood and tissue samples of patients with such diseases as colon and breast cancer. Patient information (e.g., outcome, demographic, medical, and lifestyle information) is collected with each sample. The Cell and Tissue Bank specimens are used in studies to characterize objective biomedical markers in cells for the purpose of improving markers for disease detection, monitoring, and risk assessment.

**Central Prostate Cancer Serum Repository**

The NCI supports the Central Prostate Cancer Serum Repository at the VA Medical Center in Lexington, Kentucky. The objective of the repository is to establish a serum bank to collect and store serum of patients with prostate cancer entered into Southwest Oncology Group-approved studies. Serum samples will be distributed to investigators for projects on new or existing markers or other tests in a prospective or retrospective design.

**Collection of DNA/RNA Tissue Repository for Neurodegenerative Disorders**

The Collection of DNA/RNA Tissue Repository for Neurodegenerative Disorders is located in the Department of Neurology at Baylor College of Medicine. The aims of the DNA/RNA Bank are to establish a detailed database for patients with neurodegenerative disorders and to collect blood samples for future DNA analysis. If the disease is hereditary, family members are included in the database and blood samples are collected. Subjects are asked to provide information in a questionnaire about their symptoms and family involvement. The DNA/RNA bank is for internal use only. In addition to the blood samples collected, limited brain and muscle specimens are stored at –80°C and in liquid nitrogen, respectively. Demographic and detailed clinical data is obtained for each specimen.

**DNA Bank to Detect Gene Polymorphisms in Heart Failure**

The Department of Veterans Affairs supports the establishment of a large bank of genomic DNA samples derived from peripheral blood lymphocytes from patients with etiologically defined heart failure and from matched population controls. The bank is located at the VA Medical Center in Little Rock, Arkansas. These samples will be frozen and stored for future studies that analyze specific genetic loci of interest. Ethnic group and family history will be collected with each sample.
Early Detection Research Network—Tissue Bank for Matched Tissues to Screen for Markers of Neoplastic Progression

The VA Medical Center in Birmingham, Alabama, has collected a group of matched tissues from operations and preoperative body fluids to be stored in a tissue bank. The tissue bank is supported by the Department of Veterans Affairs. Specimens will include blood, urine, and feces from preoperative patients and remnant tissue sections from the surgical specimen. Patients with inflammatory diseases diagnosed or treated by surgery/biopsy will serve as controls. These specimens will be used in studies investigating whether chemicals present in the body, in tissues, or in fluids can be measured to predict the progression of tumors. Specimens will be analyzed for biomarkers that can be correlated with early detection, diagnosis, and prognosis of the patient’s disease process.

Gift of Hope Brain Bank for AIDS

The Gift of Hope Brain Bank for AIDS at the VA Medical Center in Los Angeles, California, is supported by the Department of Veterans Affairs. The brain bank recruits, collects, preserves, and banks high-quality tissue and CSF/serum specimens. All specimens are quick-frozen and available at no charge to investigators for study of AIDS dementia and other AIDS-related neurologic symptoms. Medical and neuropathological records are also available to investigators.

Harvard Brain Tissue Resource Center

The Harvard Brain Tissue Resource Center (The Brain Bank), at McLean Hospital in Massachusetts, is a centralized repository for the collection and distribution of postmortem human brain specimens from both diseased and normal donors for use in research on the brain and nervous system. The Brain Bank is supported by the NIMH, the National Institutes of Neurological Disease and Stroke, the Alzheimer Disease Association of Indiana, the Hereditary Disease Foundation, the Tourette Syndrome Association, and the Wills Foundation. Research on brain tissue has contributed to the understanding of severe mental illness, the development of a genetic test for Huntington’s disease, and a treatment for Parkinson’s disease. The mission of the Brain Bank is to serve as a national resource for the collection and distribution of postmortem brain tissue for medical research into the causes of neurological and severe psychiatric disorders. Because the majority of research requires very small amounts of tissue, each donated brain provides a large number of samples for many researchers. Brain tissue donations are accepted by the Brain Bank from individuals or the parents, siblings, and offspring of individuals with such severe neurological dis-
orders as Huntington’s, Parkinson’s, and Alzheimer’s diseases, with a serious psychiatric diagnosis, and various other disorders. The Brain Bank also accepts brain tissue from normal individuals with no neurological or neuropsychiatric disorders for research that needs to compare normal tissue with diseased tissue. Prospective brain tissue donors must be 18 years of age or older. Donors should discuss their wishes with their families and can register with the Brain Bank by completing the “Brain Donation Questionnaire.”

Brain tissues are stored as fresh quick-frozen tissue blocks and coronal sections, passive frozen hemispheres, and formalin-fixed hemispheres. Researchers can request custom dissection of specified anatomic regions of the passive frozen or formalin-fixed hemispheres. All tissue diagnoses are confirmed by retrospective review of clinical records and a comprehensive neuropathological examination. There is no cost for distribution of brain tissues to approved researchers.

The Harvard Psychiatry Brain Collection was created as a subsidiary of the Harvard Brain Tissue Resource Center. This collection specifically attempts to collect brain tissue from families with serious mental illness. Tissues from patients with schizophrenia, manic-depression, obsessive-compulsive disorder, and first-degree relatives of individuals with these disorders are being collected for research and distributed to qualified investigators.

**HIV-Related Malignancy Tissue/Biological Fluids Bank**

A consortium of Washington, D.C., metropolitan hospitals has established a comprehensive bank of biological fluids and tissue specimens from individuals with HIV-related malignancies. The HIV bank is supported by the Department of Veterans Affairs and is in the Department of Pathology at George Washington University. Diagnostic tissue (either fresh-frozen or formalin-fixed) and biological fluids (blood, urine, and other fluids) are collected from HIV seropositive individuals who have HIV-related malignancies. The specimens are available to researchers throughout the United States for approved requests.

**Human Brain Bank**

The Human Brain Bank Core at the University of Pittsburgh, Department of Psychiatry was established in 1990 and is supported by the NIMH. The goal of the brain bank is to identify, recover, assess, and distribute postmortem human brain specimens from cases of schizophrenia and matched normal control and nonschizophrenic psychiatric comparison subjects. Clinical features of each specimen and its availability are stored in a database and are accessible to center investigators.
Human Gastrointestinal Tumor Bank

The Human Gastrointestinal Tumor Bank was established to provide human tissue samples for the investigation of the molecular basis of carcinogenesis. The tumor bank is located at the VA Medical Center in Nashville, Tennessee, and is supported by the Department of Veterans Affairs. Tissue samples will be obtained from surgical specimens of esophageal, gastric, pancreatic, and colon carcinoma cases. Specimens are fixed or frozen. Clinical diagnoses and relevant clinical information are collected and maintained for each specimen. Current research projects utilizing these tissue samples include determination of the proliferative index by PCNA immunohistochemistry and in vitro staining and localization of the epidermal growth factor/transforming growth factor family of ligands and receptors in normal, adenomatous, and malignant tissue.

Human Lung Cancer Tissue Resource

The VA Medical Center in Albuquerque, New Mexico, has established the Human Lung Cancer Tissue Resource. The tissue resource is supported by the Department of Veterans Affairs and its objective is to collect samples of lung tumors for long-term tissue banking. The tissue resource provides specimens for investigators interested in lung carcinogenesis. Data, including exposure history and employment history, are collected from each specimen. Tumor specimens as well as normal specimens are collected. Currently, the tissue resource has collected 236 tumor samples.

