The collection of blood specimens for disease testing, paternity testing, or forensic testing has grown enormously in the last quarter of the twentieth century. As biomedical technology advances, more and more testing will be performed on smaller and smaller sample sizes. Although tissue samples may be collected for a specific purpose, it is not unlikely for them to be used for other reasons. These large collections of human tissue samples have been a matter of concern for privacy advocates.

NEWBORN SCREENING LABORATORIES

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

A 1994 survey of all newborn-screening programs in all 50 states, the District of Columbia, Puerto Rico, and the Virgin Islands revealed that the majority of laboratories have accumulated less than 500,000 Guthrie cards over the years, seven have amassed more than 500,000, four reported collections of between one million and five million cards, and one reported a collection of six million (McEwen and Reilly, 1994). The number of cards collected over a one-year period ranged from <10,000 in four labs to >500,000 in two especially populous
states (McEwen and Reilly, 1994). For example, better than 99 percent of the 550,000 children born each year in California are tested for three genetic conditions (Reilly, 1992).

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

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

All states participate in some form of newborn screening, but few have issued regulations that explicitly define the scope of permissible use of Guthrie card samples (Andrews, 1995). Seven state departments of public health have issued written regulations on third-party access to Guthrie cards, and 10 of the laboratories have internal written policies on this matter (McEwen and Reilly, 1994). Over a five-year period, 28 laboratories estimated that they had received either no requests or fewer than six third-party requests, seven received six to 20 requests, two received 21–100 requests, and one, from a very large state, received more than 100 requests (McEwen and Reilly, 1994).

FORENSIC DNA BANKS

In 1989, the Virginia Division of Forensic Science was the first state laboratory to offer DNA analyses to law enforcement agencies and the first to create a DNA databank of previously convicted sex offenders. By November 1997, 48 states had established forensic DNA data banks of convicted criminals, especially vio-
lent sex offenders and other violent felons (Finn, 1997). The two states without forensic DNA banks, Vermont and Rhode Island, are planning legislation to create them (Finn, 1997). In addition, the Federal Bureau of Investigation (FBI) is exploring ways to create a forensic DNA bank for the District of Columbia (Finn, 1997).

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

CODIS provides a framework for storing, maintaining, tracking, and searching DNA specimen information. Currently, CODIS has been implemented in 45 states, encompassing greater than 90 percent of the U.S. population. Each CODIS database consists of three distinct indexes—casework, convicted offender, and population. The casework and convicted felon indexes are used to search for matching DNA profiles of specimens from crime scenes.

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

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

DNA profiles prepared from these samples have already proven valuable for tracing biological material found at crime scenes to felons with prior convictions. By February 1997, forensic DNA databanks had achieved more than 200 cold hits linking serial rape cases or identifying suspects by matching DNA extracted from biological evidence found at a crime scene to that of a known offender whose DNA profile was in the databank. For example, Minnesota’s DNA data bank was used to tie the same individual to 18 separate assaults (McEwen, 1997).

DNA testing has the power to not only implicate an individual in a crime, but also to exonerate an apparently innocent individual. Recently, a Texas man who had served 12 years in prison for rape was pardoned after he was cleared of the crime by DNA tests (Holmes, 1997). Semen samples kept from 1985 were tested and failed to match his DNA. Several private laboratories have been established in the last 20 years that offer DNA testing services, such as paternity testing, parentage testing, forensic DNA analysis, and expert witness services.