

Chapter 2

Sources of Liability

2.1 Forms of Legal Complaints

You get sued because someone (the plaintiff) thinks you (the defendant) have harmed her in some way. The plaintiff's issues can take different forms. Below is a brief introduction to some of the causes of action or forms these lawsuits can take. We will discuss some of these later in more detail as they apply to our day-to-day practice.

2.1.1 *Tort Law*

One of my neighbors drove a truck across my lawn so that he could trim the trees on his own property. My grass was torn up and the ground was left with deep ruts. My neighbor had knowingly damaged my property.

A tort is a civil wrong or injury for which the law provides a remedy. The wrong can involve individuals or a company, as opposed to an individual and some level of the government. The injury may be a wrong committed against a person, such as a bad faith breach of contract, or against a person's property, such as my lawn. It may be either a direct invasion of some legal right of an individual, an infraction of a public duty, or the violation of some private obligation. The wrong or injury has to be one that is recognized by the law and for which a court will provide a remedy (damages).

The remedy for the injury, the damages paid, is the compensation of the plaintiff. Damages are generally intended not so much to punish the tortfeasor, the negligent defendant, but to restore the injured person as nearly as possible to the position she would have been in had the wrong not occurred. The fundamental policies of tort law are (1) to compensate the victim, (2) to deter negligence, and (3) to encourage due care. One basic purpose of tort law is to keep the peace between people with issues by providing a mechanism for finding fault for wrongdoing and preventing individuals from seeking vengeance. In my case, my neighbor had to resod my lawn.

A number of forms of torts are applicable to health care and are reviewed below.

2.1.1.1 Malpractice

Negligence is the failure to comply with the standard of care to protect a person from harm. It may result from the performance of an act, which is an error of commission, such as removing the healthy kidney from a person with a multicystic, displastic kidney. It can also result from a failure to act, which is an error of omission, such as not obtaining an allergy history for a patient before administering penicillin.

The determination of whether a person was negligent requires a comparison of her conduct to a standard of care. If that conduct is found to have fallen below the accepted standard of care, then that person was negligent. Malpractice applies to all professions, and is called professional negligence. Negligence in medical practice is called medical malpractice.

An individual who thinks she has been injured by the malpractice of a health-care provider may bring an action against that provider for compensation. The time period within which a person has the opportunity to bring a malpractice action is set by state statute (statute of limitations). In the past, the statute of limitations for malpractice actions was often considered to begin at the time the treatment was rendered. That would be the time of the surgery during which the wrong kidney was removed.

Not everyone realizes, however, that she has been injured within that time frame. To avoid precluding justified claims for injuries that were not discovered until after that time period had elapsed, many states have rewritten their statutes of limitations. The revised statutes allow the time period to begin when the patient discovers the fact that medical malpractice has occurred. A woman whose Pap smear was misread would not necessarily know that at the time the test was performed. She would find out or discover that fact at the time she was diagnosed with advanced cervical cancer three years later. Under a revised statute of limitations, the time period for bringing a malpractice action would begin with the discovery of the error, not when the laboratory actually incorrectly read the preparation. Many of the negligence cases mentioned here were foreclosed by the statute of limitations in existence at the time of the case.¹⁴

Everyone wants and expects a normal, healthy child. We often meet people in our practices who do not realize that 2%–3% of all children are born with a major problem. As we have also experienced sometime in our careers, families look for someone (the mother, the doctor) or some thing (the bug spray, the evil eye) to blame when it is their baby who has been born with problems. Some birth defects or diseases could have been anticipated through counseling or testing. Others could have been avoided through alternative pregnancy management. Sometimes the problems that babies are born with can, with certainty, be attributed to malpractice.

A. Wrongful Birth

Wrongful birth suits can be brought by the parents of an unwanted child (these are also called wrongful pregnancy suits) or the parents of a child born with a disease or

defects. A wrongful pregnancy suit usually involves a failed sterilization, with the birth of an unplanned, unwanted, but healthy child.¹⁵

Some wrongful pregnancy suits involve the unplanned pregnancy and birth of a child with a genetic disorder or birth defect. For example, following failed sterilization of either the man or the woman, a child has been born with alpha-1 antitrypsin deficiency (*Weethee v. Holzer Clinic, Inc.*),¹⁶ albinism (*Pitre v. Opelousas General Hospital*),¹⁷ neurofibromatosis (*Speck v. Finegold*)¹⁸ and a congenital heart defect (*Simmerer v. Dabbas*).¹⁹

We will be looking mainly at those lawsuits brought by families affected by the birth of children with defects or diseases.

Prior to *Roe v. Wade*,²⁰ wrongful birth suits alleged that the physician's negligence, that is, her failure to act appropriately, was the proximate cause of the child's birth. After *Roe v. Wade*, the legal harm claimed in the majority of wrongful birth actions was not necessarily the birth of the child but the parents' lost opportunity to decide for themselves whether to continue the pregnancy of an affected fetus.

The parents' interest in self-determination has become the basis of these suits. Courts have found that a physician who negligently or intentionally withholds information about or misdiagnoses a disorder affecting a fetus has "impermissibly" deprived the pregnant woman and her partner of the opportunity to exercise the constitutionally protected right to make reproductive decisions. It also deprives these parents of the "opportunity to cushion the blow, mute the hurt, or prepare themselves as parents for the birth" of a seriously impaired child.²¹ The duty considered to be owed to the parents of the child is based on the public policy of promoting family unity in making decisions. It is also based on the recognition that when such a duty is breached, both parents share the emotional and financial burdens of a child's care. The first recognized successful wrongful birth case was in 1975, *Jacobs v. Theimer*.²² It involved a woman who contracted rubella during her pregnancy and was not warned of the possible consequences to the fetus.

Genetic counseling has become a more visible part of healthcare as it has been integrated into medical services in a variety of subspecialties. Errors in obstetrics and gynecology, family practice and internal medicine, for example, can impact the outcome of a pregnancy. In a case of negligent genetic counseling, the plaintiff would have a number of actions she could pursue. She could allege that the genetic specialist, or other healthcare professional offering genetic services, has failed to inform her that she was at an increased risk of having an affected child based on the fact that there was a genetic disorder in the family or on the basis of her ethnic background. She could claim that there were tests that were available but not offered that could have determined whether a disease or birth defect was present, or that the testing that was done was improperly interpreted. She could claim that tests were done but the results were not communicated to her. Birth defects could be attributed to medication used during pregnancy that was/may have been harmful to the fetus.