Inflammatory Bowel Disease Tissue Bank

The Inflammatory Bowel Disease Tissue Bank at Massachusetts General Hospital, established in 1988, is funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The tissue bank stores specimens from cases of Crohn’s disease and ulcerative colitis, as well as colon cancer, adenocarcinoma, and diverticular disease. More than 250 cases are archived with three to five specimens from each case and data regarding final diagnosis, age, and sex of the patient are catalogued with each specimen. The specimens are available to investigators at no cost.

International Registry of Werner Syndrome/Cell Bank

The University of Washington has established the International Registry of Werner Syndrome/Cell Bank supported by the NCI. Werner syndrome is a rare disorder that causes premature aging and early death. The registry has been in existence since 1990 and has collected lymphoblastoid cell lines, primary skin
fibroblasts and SV40-transformed fibroblast cultures containing a wide range of Werner syndrome mutations. A collection of sib-pairs (wild type versus heterozygotic carrier) will be available for retrospective and long-term prospective studies of the susceptibility of heterozygotes to various types of neoplasms. All specimens are available to investigators associated with the Program Project grant. In addition, cultures representative of a variety of mutations are available to the general community.

**LSU Neuroscience Center Brain Tissue Bank**

The Neuroscience Center of Excellence at Louisiana State University maintains a Brain Tissue Bank. The Brain Tissue Bank obtains, processes, and distributes postmortem human brain tissue to investigators for neuroscience research.

**Lung Cancer in Uranium Miners: A Tissue Resource**

The VA Medical Center in Albuquerque, New Mexico, has established a tissue bank to store samples of lung cancers and other tissues of lung cancer patients. The tissue resource is supported by the Department of Veterans Affairs. Tissue samples collected from lung cancer patients include cancer, blood, and sputum. Currently, tissue samples from 248 patients with lung cancer have been collected.

**Massachusetts General Hospital Tumor Bank**

The Massachusetts General Hospital (MGH) Tumor Bank was established in 1996 as a joint effort by MGH Cancer Center, the Hematology/Oncology Division of the Department of Medicine, and the Department of Pathology. Its goal is to collect and distribute surgical specimens of human tumors for biomedical research. Tumor specimens are collected from surgeries conducted at MGH. Resected specimens are sent to the pathology lab for diagnosis and excess tissue is snap-frozen and stored at the Tumor Bank. Specimens are distributed to researchers for approved scientific studies.

**Mental Health Clinical Research Center Brain Bank**

The Mental Health Clinical Research Center Brain Bank was established to provide neuroscientists with normal and abnormal brain morphology and neurochemistry in psychiatric conditions. The brain bank at the VA Medical Center in Iowa City, Iowa, is supported by the Department of Veterans Affairs. Tissues collected include brains from normal individuals and persons suffering from major mental illness. Brain specimens are sliced coronally in the fresh
state, and alternate slices are fixed or flash-frozen. Tissues are digitized to record anatomical appearances prior to storage. Tissue blocks are available to investigators for morphometric and chemical analyses.

**Mucosal Immunology Core**

The Mucosal Immunology Core at the University of California, Los Angeles, is supported by the National Institute of Allergy and Infectious Diseases. Mucosal lymphoid tissue has been shown to be a major reservoir of replicative HIV-1. Recent studies are investigating differential rates of CD4+ T-cell depletion in lymphoid tissue versus peripheral blood. The gut-associated lymphoid tissue is the body’s major lymphoid organ and is accessible by endoscopic biopsy. The Mucosal Immunology Core provides investigators with clinically well-characterized tissue specimens from gastrointestinal mucosal sites. Fresh and frozen samples will be collected from seropositive subjects and seronegative controls. Site-specific biopsies can be obtained via request for studies requiring esophageal, stomach, duodenal, ileal, colonic, and rectal tissue. Mononuclear mucosal preparations and immunoglobulin secretions from saliva or rectal mucosa may also be collected prospectively. In addition, other mucosal tissues (pharyngeal, pulmonary, vaginal, urinary system) and samples from other patient populations (women and minorities) are available.

**Neuropathology Core**

A Neuropathology Core has been established in the Department of Microbiology at the University of Pennsylvania. The project was initiated in 1994 and is supported by the NINDS. The objectives of the core are to conduct histopathological-based studies to compare the cellular distribution of HIV and cytokines with pathological lesions and to establish a brain tissue bank. Brain tissues will be stored in various ways to optimize their use in other projects. About 10 brains will be collected each year.

**Oral Cancer Research Center**

The Oral Cancer Research Center at the University of California, San Francisco, has established a tissue and histopathology core to provide fundamental support to research investigators. The core makes available human oral cancerous and precancerous tissues for applied research studies, develops a patient database for correlation of patient outcome with molecular tumor markers, and provides basic, technical, histologic, and immunohistologic services to center investigators. Tissue will be collected from new patients treated at UCSF clinical sites and from pathology archives of five UCSF hospitals and two large San
Francisco oral pathology biopsy services. Biopsies and surgical specimens with a diagnosis of oral epithelial dysplasia, carcinoma in situ, invasive carcinoma, and verrucal carcinoma will also be collected.

A secondary source of tissue will be five additional California oral pathology services and two west coast oral medicine clinics. More than 3,000 archived oral cancers and precancers are immediately available for study, and an estimated 125 new tumors will be accessioned annually from the San Francisco Bay area for use in prospective studies.

**Prediagnostic Breast Cancer Serum Bank**

The Prediagnostic Breast Cancer Serum Bank was created as part of the Biological Markers Project at the NCI. Between 1977 and 1987, blood from more than 7,300 women free of breast cancer was collected. The Division of Cancer Prevention and Control maintains demographic data, and medical and reproductive histories were collected along with each blood sample. The goal of the serum bank is to provide specimens for prospective studies evaluating relations of serum concentrations of various analytes, such as hormones and antioxidant nutrients with breast cancer risk. Positive associations of bioavailable estradiol and testosterone with postmenopausal breast cancer have been found in these women.

**Pittsburgh Cancer Institute Serum Bank and Tissue Bank**

The Pittsburgh Cancer Institute (PCI) Serum and Tissue Bank is supported by the Department of Veterans Affairs and located at the VA Medical Center in Pittsburgh, Pennsylvania. The serum bank collects specimens and freezes sera for use in current and future studies. Surgically removed tumors are banked after informed consent is obtained. These specimens and accompanying data are available to PCI investigators and collaborating physicians in the community for clinical research.

**Program for Critical Technologies in Breast Oncology**

Yale University has established a core technical and tissue resource of human breast tissue. The goals of the tissue resource are to maximize access to human breast tissues and tumor DNA for researchers and to facilitate the application of molecular technologies in clinical breast cancer oncology. Breast tissue from patients treated at Yale New Haven Hospital and other hospitals in Connecticut is stored as fresh, fixed, or paraffin-embedded. A database has been established to support correlative multidisciplinary studies that utilize tissue samples.
Minimal fee-for-service routine molecular and histological tissue analyses of relevance to breast cancer are performed.

**Program for Critical Technologies in Molecular Medicine**

The Program for Critical Technologies in Molecular Medicine is a shared resource of the Yale Cancer Center, within the Department of Pathology at Yale University School of Medicine. The program was established in 1992, built on the existing tissue bank in the Department of Pathology. The Tissue Procurement Module and Tissue Products Module are two components of the program. The program is supported by several sources, including the G. Harold and Leila Y. Mathers Charitable Foundation, the NCI, the U.S. Army Medical Research and Materiel Command, and the Department of Pathology.

More than 10,000 frozen tissue samples have been collected for research purposes, and more than three million archived paraffin blocks from clinical cases are available. Tissue specimens are either frozen in OCT (optimum cutting temperature) or snap-frozen. Tissue specimens may also be formalin-fixed and paraffin-embedded for research use in addition to the paraffin blocks from archived clinical cases. Approximately 25,000 cases are archived from clinical paraffin blocks each year.