*Park v. Chessin*²³ is a good example of a negligent genetic counseling case. The Parks were parents of a child who died at 5 hours of age with polycystic kidney dis-

ease (PKD). They were told the recurrence risk for PKD was “practically nil.” The parents accepted that risk, relied on the information provided and had a second child. The second child was also affected and she died at age 2 years. A second example of negligent genetic counseling is *Lininger v. Eisenbaum*.²⁴ The physicians in this case failed to diagnose the first child’s blindness as Leber’s congenital amaurosis before a second affected child was born.

These cases illustrate the expansion by the courts of the definition of breach of duty to include the deprivation of the parents’ right of choice through the absence of or negligent provision of genetic counseling. Parents were found to have the right to recover for that tort of deprivation of their rights. We will be discussing other cases of negligent genetic counseling as they relate to aspects of our practice.

The plaintiff in a wrongful birth action does not need to prove that the doctor’s negligence caused the defect or disease. She must prove that her emotional and economic injuries were proximately caused by the negligence that deprived her of the opportunity to decide whether or not to continue the pregnancy.

B. Wrongful Life

Have you ever pondered the question of why you were born, or how you came to be you? These are philosophical questions that courts of law rarely address. More concrete claims concerning having been born, however, have come under consideration by the courts.

Wrongful life suits are brought by children born with birth defects or disease who claim they should not have been born at all, or having been born, should have been born whole (free of disease or defects). The infant or child does not claim that the physician caused her disease or her birth defects. Her claim is that the physician’s negligence failed to identify the problems, thus allowing her to be born into a life of suffering. The child claims she was harmed by being born impaired.

There have been very few successful wrongful life suits. They are almost uniformly rejected by state courts. In *Phillips v. United States*²⁵ and *Speck v. Finegold*,²⁶ the parents’ claims were recognized, but the affected children’s claims were not. A major exception was the 1980 case of *Curlender v. Bio-Science Laboratories*.²⁷ The plaintiffs claimed that the laboratory did not properly perform Tay–Sachs disease carrier testing and misinterpreted the test results. They were not identified as a carrier couple. The parents had a child with Tay–Sachs disease. That court found that a child born with Tay–Sachs disease has the right to recover for the pain and suffering she would have to endure during her lifetime.

The New Jersey Supreme Court, in the case of *Gleitman v. Cosgrove*,²⁸ is quoted most frequently by other courts when explaining why wrongful life cases should not be recognized. The New Jersey court rejected the child’s cause of action for wrongful life because it thought that damages in such a situation were impossible to ascertain. Remember, the definition of a tort is a cause of action

for which damages can be awarded. The court in *Gleitman* refused to weigh the value of life with impairments against nonexistence. In the court's view, nothing the defendants in a wrongful life lawsuit could have done would have given the child plaintiff an unimpaired life. That is, if the defendant had performed her job properly—for example, interpreted the parents' test results correctly—the child would not have been born unimpaired; instead, she would not have been born at all.

In contrast is the interesting “Perruche judgment” in France. This judgment established the right not to be born in a case of misdiagnosis of rubella during pregnancy. Public opinion was so strong against the decision that the outcry caused the judgment to be overruled by a majority of the National Assembly of the French Parliament.²⁹ More recently, wrongful life claims have been recognized for extraordinary medical expenses (see *Moscatello*).³⁰

Claims by or on behalf of children are typically tolled. That means that the statute of limitations that would ordinarily apply to the cause of action is suspended. It does not begin to run during the child's minority. Traditionally, injured children can bring claims up until they are 23 years old—once the child becomes 21 years old plus the typical two-year statute of limitations for malpractice actions. These claims can be brought by the child only if no action has been brought on her behalf by her parent or guardian.

2.1.1.2 Unauthorized Disclosure of Confidential Information

An acquaintance of mine received a telephone call from a friend who worked as a hospital clerk. My acquaintance's brother was a patient in that hospital. This individual thought my acquaintance would want to know that her brother had HIV/AIDs. There was no signed release, the brother is an adult, and the clerk had no authority to access his medical records. My acquaintance has not shared with her brother the fact that she has this knowledge.

The causes of action that may be brought for the unauthorized disclosure of confidential information include breach of privacy, breach of confidentiality, breach of loyalty, breach of contract (discussed in more detail below) and breaches listed in some state statutes.³¹ A communication that is confidential is one that has been shared with the intention of keeping it secret. A person seeking medical attention has an expectation of confidentiality based on the physician–patient relationship.

Violation of privacy was claimed in *Bazemore v. Savannah Hospital*)³² for the unauthorized production and publication of photographs of the plaintiff's child, who was stillborn with malformations. Breach of fiduciary duty was claimed in *MacDonald v. Clinger*;³³ when a patient's psychiatrist disclosed to the patient's wife some personal information that was learned in the course of treatment. Such a disclosure may have been justified if there had been a danger to the patient, his spouse or another person, but since these conditions did not exist, the psychiatrist was found to be liable for breach of fiduciary duty.

The physician–patient relationship has also been privileged, and thus protected, by state laws. As a rule of evidence, it gives the patient the right to exclude from evidence communications made by her to her doctor. Violation of this privilege is a statutory breach. The confidentiality of a patient’s medical records would be waived only if a malpractice suit was filed (see below).

2.1.1.3 Informed Consent

When I had genetic testing myself many years ago, I had to sign a consent form. Careful reading of that form revealed that the confidentiality of my test results was actually not well protected. I wanted the test and no other laboratories offered the analysis. I signed the consent form anyway. I have since been informed that my sample has been used for research purposes.

When a patient has a genetic test, the results can be straightforward or they can be unusual. We often see this, for example, with testing results for breast cancer genes and for cystic fibrosis mutations. Amniocentesis, when done for any reason, can reveal chromosomal abnormalities that are not common and are not common knowledge. More than one of my patients has been referred for counseling when her amniocentesis results were not normal, although I had not seen her prior to her testing. Sometimes I find that the patient does not know what a normal chromosome is, let alone what a chromosomal abnormality means. It makes me wonder how, with such a lack of understanding and information, she could have given informed consent for a procedure that is designed to count and look at chromosomes.

A claim based on the doctrine of informed consent is predicated on the patient’s right to self-determination—the right to make personal decisions. The doctrine of informed consent is rooted in the premise that every adult with a sound mind has a right to determine what will be done with her own body.³⁴ As we will discuss in greater detail later, a healthcare provider has a duty to disclose information to a patient that will enable that patient to make decisions about the options, risks and treatment involved in her care. The standard applied is what information a reasonable patient would want to know in order to make those decisions. The patient has to prove that there is a connection between the risk that was not disclosed to her and the harm that she ultimately experienced.

Informed consent actions are similar to wrongful birth causes of action in that they are based on a patient’s right to determine for herself the course of her care. There are important differences, however. In an informed consent case, the plaintiff must show proximate cause by proving that the risk that was not disclosed actually occurred and was caused by the treatment. In a wrongful birth case, the plaintiff does not have to prove that the negligence was the medical cause of the birth defect or disease, only that the risk to the fetus that was not disclosed was material to her decision, that it occurred, that it was reasonably foreseeable, and that if she had known of the risk, she would have terminated her pregnancy.

2.1.1.4 Emotional Distress

We all worry about the emotional response of a patient when we offer presymptomatic testing. The protocols for Huntington disease testing have taken into consideration and have prepared for some of the expected emotional responses to positive and negative test results.³⁵ Not all practitioners realize that harms or injuries are not all physical. Mishandling a case or a test result can lead to outcomes for patients that cause great emotional harm. An award of damages for emotional distress has been recognized as one of the few avenues of compensation for tortious conduct in wrongful birth cases (see *Berman*).³⁶

The courts do recognize that the death or serious injury of a family member may often produce emotional distress, sometimes quite severe, in another member of the family. Early claims for emotional distress were not found to be compensable unless there was an accompanying physical manifestation, such as agitation or sleep disturbance. Courts have come to recognize that mental distress and emotional distress are just as real as physical pain. They also realize that placing a financial value on emotional distress is no more difficult than placing a financial value on physical pain (see *Berman v. Allan*,³⁷ *Schroeder v. Perkel*³⁸).

In some situations, emotional distress can be anticipated. Every time a physician (or anyone for that matter) injures a child, it is foreseeable that the parents will suffer emotional distress. The physical and emotional ties between a mother and a fetus unite the two in such a way that a physician should anticipate that any malpractice that adversely affects the fetus will cause emotional distress to the mother. The father's interests have been found to be no less deserving of protection than the mother's. The physician's duty to the father is similar to that owed to the mother, as long as the father is sufficiently involved in the care of the pregnancy.

There have been attempts to extend wrongful birth claims to include members of the family other than the parents of an affected child. The grandfather of a child born with Tay-Sachs disease sued for emotional distress. The court pointed out that a grandparent does not have a physician-patient relationship with either the parents' or the child's healthcare provider. Although he may have been impacted by the claimed breach of duty, the grandfather has no legal basis on which to act regarding the information that resulted in the claim.

Grandparents have not been included along with the parents of an affected child as individuals who may recover for pain and suffering (*Michelman v. Erlich*).³⁹ Siblings have also attempted to bring wrongful birth lawsuits, but have been unsuccessful.⁴⁰ The duty of the healthcare provider is owed to the parents and the child with birth defects or disease, and at this time to no one else.

2.1.2 Fraud

The false representation of a material fact is fraud. In the nineteenth century, many medicines were marketed as panaceas or miracle cures. The ingredients were usually kept secret, unidentified or mischaracterized and mostly ineffective. The men who

touted these cure-alls, AKA snake oil peddlers, used exaggerated marketing as part of an elaborate and fraudulent scheme.

Fraud is the intentional distortion of the truth or deception through an act, omission or concealment in order to induce someone to give up a thing of value, such as money. It can be a single act or a combination of circumstances. The difference between fraud and negligence is that fraud is always intentional.

Fraudulent statements or intentional misrepresentation of results can, for example, include claims about what can be expected from a particular treatment, such as snake oil. The disappointed patient—the plaintiff claiming fraud—has to prove that the statements of reassurance were made with malice and were knowingly false. That can be based on an obvious existence of clinical findings, such as diabetes, which clearly indicate both before or after treatment that less-than-desirable results were inevitable.

2.1.3 Contract Law

A contract involves at least two parties, one who makes an offer of something, a product or a service (such as a consultation), and one who accepts the offer for a consideration or payment of a fee (such as a chicken). Contracts can be implied or express.

The relationship between a healthcare provider (physician, genetic counselor) and a patient (client) can be considered to be based on a contract in which there is an implied promise by the physician to the patient that the physician will function within the accepted standard of care. An express contract is created if the provider promises to cure the patient or to produce a specific result: “When we’re done, you’ll look like a movie star.” Not making good on an express promise may be a breach of express contract or breach of warranty. Of course, not everything a provider says becomes a contract.

Healthcare professionals can find themselves subject to a contract if specific promises are made (“You’ll be better than before.”). Overzealous assurances to a patient by a healthcare provider can be construed by that patient as a guarantee of a cure or a good result. These assurances can be as mild as, “You will be fine,” “You will return to normal,” “You will improve considerably.” Patients may transform such statements into firm promises in their own minds. An expressed guarantee of a stated result can create a contract (*Murray v. University of Pennsylvania Hospital*).⁴¹

In *Hammonds v. Aetna Casualty & Surety Co.*,⁴² the claim was interference with contractual relations. The plaintiff threatened to file a malpractice suit, prompting his insurance company to induce the physician to disclose information without authorization. The insurance company was found to be liable for inducing breach of confidentiality. This breach of confidentiality lawsuit claimed that the promise of secrecy is as much an express warranty on the part of the healthcare provider as a commercial advertisement. Actions for breach of warranty are usually against the manufacturer of a product. *Horne v. Patton*⁴³ claimed breach of contract as well as breach of confidentiality when the physician released personal medical information about an employee to his employer.

	Statute of Limitations	Level of Proof	Damages
Negligence			Higher
Breach of Contract	Longer	Easier	

Fig. 2.1 Comparison of actions for negligence and breach of contract

2.1.3.1 Abandonment

In general, a provider does not have to provide care to anyone who requests it. Once a person is accepted as a patient, however, there is a duty to provide continuity of care. A suit claiming abandonment may be based on the contractual obligation to attend to the patient properly and continuously until care in the particular illness is no longer needed. Abandonment is the total neglect of a patient, or the failure to give any care or attention to a patient for an extended period of time. A physician may not unilaterally discontinue the care of a patient without proper notice to the patient and the opportunity for the patient to reasonably secure other medical care.