Each investigator interested in obtaining tissue from the program must have a protocol for tissue use approved by the Yale Human Investigation Committee. Investigators from outside of Yale must have a Material Transfer Agreement negotiated and signed before tissue can be released. Tissue products are provided as small sections, depending on the researcher’s requests, rather than as bulk tissue, as a more efficient use of a valuable resource. Patient information disclosed with each tissue specimen includes age, sex, and pathology diagnosis. However, more information can be obtained after consultation with the investigator.

**Prostate Cancer Tumor Bank**

The Prostate Cancer Tumor Bank at the VA Medical Center in San Antonio, Texas, is funded by the Department of Veteran Affairs. The purpose of the Tumor Bank is to establish a high-quality bank of prostate tumors and an associated database of relevant clinical and follow-up data. The long-term goal for the banked tumor specimens is for use in studies for the discovery and validation of biological markers, such as oncoproteins and growth factors, which would correlate with clinical outcome and could be used as a prognostic indicator of tumor behavior.
Bank specimens are collected from excess tissue removed at biopsy or surgery. Fresh tumor specimens are snap-frozen in liquid nitrogen. In addition, archived paraffin-embedded material will be identified and assessed for potential use in immunohistochemical or molecular biological studies. The blocks are recut and reembedded if necessary and stored in the Tumor Bank under controlled conditions. Both abnormal and adjacent normal tissue is collected. More than 850 cases from paraffin-embedded archived tissues have been collected. Hematoxylin and eosin slides have been prepared, and tumor analysis has been performed and the data entered into the database. More than 180 specimens of fresh-frozen prostate tissue have been entered into the bank.

The database includes demographic, clinical, and outcome data for each specimen. Patient-specific data is obtained from existing sources, primarily hospital tumor registries, and thus, there is no direct patient contact. Access to banked material is strictly controlled, and use of specimens requires approval by the bank’s executive committee.

**Regional Tumor Bank**

A regional tumor bank has been established at the VA Medical Center in Salt Lake City, Utah, and is supported by the Department of Veterans Affairs. Fresh tumor tissue will be snap-frozen and stored, and small samples will be stored as paraffin blocks. Tumor specimens will be available for future studies for current and future hypotheses regarding tumors.

**Resource for Tumor Tissue and Data**

The Resource for Tumor Tissue and Data at Kaplan Comprehensive Cancer Center, NYU School of Medicine, provides fresh human tissue specimens, data required for quality control as well as for correlation of research findings with clinical outcome, and identification of hospital patients with specific malignancies for administration of epidemiologic questionnaires and for recruitment for protocol studies. Services are provided free of charge. Tissue specimens can be either fixed or snap-frozen, according to the investigator’s needs, and cell suspensions are also available. If no immediate need exists for tumor specimens obtained, these are stored and frozen until requested. Tissue paraffin blocks are available for immunophenotypic or immunogenotypic studies. Tumor and control blocks are provided to an investigator with a copy of the pathology report. Unused sections of the blocks must be returned on completion of the study.
Specialized Programs of Research Excellence

The Specialized Programs of Research Excellence (SPOREs) are highly interactive, multidisciplinary programs of translational research directed at reducing the incidence, morbidity, and mortality of cancer. SPOREs are NCI-funded, NIH-Designated Clinical Research Centers at research universities and consist of cancer-specific research programs supported by core resources, including administration, tissue and serum banks, and biostatistics. SPOREs are designed to develop areas of basic science with potential impact on cancer and to move these promising areas into clinical trials. The SPOREs are also designed to communicate important findings rapidly into the research community to stimulate investigation and to bring validated translational findings into the medical community, where the research can ultimately reduce incidence and mortality of cancer. In 1993, NCI funded 22 SPOREs at a cost of almost $20 million—nine breast cancer, two gastrointestinal (colorectal and pancreatic cancer), four lung cancer, and seven prostate cancer centers. Several SPOREs have core tissue banking facilities that support both their own research and collaboration with other SPOREs and researchers worldwide—for example, the SPORE in Prostate Cancer at the University of Michigan Comprehensive Cancer Center; SPOREs in Breast Cancer at Sloan-Kettering Institute for Cancer Research, Georgetown University Medical Center and Lombardi Cancer Center, and at Baylor College of Medicine in Houston; the SPORE in Lung Cancer at the University of Colorado Cancer Center; and SPOREs in Gastrointestinal Cancer and Prostate Cancer at Johns Hopkins.

Gastrointestinal. The SPORE in Gastrointestinal Cancer at Johns Hopkins is a translational research program aimed at reducing the incidence of and mortality from colorectal and pancreatic cancer. The SPORE includes four research programs involving six projects supported by four core resources. All programs in this SPORE use human specimens. The Human Tissue Resource and Logistics Core, built on an existing bank established in 1986 for the Bowel Tumor Working Group, banks a wide range of tissues from resection specimens of colorectal and pancreatic cancers. By the end of 1995, the bank contained 910 colorectal cancer resections, 169 colorectal adenoma resections, 52 colorectal polypectomy specimens, 62 hepatic resections for metastatic colorectal cancer, 201 pancreatic cancer resections, 112 xenografts of pancreatic carcinoma, 127 fecal specimens, and 2,574 blood specimens. The core also provides for the procurement of fecal and blood specimens, including peripheral blood leukocytes, plasma and serum, nasogastric and duodenal capsule fluid, and peritoneal washings. The core also maintains the Colorectal and Pancreatic Cancer Patient Registry. The registry is maintained in a database and includes family histories and food frequency questionnaires for patients evaluated for colorectal neoplasia. In addition, 2,120 families have been enrolled in the registry.
based on family history, including families with hereditary colorectal cancer syndromes and familial aggregation of colorectal cancer and early onset of colorectal cancer.

The University of Nebraska Medical Center Gastrointestinal Cancer SPORE largely focuses on issues in pancreatic cancer. There are no effective clinical approaches to prevention or early detection for pancreatic cancer. Therefore, this SPORE focuses on prevention, early detection, and therapy. The Nebraska SPORE consists of three cores designed to support existing research projects and provide for future research studies: Biostatistics, Tissue Bank, and the Pancreatic Cancer Family Registry. The tissue bank and family registry provide both normal and diseased pancreatic tissues for specialized studies and serve as a clinical resource for testing strategies for prevention and early detection approaches.

A Pancreas Tumor SPORE Tissue bank has been established to provide SPORE investigators with human specimens for translational research. The tissue bank will store normal, benign (acute and/or chronic fibrosing pancreatitis), and malignant pancreatic tissues (both primary and metastatic pancreatic carcinomas), peripheral blood lymphocytes, and plasma and serum from patients with pancreatic malignancies.

Prostate. The Prostate SPORE at Johns Hopkins takes a multidisciplinary approach to reduce the incidence, morbidity, and mortality of prostate cancer through prevention, genetics, early detection and diagnosis, morbidity reduction, and treatment. Research in early detection and diagnosis will be correlated with cancer risk in the Baltimore Longitudinal Study of Aging, the world’s largest and longest longitudinal aging study (see Chapter Five). A large core tissue bank was established to accelerate translation of human prostate research to clinical medicine. The Prostate SPORE at Johns Hopkins is an interactive clinical and basic research team dedicated to translating new discoveries into the control of prostate cancer.