Malpractice suits are not often brought under contract law. Most courts think that negligence is the only type of lawsuit that applies to the physician–patient contract because malpractice constitutes a breach of duty to the patient by the physician. There are advantages to claiming breach of contract rather than negligence. Many personal injury actions against physicians for breach of contract are recognized as thinly disguised attempts to avoid the unfavorable aspects of tort actions that would apply for negligent medical care. Proof and procedural rules are easier for the plaintiff to comply with in a breach of contract lawsuit than in a negligence suit. The statute of limitations is longer for breach of contract than for tort actions. In breach of contract actions, a medical standard of care does not have to be shown and allegations of fault are irrelevant. The plaintiff only has to prove (1) that a promise was made and relied on, (2) that the promise was not kept, and (3) that damages resulted. A limitation of breach of contract suits is that only out-of-pocket losses can be awarded. Damages for emotional distress and punitive damages for breach of contract are more limited than for negligence. Suing for negligence has the potential for large general damages for pain, suffering and mental anguish.

Figure 2.1 presents a comparison of actions for negligence and breach of contract.

2.2 Legal Initiatives

There is legislation on both the state and federal levels that addresses issues that are of interest to genetic counselors. Although these laws may not directly influence our day-to-day decisions, they do impact the lives of our clients. They were enacted in part to address the fears of the public and professionals of unfair use of genetic

information and discrimination against those with positive presymptomatic genetic test results. On a public policy basis, they also encourage the participation of people in genetic testing for purposes of treatment, prevention and research. The following is an introduction to some of these laws.

2.2.1 Federal Regulations

2.2.1.1 Disability Discrimination Legislation

Disability discrimination legislation has been enacted on the federal and state levels to protect individuals from employment and/or insurance discrimination. The Federal Rehabilitation Act of 1973⁴⁴ protects individuals with physical or mental impairment who are otherwise qualified from being excluded from participation in any program or activity receiving federal financial assistance solely on the basis of their impairment.

This act was intended to prevent employers from not hiring an individual who they may think may increase the costs of healthcare within the company or who may not be able to work on a regular basis. A person who (1) has an impairment that substantially limits one or more major life activity, (2) has a record of such an impairment, or (3) is regarded as having such an impairment is protected by this Act. For our patients, this might include someone, for example, with a known gene mutation.

The Americans with Disabilities Act (ADA) of 1990⁴⁵ broadened the scope of the protection afforded by the Rehabilitation Act by including private employment in companies that have 15 or more employees. The U.S. Supreme Court, however, has held that the ADA requires proof under the first part that the limitation on a person's major life activity by the impairment be substantial.⁴⁶

The ADA requires that people who may have a genetic disorder not be treated in any way that is different from others in all aspects of employment (Title I), public access to services (Title II) and facilities (Title III). Under the ADA, an employer is not compelled to prefer an applicant with disabilities. The employer is restricted from rejecting the applicant on the basis of the disability or on the need to make reasonable accommodations for the individual. The ADA prevents the use of genetic tests or medical examinations to discriminate against a job applicant. Once a job is offered, the employer may then require a medical examination. For further illustrations of the application of the ADA to individuals with genetic conditions, Alper and Natowicz (1993)⁴⁷ offer some interesting hypothetical cases.

An employer is required to keep any medical information about an employee confidential and separate from the employee's general personnel records. The ADA has been interpreted by the Equal Employment Opportunity Commission (EEOC) to include genetic information. EEOC policy is not law. It only offers guidance in applying the law. The first case brought to the EEOC alleging job discrimination was filed by a woman from North Carolina who was fired when she began

treatment for alpha-1 antitrypsin deficiency. Terri Seargent was tested following the diagnosis of her brother, who died about 18 months later. Ms. Seargent was employed by an insurance broker who was self-insured. Even with good performance evaluations she was fired. The EEOC supported Ms. Seargent's claim of genetic discrimination.⁴⁸

In 1995, the EEOC issued a statement supporting the view that having a gene mutation creates the perception of disability in Title I (employment) cases. This means that discrimination against asymptomatic individuals by employers on the basis of a genetic predisposition falls under the ADA, because those individuals meet the third part of the definition of impairment when they are regarded as having a disability.⁴⁹ A woman who loses a job because she has a breast cancer gene mutation, although she is presently healthy and cancer-free, would be protected under the ADA.

The Civil Rights Act (CRA) of 1964⁵⁰ is a comprehensive civil rights law. As amended, it addresses discrimination on the basis of race, nationality and gender, among other classifications. These are considered "immutable characteristics," that is, characteristics with which an individual has been born. Title VII of the CRA addresses equal employment opportunities and broadly prohibits discrimination in employment. Classification of employees on the basis of race, for example, is not permissible, whether a particular practice has a discriminatory purpose to begin with or a disparate impact on any one race. It has been suggested that Title VII could also be used to protect individuals with genetic disorders or traits that are found in a specific race or sex from discrimination in employment. Discrimination against a person with sickle cell anemia, for example, because hemoglobin S is found more often in the black population, might conceivably be interpreted as prohibited under Title VII.

2.2.1.2 Privacy Legislation

The Privacy Act of 1974⁵¹ protects personal information that has been gathered and is maintained by the government. It prohibits federal hospitals and agencies, among others, from disclosing any information that is in patient medical records without a written consent.

The Privacy Act lists the practices that the government must follow when collecting, using or disclosing personal records. These "fair information" practices also include, besides the requirement of a written consent, the opportunity for individuals to review and correct the personal information in their records. The government allows public access to records maintained by federal agencies within the executive branch of the government through the Freedom of Information Act (FOIA).⁵² Exceptions to the FOIA include personal information that would be used for commercial purposes, and personnel and medical files, that is, those files that might result in an invasion of privacy if released.

Both the Privacy Act and the FOIA have limitations. They only protect federal records, and do not, most importantly, extend to the records kept by state governments or in the private sector. Under these acts, federal agencies retain

the ability and discretion to disclose some data without the consent of the individuals involved. Also, the judiciary is empowered to require federal agencies to disclose healthcare records if they are necessary for the administration of justice.

Medical records no longer exist only in paper form. Congress recognized the need for a comprehensive law that would address the confidentiality of patients' electronically maintained medical records. One goal of any legislation was to maintain the public trust in the healthcare provider-patient relationship without undermining the efficiency of the modern healthcare delivery system.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996⁵³ set national standards for protecting the privacy of a patient's health care information and medical records that are transmitted or maintained. Paper records and oral statements are included under HIPAA. It protects healthcare information that would, or might, identify a particular patient.

Congress was given a time limit within which to pass privacy legislation. When no new legislation was passed, the U.S. Department of Health and Human Services (DHHS) Secretary had the responsibility to develop the rules and regulations for HIPAA. These rules are based on principles outlined by then DHHS Secretary Donna Shalala. She wanted boundaries that prevented healthcare information from being used for purposes other than healthcare.

Information needs to be secure in the absence of the patient's approval for distribution. Consumer control over the content of and access to records, as well as the accountability of those who disclose that information, were recommended. Public health research and safety were recognized as exceptions.⁵⁴ The final regulations had to be fully implemented by April 14, 2003 (April 14, 2004 for small health plans).

HIPAA was not the first privacy law enacted, but it is a broad law that sets a minimum level required for the protection of patient confidentiality and medical privacy. Some states may have stricter rules than HIPAA, and those rules apply in that particular state.⁵⁵ HIPAA applies to what are called "covered entities." These include health plans, healthcare clearing houses, healthcare providers and any person or organization that furnishes, bills or is paid for healthcare in the normal course of business.

For purposes of HIPAA compliance, "covered entities" includes the workforce of that entity. If you work in any setting that is within the definition of a covered entity, you must comply with HIPAA regulations. For private practitioners, any licensed or certified professional is considered a covered entity. HIPAA regulations will apply to the electronic transmission and storage of the patient's medical records. Although there are no differences made among the types of information covered by HIPAA, genetic information, test results and family histories contained in a patient's record would be included in the definition of personal information. You must have reasonable safeguards in place to protect, limit the use or disclosure of your patient's information to the minimum necessary.

Glaring violations of HIPAA carry federal criminal consequences including fines as high as \$250,000 and ten years in prison. HIPAA regulations impact many differ-

ent aspects of healthcare. We will return to them in our discussion as and when they affect our practice.

2.2.2 *State Regulations*

2.2.2.1 Nondiscrimination

Many states have genetic privacy acts. These acts define what constitutes a genetic test, what protections need to be in place to protect the patient's privacy, and what points need to be included in the written consent for genetic testing. There are regulations that address discrimination in employment and in health insurance. There does not seem to be agreement among the states as to what constitutes genetic information. The first state to address genetic discrimination was North Carolina in 1975. It prohibited discrimination in employment on the basis of sickle trait. Wisconsin became the first state (1991) to enact a comprehensive law prohibiting discrimination on the basis of the results of genetic tests.⁵⁶ Each person should be familiar with the regulations in his or her state.⁵⁷

Both federal and state agencies also prosecute fraud in healthcare. In healthcare, fraud has been found⁵⁸ in billing for services, supplies, or prescriptions not provided; in billing for a procedure that is more expensive than the one provided; in the use of treatments that are not required; and in taking payment in the form of rebates and referral fees. Knowingly making false and fraudulent claims under the Medicaid and Medicare programs is a felony. Using the U.S. Postal Service to commit such fraud adds penalties. Criminal prosecutions can involve going to jail, paying high fines, and losing your private property.

2.2.2.2 Licensure Boards

Licenses to practice certain professions are provided under state regulation. To protect the public's health and welfare, a state has the right to exclude any incompetent practitioner, as well as to evaluate professional practice on a continuing basis. Licensed professionals are obligated to act within the parameters set out by their licensing act. Medical practice acts create and define the composition of a state medical board with the authority to license candidates. Medical boards receive and investigate complaints of unprofessional medical conduct. Revocation of a license is the most severe consequence of medical discipline.

Genetic counselors are not licensed in all states. As of July 2006, the five states listed in Table 2.1 have enacted licensing requirements for genetic counselors.⁵⁹ In those states, a mechanism for receiving and investigating such complaints has been established. In Utah,⁶⁰ for example, the Commerce Department, Division of Occupational and Professional Licensing oversees the licensing of genetic counselors. An appointed Genetic Counselors Licensing Board assists and advises the division with the review and investigation of complaints.

Table 2.1 States with licensing requirements for genetic counselors (as of July 2006)

California (2000)
Illinois (2004)
Massachusetts (2006)
Oklahoma (2006)
Utah (2001)

Master’s-trained genetic counselors are not physicians. The line between what a medical geneticist may do for a patient and what a genetic counselor may do must be kept clear. Licensing boards define what a licensed medical practitioner is permitted to do as far as concerns procedures, actions and processes. Usually, these are limited to what the individual has been taught and trained to do, and what she has demonstrated competency in. Professional organizations can also develop a scope of practice for their members. A Scope of Practice for genetic counselors has been approved by the Board of Directors of the NSGC.⁶¹ Patients should not leave your office with the impression you are a physician. People need to be corrected when they call you “doctor.”

2.2.3 Criminal Complaints

Some cases of negligence are so extreme that civil liability is considered insufficient to address them. These rare cases almost always involve charges of either reckless (a perceived risk has been disregarded) or intentional gross deviation from the accepted standard of care. A state can begin criminal procedures against a physician for an action that was a gross deviation from the professional standard care. The state must prove beyond a reasonable doubt that there was reckless disregard of a patient’s safety. This is a higher standard than the standard that applies for medical malpractice (Table 2.2).⁶²

The following case represents a good example of intentional gross deviation from standard of care. In 1969, a chiropractor discouraged the parents of a child with cancer of the eye from seeking the traditional, known treatment. He was convicted of second-degree murder when the child died despite his attempts at faith healing.⁶³

The American Medical Association has issued a position statement that opposes the criminal treatment of medial negligence,⁶⁴ unless the physician’s conduct is found to be reckless, or an injury to a patient is the result of willful and intentional behavior. In *People v. Klvana*⁶⁵ the physician was charged with nine counts

Table 2.2 Standard of proof required

Medical Malpractice: Proof of a breach of duty resulting in harm to the patient by preponderance of the evidence.
Criminal Prosecutions: Reckless or intentional gross deviation from the accepted standard of care beyond a reasonable doubt.

of second-degree murder. The counts all involved the deaths of fetuses around the time of delivery.

Practicing outside the scope of your practice as defined by your licensing act or your professional scope of practice might be a source of liability. Practicing medicine without a license has been found to be a criminal activity. Anyone who practices as a physician when not qualified to do so can be prosecuted. The definition of what constitutes practicing medicine can be found in the scope of practice included in each state medical licensing act. People who have had medical licenses revoked but continue to provide medical services, and healthcare providers who misrepresent their credentials, are included in this category.