The goals of the University of Michigan Comprehensive Cancer Center (UMCCC) Prostate SPORE are to reduce the morbidity and mortality of prostate cancer by supporting and establishing a translational research program directed at understanding the biology of prostate cancer as well as developing new tools for the diagnosis, prevention, and treatment of prostate cancer. The UMCCC SPORE consists of multidisciplinary projects with emphasis on molecular and clinical epidemiology and novel therapeutics. Four cores support these research projects: administration, tissue and serum bank resource, animal and cell line models, and biostatistics. The Tissue and Serum Bank provides tissue and known clinical follow-up to evaluate chromosome alterations discovered in research studies in the SPORE.
The Prostate SPORE at Baylor College of Medicine provides researchers with resources to work toward the goal of reducing the incidence, morbidity, and mortality from prostate cancer. Five translational research objectives have been designed to expand successful intervention strategies against prostate cancer. Research projects include defining new markers of progression and metastasis, identifying novel methods for low-risk definitive therapy of early stage cancer, defining chemoprevention with such biologic agents as retinoids or vitamin D analogs, and designing treatment protocols for advanced disease with biologic agents.

**Breast.** The University of North Carolina (UNC) Lineberger Comprehensive Cancer Center SPORE in Breast Cancer currently consists of seven research projects and four core resources. The goal of the UNC SPORE is to reduce breast cancer mortality and incidence in North Carolina through an interdisciplinary program of research. The UNC SPORE integrates studies in cancer prevention and control, molecular epidemiology, clinical research, and laboratory clinical research. It also targets behavioral and biologic issues relevant to the African-American population. The tissue procurement and analysis core facility will provide tissue procurement, processing, and distribution services of breast tissue to SPORE investigators. The core accesses all breast surgical procedures and obtains blood samples and fresh tissue. All collected tissues are entered into a database and may be distributed as DNA, RNA, or tissue sections to investigators.

The Carolina Breast Cancer Study, one of the seven research projects at the UNC SPORE, is a case-control study that integrates molecular biology and epidemiology in the search for causes of breast cancer. Women from eastern and central North Carolina who are diagnosed with invasive breast cancer for the first time and who are between the ages of 20 and 74 are being recruited from September 1, 1995, to March 31, 2000. Comparison subjects will be frequency-matched by age and race. It is expected that 1,600 women with invasive breast cancer and an equal number of controls will be involved in the study. Blood samples will be collected for extraction of germ line DNA from all consenting participants, and paraffin-embedded tumor specimens will be requested for all breast cancer cases. Clinical data, stage, and prognostic characteristics will be collected with each specimen. This collection of specimens and data will be the basis for studies investigating the contributions of genes and the environment to breast carcinogenesis.

The SPORE in Breast Cancer at the Sloan-Kettering Institute for Cancer Research proposes to meet the needs of the oncologic community for an integrated clinical and laboratory setting committed to reducing the incidence of and mortality from breast cancer. The SPORE consists of five main research
projects and two core resources. Research projects include studies of the erb family, BRCA-1, heregulin, and TGF-beta genes.

(Tissue banks at the Breast Cancer SPOREs at Georgetown University, Baylor College of Medicine, and Duke University are described in Table 3.1).

**Lung.** The goals of the University of Colorado Cancer Center (UCCC) Lung Cancer SPORE are to expand the understanding of the biology of lung cancer, to find new methods of diagnosis, prevention, and treatment, and to serve as a resource for the study of lung cancer. Since its inception, the UCCC SPORE has collected more than 900 sputum samples from high-risk individuals and more than 200 lung cancer specimens of all histologic types with matching pre- and postsurgical sputum samples for genetic testing of specific genes. During the next five years, the UCCC SPORE is planning to conduct eight interrelating full research projects, initiate four or five pilot projects annually, conduct more than 12 clinical trials, and support five core resources, including a premalignant and cancer bank. Specimens collected in the tissue banks will be available to scientists worldwide.

A Tissue Banks Core has been established to provide SPORE investigators well-preserved and well-characterized tumors, dysplastic lesions, benign tissues, cell lines, and cell and tissue fractions as well as associated clinical data for research projects. Tumor specimens, peripheral blood cells, urine, and sputum from patients with lung cancer or at risk for lung cancer will be collected. Tissue from invasive tumors and adjacent nonneoplastic lung tissue, pretreatment plasma, and peripheral blood cells from patients with these tumors are collected and processed from patients treated at SPORE-affiliated institutions. The Tissue Banks Core will thus serve as a national resource for uniformly typed, staged, treated, and observed tumors and preneoplastic lesions. Tissue specimens will be available to SPORE investigators and outside approved investigators.

**Sloan-Kettering Institute**

The Memorial Sloan-Kettering Cancer Center (MSKCC) was established in 1884 and is the oldest and largest private institution dedicated to the prevention, patient care, research, and education in cancer. MSKCC is composed of two institutes, Memorial Hospital and the Sloan-Kettering Institute. The Sloan-Kettering Institute is the basic science research facility and conducts innovative programs in biology, genetics, biochemistry, structural biology, immunology, and therapeutics. The Human Tissue Procurement and Tissue Bank Facility is one of the Core Research Facilities. It serves as a collection and distribution site for human tissue specimens to be used in MSKCC research projects.
The Soft Tissue Sarcoma (STS) Project within the Sloan-Kettering Institute is one of many ongoing research projects and is supported by the NCI. The STS project seeks to implement a comprehensive and integrated multidisciplinary program focused on the biology, pathogenesis, and natural history of soft tissue sarcoma and translate the research data into improved treatment strategies. The Pathology Core provides project investigators with fresh tissue surgical specimens and pathologic and histologic characterization of all soft tissue sarcoma cases from Memorial Hospital. The core also maintains a bank of frozen sarcoma tissue and provides tissue specimens for molecular, biochemical, and genetic studies. This tissue bank is one of the largest collections of its kind in the United States.

**St. Louis University Alzheimer’s Brain Bank**

The Department of Geriatric Psychiatry at St. Louis University Health Sciences Center has established a community brain bank subsidized by the Alzheimer’s Association. Almost 1,000 brains are stored at the brain bank. The brain bank specializes in degenerative brain diseases and dementias and is also involved in basic/clinical correlative research. Tissue samples are available to qualified investigators throughout the United States and abroad.

**St. Paul–Ramsey Medical Center**

A brain bank has been established at the St. Paul–Ramsey Medical Center in Minnesota. The brain bank currently contains frozen slices of brain tissue from more than 700 people with Alzheimer’s disease and other forms of dementia. Tissue samples have been sent to Alzheimer’s investigators at other institutions for research into the diagnosis, treatment, and cause of Alzheimer’s disease.

**Tissue Bank for Research on HIV-Associated Malignancies**

A tissue bank for research on HIV-associated malignancies was established at the University Hospital of Downstate Medical Center in New York. The tissue bank is supported by the NCI. The goals of the tissue bank project are to maintain a central repository and database of neoplastic tissues and biological specimens of HIV-related malignancies with clinical and outcome data, to emphasize and prioritize the accrual of HIV-associated invasive and in-situ carcinoma of the uterine cervix, and to make available specimens for molecular, immunologic, genetic, and epidemiologic analysis to the scientific community. The participating institutions include the State University of New York Health Science Center at Brooklyn, King’s County Hospital Center, and Woodhull Medical and Mental Health Center. Specimens may be shipped fresh to inves-
tigators, frozen as sterile, single-cell suspensions, or flash-frozen in a cryopreservative reagent. Parallel paraffin blocks to frozen specimens are also made and stored.

**Tissue Banking for Early Detection Research Network**

The VA Medical Center in Pittsburgh, Pennsylvania, has established a tissue banking network that is supported by the Department of Veterans Affairs. Tissues from patients at risk for head, neck, and lung cancers will be obtained at surgery and stored in a tissue bank. These specimens will be used locally and distributed to requesting investigators at other institutions.

**Tissue Core Facility at the Oral Cancer Research Center**

The Oral Cancer Research Center of the University of Texas M.D. Anderson Cancer Center maintains a tissue core facility. The tissue core facility is supported by the National Institute of Dental Research. The core will function as a central repository for patient specimens, including peripheral blood lymphocytes for different projects in the Oral Cancer Research Center. The core is responsible for the acquisition, storage, and distribution of histologically characterized samples from various lesions representing the histopathological spectrum of oral squamous neoplasia.

**Tissue Culture Core**

The Tissue Culture Core at Weill Medical College of Cornell University serves as a common resource to provide specifically characterized cell cultures for faculty investigators. The Tissue Culture Core can provide human arterial smooth cell muscle cells, adventitial fibroblasts, umbilical vein endothelial cells, human monocyte-like cell lines, and peripheral blood monocytes. Fresh human platelets and neutrophils can be isolated per investigator request. All cell cultures are characterized immunocytochemically and tested for mycoplasma contamination.

**Tissue/Pathology Core**

The Tissue/Pathology Core is the central facility providing tissue collection and services for investigators of the University of Michigan Specialized Center of Research (SCOR). The core processes human lung tissue from patients with interstitial lung disease and controls for protein and mRNA analysis. Human bronchioalveolar lavage fluid and cells are also collected and processed for protein and mRNA analysis.
Tissue Procurement and Banking Facility

The Tissue Procurement and Banking Facility (TPBF) is an established CCSG-supported core facility at the University of Texas M.D. Anderson Cancer Center and is funded by the NCI. The TPBF provides human tumor tissues that have been removed for biopsy or therapeutic resections for ongoing research projects. The TPBF attempts to procure all pathologic tumor tissue from patient procedures for cryopreservation and characterizes tissues prior to distribution. Clinical data (epidemiology, family history, patient treatment, and patient outcome) for collected tissue specimens will be available through interactive databases.

Tissue Procurement Core

The Tissue Procurement Core at the University of Michigan Comprehensive Cancer Center (UMCCC) is funded by the NIC and the University of Michigan. The Tissue Procurement Core is a service of UMCCC based in the Surgical Pathology Laboratory of the University of Michigan Hospital. The Tissue Procurement Core prospectively obtains surgically resected tissue for research and maintains a -80°C freezer for limited storage. Tissue Procurement Core Services are available to UMCCC members only. For a nominal charge, histology services are available, including preparation of histologic sections from frozen and paraffin-embedded tissues, routine stains, and immunohistochemical stains. Acquisition of any tissue that is to be the subject of research or development requires IRB approval.

Tissue Procurement Core Facility

The Tissue Procurement Core Facility at Dartmouth College is designed to serve as a central tissue acquisition and distribution facility. Tissues are obtained from the reproductive tracts of patients undergoing hysterectomy or endometrial biopsy for program project investigators. Cell suspensions and vibratome sections are made from tissues of the fallopian tube, uterus, cervix, and vagina. Pertinent patient information from chart and patient interview and clinical/pathological evaluation of tissue specimens is collected.

Tissue Procurement Shared Resource

The Tissue Procurement Shared Resource (TPSR) at Ohio State University (OSU) Comprehensive Cancer Center was established as a shared service in 1975 to provide investigators with quality human tissue for research. TPSR obtains fresh tumor specimens to distribute around the world. The goals of the
Large Tissue Banks

center are to provide an organized structure to access human tissue; to increase availability and diversity of tissues; to provide quality specimens, pathology data, and maintain patient confidentiality; and to maintain efficient and cost-effective service. The service has handled more than 75,000 specimens, approximately 3,000 per year. TPSR currently is funded by a Cancer Center Support Grant, OSU funds, and other grants. Investigators can receive remnant surgical or autopsy tissue after filling out a TPSR application. The application must have an approved human subjects IRB evaluation. All tissues are uniquely coded, and investigators receive a pathology report specifically about the tissue. For an additional fee, TPSR will perform a histology quality-control analysis on a small sample of the investigator’s specimen.

Tumor Bank for Solid Tumors

The Tumor Bank for Solid Tumors at the Louisiana State University’s Stanley S. Scott Cancer Center Tumor Bank, Department of Surgery, is supported by the Department of Veterans Affairs. All patients who have been previously scheduled for resection of malignancy are eligible to donate, and all tumor sites are collected. Aliquots of tumor and surrounding normal tissue are harvested. All tissue specimens are frozen, and routine pathology reports are collected with each specimen. Specimens are available for molecular analysis and correlative studies through the Stanley S. Scott Cancer Center. All tissue requests must have IRB approval and approval by the Director of the Louisiana State University Tumor Bank.

Western Genitourinary Tissue Bank

The Western Genitourinary Tissue Bank is located in the Department of Pathology at the University of Pittsburgh Medical Center (UPMC). The Tissue Bank was established in the early 1990s and has successfully banked over 250 prostatectomy specimens. The bank also stores serum and lymphocyte components for each individual collected prior to the radical prostatectomy surgery.

In addition to collecting specimens in house, a collaborative effort with the Veterans Affairs Medical Center in Pittsburgh also provides tissue specimens for the bank.

Wisconsin’s Alzheimer’s Disease Brain Tissue Bank

The Medical College of Wisconsin maintains an Alzheimer’s Disease Brain Tissue Bank. More than 500 brain autopsies have been performed since its inception. Other tissue specimens and CSF samples from 267 cases are stored at –70°C. Brain and tissue specimens are from cases of Alzheimer’s, Lewy body...
dementia, CJD, Huntington’s, and normal controls. The brain bank no longer accepts brain tissue donations for research. All stored tissue specimens are available to investigators at the Medical College of Wisconsin and outside investigators on special request.

COMMERCIAL ENTERPRISES

Some commercial enterprises maintain tissue banks for proprietary use, while others establish banks for storage and distribution purposes. LifeSpan BioSciences, Inc., is an example of a company that maintains a proprietary tissue bank and offers services using their tissue bank, while PathServe collects human tissues and organs to market them to the research community. Other commercial entities market products to facilitate analysis of human tissues—normal and diseased—such as Clontech. Materials with multiple tissue types, kits containing DNA/RNA samples, and even protein samples from human tissues are currently on the market. These types of products will most likely expand with the demand to find target disease genes and are useful to both academic and industry researchers.

LifeSpan BioSciences, Inc.

LifeSpan BioSciences, Inc., founded in 1995, is a genomics company focused on the discovery and licensing of genes that play a role in the aging process and identifying disease-associated genes for use as therapeutic or diagnostic targets. Because highly characterized samples of normal and diseased tissues are critical in localizing disease-associated genes, LifeSpan has an on-site tissue bank. LifeSpan’s Tissue and Disease Bank contains one million normal and diseased human samples. The tissue bank has more than 175 different types of tissues from virtually every organ in the body, covering all ages. The tissue bank also includes more than 1,500 different pathologic disease categories, such as autoimmune diseases, infectious diseases, degenerative diseases, cancer and benign proliferative diseases, and genetic diseases. LifeSpan BioSciences, Inc., does not sell its tissues per se but performs custom services using its tissue bank.

LifeSpan BioSciences, Inc., performs a variety of services on its proprietary tissues, including high-throughput gene expression analysis, bioinformatics, immunocytochemistry and in situ hybridization (ICC/ISH), and anatomic mapping. ICC and ISH are customarily performed using one tissue per slide and are accompanied by a pathologic report of the lesion and the result from the test.
**PathServe**

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

**Clontech**

Clontech was established in 1984 as a developer and marketer of biological products to the life sciences market worldwide. Clontech’s mission is to accelerate the discovery process by providing innovative tools that enable researchers to answer complex questions more expediently. Clontech was the first to make several key technologies available to the biomedical field, including the green fluorescence protein-based reporter system, two-hybrid analysis systems for the study of protein interactions, and gene array technology for high-throughput differential expression analysis. Such recent products as RNA Master Blots and high-quality protein samples facilitate screening of normal and diseased human tissues from multiple organs. These products enable researchers to profile tissue expression patterns of known genes or expressed sequence tags (ESTs), to obtain high-throughput analysis of gene expression profiles in different tissues, and to perform rapid screenings of tissue-specific patterns of genes.