There are several defenses that can be used to try to excuse criminal responsibility:

- *Infancy*: Children under 7 are usually presumed to be incapable of committing a crime. This presumption changes as a child gets older, with increasing responsibility through age 18, the usual age of majority. For medical negligence crimes, this defense would not be useful. The training requirements for physicians and for genetic counselors would preclude an individual attaining the skills and knowledge for practice before the age of 18 years. An individual can theoretically graduate from high school at 15 years old, complete college in two years and do her graduate training in one year. She would still be more than 18 years old at the completion of her education. In reality, a genetic counseling graduate student could be 17 years old at the start of her training. Because she would want to become a certified genetic counselor, she would choose to attend an ABGC-accredited training program. The guidelines for ABGC accreditation of training programs include a minimum amount of academic and clinical hours that is recommended to extend over a minimum of 21 months.⁶⁶
- *Mental illness* as a defense to criminal charges presumes an inability to hold the defendant morally responsible for her conduct if she lacks the capacity to appreciate the criminality of her conduct or to conform to the requirements of law. A genetic counselor who is experiencing difficulty maintaining her emotional balance hopefully would feel comfortable asking for help or be identified as needing help by her colleagues. The NSGC Code of Ethics reminds us that our relationship with colleagues is based mutual respect, caring and support.⁶⁷ This would include helping colleagues in emotional distress.
- *Intoxication* may result in the impaired ability of an individual to appreciate the significance of her conduct. Genetic counselors do not typically work in isolation, although there are a growing number of genetic counseling private practitioners, we would not expect them to be totally isolated from other healthcare providers. A counselor who is working while intoxicated, whether on drugs and/or alcohol, will eventually reveal her limited abilities to her colleagues. This is not a defense, but an excuse, and would add an additional count to any criminal complaint.
- *Mistake of law* is an unusual excuse, as there are very few exceptions to the rule that ignorance of the law is no excuse. It is also not a real defense. I often hear people discuss legal questions with great authority despite any understanding or knowledge of the law. If there is a legal issue that may impact how you han-

de a case, the best course of action for you is to consult with your attorney or risk manager. Institutions have legal counsel available for just that purpose. For private practitioners, it would be wise to have an attorney with whom you can consult. The long-term savings are worth the short-term costs.

- *Entrapment* excuses the commission of a crime if a law enforcement office or agency has actually instigated or induced an otherwise innocent person to commit the crime in question. This is an unlikely, although not impossible, scenario for genetic counselors. I have had telephone calls inquiring as to my professional position regarding pregnancy termination and amniocentesis as a path to abortion. If I put on my conspiracy-theory hat, I can imagine those calls being made by a government agency. It is not too far-fetched to imagine a future in which *Roe v. Wade*⁶⁸ has been overturned and the government attempts to identify those who may be still providing termination services by setting up appointments, for example. Think back to the government activities that occurred during the Prohibition era.
- *Duress* occurs when a person commits a crime under the threat of personal danger (death or great bodily harm) by someone else. I cannot stretch my imagination enough to conceive of a genetic counseling situation that would include doing genetic counseling under duress.

2.2.4 Organizational Requirements

Institutions are not immune to lawsuits. If a hospital, for example, has failed to act to protect the interests of the patients admitted to its facility when it has had notice of the negligence of a physician, liability can be imposed on it through vicarious liability.⁶⁹ Organizations, institutions and corporations have written policies regarding many aspects of the services provided under their auspices in part in order to avoid such circumstances.

Codes of conduct are often included in written policy manuals, as are procedures for test, medical and personnel record confidentiality, storage and retention. Conflict of interest concerns inform the policies on gifts from clients and from industry contacts, on honoraria for various professional activities, on relationships with suppliers, and on either concurrent or subsequent outside employment. Policy manuals that present these organizational requirements are available to the public.⁷⁰ Organizations employ clinical professionals directly or indirectly through contractual relationships with them.

Management decisions and policies may affect the way your job is performed. Dilemmas can arise when you are expected to perform your duties in a manner that may be contrary to your professional ethos. I know a genetic counselor who was directed to present testing options to her clients in such a way that they would opt for one particular procedure. There was an institutional need to provide a new physician with a large number of patients. I had a similar experience when I was instructed by my organization to “Never use the ‘A’ word.” All the many ways to say abortion were

included, such as termination of pregnancy, voluntary interruption of pregnancy, change of pregnancy management plans. My Code of Ethics, however, says “Clarify alternatives” (II.4), and my Scope of Practice says “Discuss available options” (I.7). This put me in a very difficult position, both personally and professionally.

Everyone agrees that patients’ questions always have to be answered honestly. In my particular case, I found that, although this organizational policy seemed to put me in a bind, I did not need to initiate that discussion very often. If the situation required such a discussion, though, I felt that I had to put the patient’s needs first. Patients have a need and a right to know all of their options, whether or not they can access them at that institution. The organization changed its policy over time to one of inclusion. I was, of course, happy to comply with the new policy. If you find yourself caught in the position of having to decide between conflicting organizational requirements and professional expectations, you can seek advice from your organization’s ethics committee and/or the ethics committee of the NSGC.

There are corporation compliance programs at institutions that emphasize the ways in which employees can conform to the laws and regulations that apply to healthcare. It is the responsibility of the compliance officers in those organizations to develop a program that raises the awareness of the employees with the aim of keeping them from violating any rules or regulations, either knowingly or unknowingly.

A campaign to stop employees from talking about patients in elevators is one such program designed to protect patient privacy. It is the individual provider/employee’s responsibility to acquaint herself with the legal regulations and policy standards and restrictions that apply to her own assigned duties and responsibilities, and to conduct herself accordingly. In an adolescent clinic, for example, you would need to know and understand when and how a minor becomes emancipated. You would also need to know the rules about when and what you may discuss with an emancipated minor’s guardian. We will discuss this, and other rules and regulations that impact genetic counseling practice, throughout this book.