**NONPROFIT ORGANIZATIONS (NONEDUCATIONAL)**

A variety of nonprofit institutions bank tissues for storage and distribution. Nonprofit institutions, such as the American Type Culture Collection, Coriell Institute for Medical Research, the Research Foundation for Mental Hygiene, the Rocky Mountain Multiple Sclerosis Center, the National Psoriasis Tissue Bank, the Kaiser Permanente Center for Health Research, and the Hereditary Disease Foundation, receive millions of dollars in federal funding. Descriptions of these nonprofit centers that bank tissue are detailed below.
American Type Culture Collection

Since its establishment in 1925, the American Type Culture Collection (ATCC) has served as an archive of living cultures and genetic materials for researchers in the biological sciences. The mission of the ATCC is to acquire, authenticate, and maintain reference cultures, related biological materials, and associated data and to distribute these to qualified scientists in government, industry, and education. The ATCC has approximately 2,300 human cell lines. All of the human cell lines are immortalized cultures and the genetic material is mainly the products of recombinant DNA research. ATCC is creating new products to facilitate screening of multiple cell lines/tissue types. For example, the ATCC Express-Check is a kit that contains DNA from human tissue-specific cDNA libraries.

Biologic Specimen Bank

The Research Institute on Addictions in New York has established a biologic specimen bank to support scientific research projects at the institute. The bank will collect and store frozen specimens of plasma, serum, cells, cell membranes, and urine from randomly selected African-American and Caucasian men and women, aged 35 to 79. Control tissue specimens will be collected from two case-control studies on myocardial infarction and lung cancer and participants in the research component project on the epidemiology of treated and untreated alcoholics. Blood samples from more than 7,500 men and women are expected to be collected and stored.

Biomedical Research Institute

The Biomedical Research Institute is a nonprofit entity established in 1948 to provide research and development services. The Biomedical Research Institute specializes in tropical disease vaccines and provides biological repository services to federal agencies. The National Institute of Child Health and Human Development (NICHD) is conducting a trial of calcium supplementation in pregnancy. The Biomedical Research Institute will store, monitor, and distribute serum, plasma, and urine samples collected from this trial. More than 4,500 pregnant women are expected to enroll in this study from five clinical centers. NICHD has also contracted with the Biomedical Research Institute for banking blood specimens in a similar fashion for two other studies: Diabetes in Early Pregnancy and Successive Small-for-Gestational-Age Birth.
Coriell Institute for Medical Research

The Coriell Institute for Medical Research is a basic biomedical research institution that conducts research on the causes of genetic diseases, including cancer. The Coriell Institute’s three missions are research, cell banking, and public education. The largest collection of human cells for research is maintained at the Coriell Institute, and these cells are available to the general scientific community. Seminal research on the genes associated with Huntington’s disease, cystic fibrosis, Alzheimer’s disease, ataxia telangiectasia, and manic depression have utilized cells from the Coriell collection. In 1990, the NIMH awarded the Coriell Institute a $5.7 million contract to establish a cell repository for the study of the genetic basis of Alzheimer’s disease, manic depression and schizophrenia. New repositories have recently been established for the study of diabetes.

The Coriell Cell Repositories are supported by NIH and several foundations. More than 35,000 cell lines are currently stored, representing approximately 1,000 of the 4,000 known genetic diseases, and 60,000 cell lines have been distributed to more than 40 nations, resulting in 8,000-plus research publications. Cultures are established from both blood and skin, and the cells are stored frozen at the institute. Three-quarters of a million vials of cells are kept in 37 giant liquid nitrogen tanks. The Coriell Cell Repositories currently consist of four cell collections described below.

Human Genetic Mutant Cell Repository. The Human Genetic Mutant Cell Repository is sponsored by the National Institute of General Medical Sciences (NIGMS). The repository supplies scientists with materials for advancing the discovery of disease-related genes. Their resources include highly characterized, viable, contaminant-free cell cultures and high-quality DNA derived from these cultures. The repository contains both DNA and cell cultures from human and animal cell cultures, normal controls, inherited disorders and normal variants, and NIGMS extended family collections.

NIA Aging Cell Repository. The NIA Aging Cell Repository is a collection set up to facilitate cellular and molecular research studies on the mechanisms of aging and degenerative processes. Included in the collection are cell cultures from aging syndromes, Alzheimer’s, normal fibroblasts from a lifetime study, lymphoblasts for aged sib pairs, and a variety of other cell types.

American Diabetes Association (ADA) Cell Repository Maturity Onset Diabetes Collection. The ADA Cell Repository Maturity Onset Diabetes Collection is derived from the ADA Genetics of non-insulin dependent diabetes mellitus (NIDDM) (GENNID) Study. The purpose of the study is to establish a national database and cell repository consisting of information and genetic
material from families with well-documented NIDDM. The repository contains DNA samples and phenotypic data from subjects enrolled in Phase I ADA GENNID trials (170 pedigrees, all of which contain at least one affected sib pair, with a total of 650 affected individuals and approximately 1,200 subjects). The data set includes multiple metabolic factors, such as carbohydrate metabolism, lipid metabolism, and body size measures, as well as lifestyle variables. New additions to the collection include families and pedigrees, sib pairs, and DNA samples from Phase II of the ADA GENNID study.

**Human Biological Data Interchange Cell Repository Juvenile Diabetes Collection.** The Human Biological Data Interchange (HBDI) Cell Repository Juvenile Diabetes Collection contains quality-controlled cell lines and DNA from more than 400 families for distribution.

**Fox Chase Network Breast Cancer Risk Registry**

The Fox Chase Network Breast Cancer Risk Registry is supported by the Department of the Army. The goal of the registry is to establish a breast cancer risk registry to serve as a resource for research activities investigating the etiology and prevention of breast cancer. Women with one or more first-degree relatives with breast cancer are identified, and information about family history, personal medical history, lifestyle and environmental factors, health practices and beliefs, and psychological status are entered into a comprehensive database. Serum and DNA from women in this high-risk registry are stored in the Fox Chase Cancer Center/Network Breast Cancer Tissue Registry. In addition, a high-risk specimen bank contains DNA, red blood cells, plasma, and breast tissue.

**HealthPartners Human Brain Bank**

The HealthPartners Human Brain Bank in Minnesota was established by Dr. William Frey in 1977. The brain bank is supported by the Regions Hospital Foundation, pharmaceutical companies, and other private foundations and individuals. The brain bank contains frozen human brains from cases of Alzheimer’s disease, multi-infarction dementia, dementia with Lewy bodies, Parkinson’s disease, Pick’s disease, CJD, unclassified dementias, and nondemented normal controls. More than 2,000 brain specimens have been collected. These brain specimens are available to collaborating investigators.

**Hereditary Disease Foundation**

The Hereditary Disease Foundation of Santa Monica, California, is studying the genes involved in Huntington’s disease in a Venezuelan kindred of more than
14,000 people. Through study of this kindred, the gene for Huntington’s disease was localized to chromosome 4p. This kindred is a valuable resource, enabling researchers to study members who share background genes and a common environment. The Hereditary Disease Foundation is studying the unstable trinucleotide (CAG) repeat found in the Huntington’s disease gene. Huntington’s disease has afflicted more than 400 people and now threatens 4,697 at-risk children in this kindred. To study this protein, the Hereditary Disease Foundation is collecting tissue samples, including lymphoblast lines and sperm samples, to examine the effect of age, disease duration, birth order, and environmental factors on sperm. Brain and other postmortem tissues from genetically and clinically well-characterized members of the kindred are also being collected to understand how the Huntington protein specifically devastates striatal neurons.

**The International Skeletal Dysplasia Registry**

The International Skeletal Dysplasia Registry at Cedars-Sinai Medical Center in California is a referral center for the diagnosis and management of skeletal dysplasias. The registry is supported by grants from NIH and the Steven Spielberg Pediatric Research Center. Materials submitted to the registry are archived and used for future research studies. Samples collected include histology blocks and slides, frozen and fixed tissue specimens, cell cultures (including fibroblasts, chondrocytes, and lymphoblastoid cells), blood (from patient and both parents), and DNA. Clinical summaries, pedigrees, photographs, and x-rays are also collected.

**Kaiser Permanente Center for Health Research**

The Kaiser Permanente Center for Health Research (CHR) is a nonprofit healthcare research institute established in 1964. More than 40 studies are under way and some involve the storage of tissue. For example, the CHR started the Benign Breast Disease Registry (BBDR), funded by the NCI. The BBDR includes data on nearly 10,000 women diagnosed between 1970 and 1994. The registry provides both benign and malignant archived tissue to researchers. In another NCI-sponsored breast cancer study, almost 16,000 breast cancer cases and associated archived tissue are available to qualified researchers for molecular studies. In the last 20 years, more than 25,000 people in the Portland-Vancouver area have voluntarily participated in the research at the CHR. Clinical trials involving archived tissue are also undertaken. For instance, the Fracture Intervention Trial is an 11-center double-blind, placebo-controlled, randomized clinical trial to determine the efficacy of alendronate in preventing frac-
tures secondary to osteoporosis. The CHR has received more than $96 million in grants from federal and state agencies and private foundations.

**Maryland Brain Collection**

The Maryland Brain Collection (MBC) is a collaboration between the Maryland Psychiatric Research Center and the Office of the Chief Medical Examiner of Maryland. The MBC collects material for investigators interested in studying the aspects of human postmortem brain structure and function. Specimens are collected from deceased persons with schizophrenia, suicide victims, and healthy controls. Extensive clinical information is also obtained with each specimen and is available to investigators.

**McKesson BioServices**

McKesson BioServices, formerly Ogden BioServices Corporation, was established in 1986 to provide a cost-effective and focused process in several areas of drug development, such as regulatory affairs, formulation development, and biological specimen storage and distribution. McKesson BioServices currently stores more than 20 million biological specimens in their Biological Specimens Repository. Some of the nationally known collections of biological specimens stored by McKesson BioServices are briefly described in Table 3.2.

**National Disease Research Interchange**

The National Disease Research Interchange (NDRI) is a nonprofit organization that arranges for the procurement and distribution of human tissues and organs for biomedical researchers. NDRI has been operating for 17 years and has provided more than 125,000 tissue specimens of more than 100 types of tissues to scientists nationwide. NDRI is composed of three programs with different objectives to facilitate the use of human tissues and organs for researchers:

- **Human Tissues and Organs for Research (HTOR):** This unit focuses on retrieval and distribution of tissues and organs from autopsy and surgical procedures, as well as specimens obtained from eye and tissue banks. Examples include whole or partial organs, such as heart, lung, kidney, brain, liver, eyes, and bones and joints.

- **Human Biological Data Interchange (HBDI):** This unit stores genetically valuable family collections for use in the advancement and study of the genetic basis for disease. The HBDI repository currently holds biomaterials from more than 500 families and also contains family and medical history data on more than 6,500 families with diabetes.
• Odyssey One: This unit was established to respond to new and emerging needs of biomedical researchers in innovative areas related to the use of human materials in research. The unique and hard-to-get tissues that they have provided include pancreatic islet cells, malignant tumors and normal adjacent tissue, and bone marrow stem cells.

Table 3.2

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<th>Collection</th>
<th>Description</th>
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<tr>
<td>Army-Navy Serum Repository (ANSR)</td>
<td>The ANSR contains more than 18 million sera specimens collected from active-duty and reserve personnel. This repository is the largest collection of normal human sera from all race and ethnic groups and all geographic areas in the United States. This repository provides the Army with a seroepidemiology resource to assess exposure to infectious and toxic agents during deployment, to estimate immunity prevalence for a variety of diseases, and to determine the causes of, risk factors for, and determinants of acute and chronic diseases associated with military operations.</td>
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<tr>
<td>NHLBI-sponsored studies</td>
<td>The National Heart, Lung, and Blood Institute (NHLBI) contracts with McKesson BioServices to maintain a repository of blood specimens from NHLBI-sponsored studies. These specimens will be made available to investigators for research projects related to transfusion-transmitted diseases and a variety of other disorders of blood or the cardiovascular system. A serum, plasma, and cell repository is maintained and serologic and virologic assays are performed.</td>
</tr>
<tr>
<td>Collaborative Perinatal Project (CPP) Serum Repository</td>
<td>The CPP was a prospective cohort study of pregnancy and child development administered by the National Institute of Neurological and Communicative Disorders (NINCD). The purpose of the project was to enroll pregnant women between 1959 and 1966 and conduct follow-up neurological, psychological, pediatric, and speech-hearing studies on the children to determine factors responsible for the development of neurological disorders of childhood. The CPP collected serum from the women during pregnancy, delivery, and postpartum, and umbilical cord serum from the newborns, and serum from the infant at 4 months of age. More than 833,000 vials of serum were collected.</td>
</tr>
<tr>
<td>Diet Intervention Study in Children (DISC) Study Effort</td>
<td>The objectives of the DISC project are to determine whether a fat-modified diet during childhood and adolescence will lower LDL-cholesterol and to assess the feasibility and safety of this diet. The DISC project is being conducted at 6 clinical centers and a coordinating center. More than 600 children, between the ages of 8 and 10 who had LDL-cholesterol levels between the 80th and 98th percentiles and other criteria were randomized into the intervention or control group. Serum samples were collected at baseline and 12, 36, 37, 60, and 84 months and at 18 years of age after follow-up.</td>
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Table 3.2—continued

<table>
<thead>
<tr>
<th>Collection</th>
<th>Description</th>
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<tr>
<td>National Health and Nutrition Examination Survey (NHANES) Serum Bank</td>
<td>The CDC NHANES project is a national probability sample survey program serving as a source of data obtained by standardized health examinations. Serum has been drawn from over 30,000 participants and stored at −80°C for future studies. These samples are available to government agencies and for other approved sociodemographic studies.</td>
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<tr>
<td>Polyp Prevention Trial (PPT)</td>
<td>The PPT is a multicentered randomized clinical study to determine if a low-fat, high-fiber, vegetable-, and fruit-enriched diet would decrease the rate of recurrence of large bowel adenomatous polyps. Under subcontract with Westat, Inc., McKesson BioServices provides biological repository services involving blood and tissue/biopsy specimen receipt, cataloging, storage, and inventory control.</td>
</tr>
<tr>
<td>Vaccine Evaluations</td>
<td>The NICHD conducts the Group B Streptococcus Study. McKesson BioServices is subcontracted by Westat, Inc., to provide biological repository services. An estimated 65,000 vials of serum and isolates will be collected and stored by McKesson BioServices sent by participating clinical centers. A computerized inventory system will be established for tracking and retrieval of all specimens.</td>
</tr>
</tbody>
</table>

**National Neurological Research Specimen Bank**

The National Neurological Research Specimen Bank (NNRSB) was established in 1961 to provide a vital resource to neuroscientists. The NNRSB is supported by NINDS/NIMH, the Department of Veterans Affairs, and private organizations, such as the National Multiple Sclerosis Society. The NNRSB at the VA Medical Center in Los Angeles, California, collects, cryogenically stores, and distributes donated tissue to research scientists around the world. The specimen bank stores pre- and postmortem tissues and cerebrospinal fluid/blood and other neurological specimens from patients with multiple sclerosis, Huntington’s disease, Parkinson’s disease, Alzheimer’s disease, and HIV/AIDS.