2.3 Private Practice

The provision of genetic counseling is not limited to institutions. It is also offered within the private sector. A useful guide to practical strategies and recommendations for those contemplating going into private practice is available on the NSGC website.⁷¹ Many of the concerns raised for genetic counselors employed by an institution, such as the issues of privacy and confidentiality, are the same as for those in private practice. The NSGC Code of Ethics is relevant to all genetic counselors, regardless of the specific employment environment. Section II is not specific to any one genetic counseling role, but addresses the relationship with clients in general.⁷² The Scope of Practice for genetic counselors applies to those providing clinical services, regardless of the employment environment, private practice or employed by an organization.⁷³

HIPAA rules apply to genetic counselors in private practice. A genetic counselor can be considered a covered entity if (1) as a professional you are certified or licensed, (2) you provide, bill or are paid for healthcare services in the normal course of your business, and (3) you transmit any health information electronically.

Patients who come to your office for the first time must be given a notice of privacy practices that is written in plain language.⁷⁴ Over time, you have to be prepared to give a patient an accounting of any disclosures of personal health information you have made in the last 6 years. This includes the date, name of the person to whom you gave the information, the data that was disclosed and the purpose of the disclosure. This is all information you would want to have in the client's chart. You may also want to keep Title III of the ADA in mind when setting up your office. You want to make your office accessible to people with disabilities if it is easily accomplished.

The Security Rule of HIPAA may also apply to genetic counselors who contract with a covered entity, such as a hospital or medical group. As a business associate, you must safeguard the confidentiality, integrity and availability of the electronic health information you create, keep or transmit. Complying with HIPAA's Privacy Rule will help you satisfy the Security Rule standards.

There are some areas of concern that may apply in private practice that do not overlap with the genetic counseling practice of those employed by an institution due to the nature of private practice.

2.3.1 Partnerships

You may decide not to practice alone, but to form or join a partnership. You need to be aware of your liability. *Common partnerships* are formed when two or more individuals or co-owners (general partners) provide a business for profit. There is full personal liability for the debts of the partnership which may be unlimited. Your share in the profits will be consistent with the partnership agreement. A *limited partnership* is formed with at least one general partner and one or more limited partners. Limited partners contribute to the partnership and obtain an interest from it, but may not be co-owners. The liability for partnership debts for limited partners is only to the extent of their contribution. As an individual or as a partnership you may employ someone who provides genetic counseling services for you. Employers could be found responsible for the negligent acts of their employee counselor through indirect liability.

2.3.2 Billing

Fees for services provided by an institutional employee are usually set by the institution. As a private practitioner, you decide what services you will provide, you set your own fees, and you locate your office where you want to see clients. You may

find yourself in competition with other private practitioners and with institutions offering genetic counseling services. You should be aware of some potholes that may involve people in business. Although not strictly a billing issue, federal and state laws prohibit a physician from referring a Medicare or Medicaid client to a healthcare service in which she has a personal financial interest. The federal laws⁷⁵ regarding self-referral are complex and have a long list of exceptions.

Another issue is the manipulation of the market. One form of competition can be eliminated by fixing your fee at a level that can control the market. Price-fixing can be avoided by not agreeing with any of your competing providers on any term of price, quantity or quality. When competitors agree to divide geographic markets or customers, the outcome is called market allocation. This can even take the form of agreeing where to locate your office.

Payments from others or from third parties should be easily justified. If you receive payments in the form of rebates and referral fees that are used as business inducements, these qualify as kickbacks. Most kickbacks are illegal. As a private practitioner, you will most likely do your own billing. Knowingly filing a false or fraudulent claim for payments from Medicaid, Medicare or other third-party payers is prohibited by state and federal laws. If you offer group counseling sessions, you cannot bill each participant for an individual consultation.

Institutions and physicians have been charged with, for example: performing surgeries that were not necessary, billing for additional services and add-ons that were not provided, billing out-patient services as if they were provided to an in-patient, double billing, physician billing for services provided by interns, forging physician or patient signatures, and billing for cancer treatments that were covered by research grants.

After finding in 1995 that the University of Pennsylvania Health System had fraudulently billed the Medicare program, the DHHS instituted a nationwide audit program of attending physicians and physician groups at other institutions. Thomas Jefferson University in Philadelphia was the subject of the first audit and paid a \$12 million settlement. More recently, St. Barnabas Health Care System in New Jersey agreed to pay \$265 million to settle a False Claims Act lawsuit for overcharging Medicare.⁷⁶

2.4 Industry/Technology

Industry, as we use the term, refers to the production and sale of medical devices, tests, and pharmaceuticals. Genetic counselors work in industry in a number of capacities, such as clinical coordinators or educators. Many are guided by the role definition of the industry. The issues for genetic counselors working in industry encompass client privacy/confidentiality as well as truth-telling and conflict of interest. There are also potholes at the boundaries of those roles and services, with the possibility of crossing over into a clinical role.

Clients can experience injuries that are caused by a medical device or a drug. People who are injured by a device or a technology can sue a company under product

Table 2.3 Example of warning created to protect manufacturer

Caution: Using this medication alone, with other medicines or with alcohol may lessen your ability to drive or to perform other potentially dangerous tasks. Do not drive, operate machinery or do anything else that could be dangerous until you know how you react to this medicine.

liability laws for defective products. A product is considered defective if it is not “reasonably” safe. This standard can also be applied to pharmaceutical products. A drug is considered to be defective if the foreseeable risk from using the drug was so great in relationship to its benefits that no reasonable physician would ever prescribe it for any patients. Needless to say, this is very difficult to prove.⁷⁷

The Food and Drug Administration (FDA) does not usually require suppliers of medical technologies to communicate risk information directly to patients. Drug manufacturers provide warnings and instructions to the physician. These warnings create an intervening level of protection for the companies (Table 2.3).

Prescription drug inserts serve to reinforce and augment the information given by a doctor to the patient.⁷⁸ Providers, however, are expected to fulfill a separate duty to exercise good judgment particularly when applying new technologies and procedures (*Jones v. Karrker*).⁷⁹ In a case in which a woman used Accutane in the first trimester,⁸⁰ the court ruled that the manufacturer’s warnings about the dangers of Accutane therapy were adequate. The company had developed a Pregnancy Prevention Program for physicians to use which included patient information and a consent form that patients signed. The defendants were shown to have complied with the prevention program protocol.