**National Psoriasis Tissue Bank**

The National Psoriasis Tissue Bank (NPTB) is the only international public source of genetic material for psoriasis research. The bank is dedicated to finding the genetic causes of psoriasis and psoriatic arthritis. The stored tissue is available for use by international experts. The NPTB is supported by private donations through the National Psoriasis Foundation (NPF), a voluntary non-profit national health agency. The NPTB consists of nearly 300 Epstein-Barr virus (EBV)-transformed cell lines, isolated DNA, fibroblasts from families with psoriasis and psoriatic arthritis, and blood samples from sibling pairs providing an additional 1,000 DNA samples. Researchers can obtain the cell line, DNA,
family history, and medical history of any individual in the bank; however, names and locations of contributors remain anonymous. There is a small fee for the service. Blood and skin samples are obtained by a medical team at the Baylor Psoriasis Center, a regional referral Center at Baylor University Medical Center in Dallas, Texas.

**New York State Multiple Sclerosis Consortium**

The New York State Multiple Sclerosis Consortium brings together research and clinical expertise of 15 major medical centers in New York in an effort to further define the multiple sclerosis (MS) population in terms of demographic, clinical, functional, quality-of-life, and treatment parameters. The Department of Neurology at Buffalo General Hospital is the coordinating center for the New York State MS Consortium. Current research efforts involve the development of an MS patient registry and centralized database of MS patient information and the collection of specimens, including blood, tissue, and cerebrospinal fluid, for member centers. Tissue specimens are stored at the Baird Multiple Sclerosis and Neuroimmunology Tissue Repository, which was established in 1991 and is funded by a grant from the Baird Foundation to the Millard Fillmore Health, Education, and Research Foundation. The repository has collected more than 1,000 tissues and fluids from MS patients, along with detailed demographic and neurologic data.

**Rocky Mountain Multiple Sclerosis Center Tissue Bank**

The Rocky Mountain Multiple Sclerosis Center (RMMSC) Tissue Bank, one of the largest MS tissue banks in the world, was established in 1976 to procure, process, preserve, and distribute MS brain tissue to research laboratories from all over the world involved in finding the cause of and cure for MS. More than 170 CNS samples have been banked at RMMSC, representing material from a well-defined patient population. The stored tissue has led to several key discoveries in the pathogenesis of MS. The bank is funded by the National Multiple Sclerosis Society.

**St. Luke’s-Roosevelt Institute for Health Sciences**

The Neuropathology Core at St. Luke’s-Roosevelt Institute for Health Sciences has established a bank of CNS tissues from children who died with HIV-1 infection. The tissue bank is supported by the NINDS. Snap-frozen tissue blocks have been collected from 25 cases, and formalin-fixed, paraffin-embedded tissue blocks have been stored from these cases and from an additional 50 cases. Tissues will also be collected from HIV-1 negative control cases and HIV-1-
infected and negative adults. Tissue specimens are available to core investigators from the Neuropathology Division of Columbia-Presbyterian Medical Center. The core provides neuropathology support and tissue immunocytochemistry services.

The Stanley Brain Collection and Neuropathology Consortium

The Stanley Brain Collection and Neuropathology Consortium was set up in 1994 and is privately funded by the Theodore and Vada Stanley Foundation. Its mission is to make postmortem brain tissue from individuals with schizophrenia, bipolar disorder, major depression, and normal controls available for scientific investigations. The Stanley Foundation supports approximately half of all research in the United States directly related to bipolar disorder. The Stanley Foundation Brain Collection obtains brains through designated medical examiners in several cities. The brains are then forwarded to the NIMH Neuroscience Center at St. Elizabeth’s Hospital in Washington, D.C. More than 200 brains have been collected so far and hospital and outpatient records are obtained with each brain to establish a firm diagnosis. All brains are fixed in a uniform matter: Half of the brain is frozen, and the other half is formalin-fixed. Selected areas of the brain thought to be involved in severe psychiatric disorders (e.g., hippocampus, basal ganglia, and prefrontal cortex) are dissected out and then sectioned into thin slices that are fixed to a glass slide.

The Stanley Foundation Neuropathology Consortium is a collection of 60 brains. The collection consists of four sets of 15 brains each from persons with schizophrenia, bipolar disorder, depression, and normal controls. The four sets are matched for age (mean age is 40), sex, race, side of brain, postmortem interval, and quality of brain DNA.

There are four main goals of the Stanley Foundation Neuropathology Consortium. The first is to make brain tissue from individuals with severe psychiatric disorders available to researchers. Secondly, different laboratories can measure the same thing in this uniform brain collection and be able to compare results. Thirdly, the consortium attempts to provide a composite picture of what is wrong in the brains of these individuals and how each differs from normal controls. Lastly, the consortium will be able to compare results on the brains of individuals with schizophrenia, bipolar disorder, severe depression, and normal controls to determine differences and similarities.

The 60 consortium brains are available at no charge to researchers worldwide. The brain specimens are distributed coded so that the research is conducted as a blind study. When the research is completed, the results are sent to Washington, and the codes are then sent to the investigators.
State of Florida Brain Bank

A brain bank was established by the State of Florida in 1985 and is supported by state funds. The bank was established as part of the state’s Alzheimer’s Disease Initiative (ADI), which supports research, service, and training in Alzheimer’s disease and related memory disorders. The objectives of the ADI Brain Bank are to provide tissue for Alzheimer’s disease research, to establish a diagnosis for use in clinical and pathological studies, and to provide families with a confirmed diagnosis. The bank is at the Mount Sinai Medical Center in Miami, Florida, and thirteen institutes in the state serve as sources of brains.

Brain tissue specimens are stored either frozen or fixed and more than 1,000 brains have been autopsied and stored. Tissue specimens are available to approved investigators at no cost.

Tissue Accrual and In Situ Imaging Core

The Wistar Institute maintains a tissue accrual and in situ imaging core to collect tissue specimens from melanomas, nevi, and blood samples. The core is supported by the NCI. The core has one of the largest collections of primary melanocytic cell cultures and freshly isolated DNA collections from these tissues. The core also has access to human tissue biopsies, including thousands of pigmented lesions from affiliated laboratories, such as Surgical Pathology (20,000 accessions per year).

Tumor Bank Facility at the Herbert Irving Comprehensive Cancer Center

The Tumor Bank Facility at Columbia-Presbyterian Medical Center’s Herbert Irving Comprehensive Cancer Center in New York was established in 1972 to maximize investigational use of human tissues removed at surgery or autopsy. The core facility provides a mechanism for optimal collection, examination, and distribution of all human tissues for investigative purposes. The Tumor Bank contains both “targeted” and “nontargeted” specimens. The nontargeted specimens are tumors and tumor/normal tissue pairs collected and cryopreserved in substantial numbers. Most tissue specimens are snap-frozen to facilitate subsequent preparation of frozen sections for histology, immunohistochemistry, and other types of analyses and to preserve tissue for DNA/RNA isolation. Columbia-Presbyterian Cancer Center members may request specific tissues types. Users of the Tumor Bank Facility must be members of the Herbert Irving Comprehensive Cancer Center, and there is no charge for the specimens.