2.5 Reproductive Technology

People have many technological options available to them for family planning. The legal requirements for such technologies begin with the duty to exercise good judgment when applying new technology or procedures.⁸¹ Organizations offering preimplantation genetic diagnosis (PGD) have been sued for failure to perform proper testing.⁸² Efforts to plan technologically assisted reproduction involve the law of contracts, which has threatened to supplant family law in determinations of parentage. When couples divorce, property, contract and family law have all been brought into the conflict over what to do with stored frozen embryos.⁸³

2.6 Research

Genetic counselors fill many different roles in research. Some are the principle investigators, while others act as project coordinators. Some of us have participated as subjects. As a graduate student, I was a subject in a project that looked at the

levels of hexosaminidase A over a defined period of time. Because of questions that came up in the course of the testing process, both my parents were conscripted to be tested!

There are controls on the research community from different sources. For genetic counselors participating as coordinators or investigators in research projects, the institution that sponsors the work will have oversight responsibilities about which you need to be aware. There are also federal regulations that may apply. The boundaries between medical research and clinical practice or accepted therapy are not always clear.

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued a report that addressed this subject. Known as the Belmont Report,⁸⁴ it defines “practice” to include interventions that are designed to improve the well-being of an individual patient and that have reasonable expectations of success. “Research” is considered an activity that is designed to test a hypothesis, permit conclusions to be drawn, and to develop or contribute to universal knowledge. Formal protocols describe the objective of the research and the procedures that will be used.

2.6.1 Human Subjects

Research with human subjects is invaluable when it results in benefits that can be applied to the understanding and treatment of disease. History has taught us, however, that the abuse and misuse of human subjects, both adults and children, has been more common than we would like to think. Plutonium exposure studies were conducted in the 1940s on men, women and children who were thought to be terminally ill. The subjects were not told what the substance was with which they were injected. They were not told that they were be given 2 to 14 times the dose that was the standard at the time.

In the 1950s, women were given diethylstilbestrol (DES) during pregnancy as part of a research protocol without having been told and without having given consent to participate in the project (*Miller v. University of Chicago*).⁸⁵ In *Ahern v. Veterans Administration*,⁸⁶ the patient received doses of radiation to treat his cancer that were much higher than the dose that was the accepted standard of care at the time. The court in that case ruled that a patient must always be fully informed of the experimental nature of a treatment.

The foundation of the guidelines for research with human subjects is the Nuremberg Code.⁸⁷ The ten-point Code begins with the need for the informed consent of the participant: The voluntary consent of the human subject is absolutely essential. The Code serves as the core of all the standards that have been written since, including the Belmont Report. The Belmont Report was a response to the ethical problems in research projects such as those cases mentioned above. It developed basic ethical principles to govern research with human subjects.

Consent is required in all cases in which an investigational drug is administered for either scientific knowledge or to patients who are receiving medical treatment.

Federal regulatory agencies, such as the FDA and the DHHS, mandate extensive disclosures to subjects who are enrolled in clinical trials. Consent forms that are employed should use words that make the project understandable.

Some people argue that the standards for consent should be higher in research than in regular medical care. Their reasons include the greater uncertainty about the therapeutic benefit, the heightened concerns about conflict of interest, and greater uncertainties about the risks of the interventions.⁸⁸ Although some courts recognize a duty to simply reveal the experimental status of a treatment to the patient, others impose heightened requirements. In nontherapeutic research, that is, research that involves healthy volunteers or studies on patients that are not designed to test potential treatment, some courts have required higher requirements for informed consent.⁸⁹ This consent may include information about whether a drug used for treatment had FDA approval. An informed consent to research participation does not preclude lawsuits based on perceived poor outcomes.

In *Ande v. Rock*,⁹⁰ parents of a child with cystic fibrosis sued for failure to timely disclose the results of cystic fibrosis testing, claiming the child suffered health consequences due to a two-year delay in treatment. The child had been in the control group of a research project, and the parents claimed that they were not told that she was tested for and had cystic fibrosis. A second child was born with cystic fibrosis during the time period of the research.

If a court finds that the decision to continue a patient in a test group was negligent, serious questions may arise about the validity of exposing such groups of patients to potentially dangerous agents or environments. Monetary or other inducements to encourage enrollment in clinical trials could bias the sample or coerce continued participation, and is usually considered inappropriate.

2.6.2 Gene Transfer

Clinical trials of human gene transfer, a cutting-edge biotechnology, involve the therapeutic or experimental administration of genetic material to human beings. Gene transfer raises concerns that are different from those raised in conventional drug research. These include the threshold toxic effects, hazards of viral recombination and accidental gene transfer to personnel, poorly characterized risks of insertional mutagenesis, and the possibility of inadvertently affecting the germline of trial participants.

Human gene transfer therapy may need special safety and ethics reviews. Problems that arise can have life-threatening consequences. Recently, three cases of children who had undergone treatment for adenosine deaminase–severe combined immunodeficiency and who had developed leukemia were reported.⁹¹ The Recombinant DNA Advisory Committee recommended the continuation of retroviral human gene transfer studies, because of the lack of data to warrant stopping them.⁹² The case of *Gelsinger v. University of Pennsylvania* (Pa. 1999), which settled out of

court, raised questions of informed consent, conflict of interest, and ethics violations in the gene therapy phase one safety clinical trial for ornithine transcarbamylase (OTC) treatment.

2.6.3 Clinical Testing on Research Samples

DNA is commonly stored in the laboratory in the form of blood, saliva, and tissues removed during surgery, or is extracted from these samples. Informed consent for testing to be done on samples taken for research should be obtained prior to acquiring samples. The consent needs to be detailed and include the patient's permission to contact her if clinical information comes to light. Pathology samples, newborn screening samples, and DNA collected as part of medical care can be sources of samples for research.

The federal oversight is largely limited to economic regulation and done through government regulations that apply to funded projects. Scientific misconduct by researchers may lead to sanctions that can be administrative, such as restrictions on specific activities or expenditures or ineligibility for government grants and contracts. There can possibly be criminal sanctions for false statements and false claims that violate federal prohibitions.

Compensation from research sponsors to healthcare providers for their participation in clinical research is prohibited by federal kickback laws if it is intended to induce the purchase of drugs or services paid for by federal funds. Scientific misconduct is defined as "fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research."⁹³ Because institutions are typically the recipients of federal funding for research, the responsibility for oversight of the projects is also part of the institution's purview.⁹⁴

2.6.4 Institutional Review Boards

As a result of earlier abuse of human subjects in research projects, we now have safeguards in place to monitor research protocols. The federal government requires all institutions that receive federal funds for research with human subjects to establish institutional review boards (IRBs) and obtain voluntary informed consent from participants.⁹⁵ The federal policy that formalizes and enforces the protection of human subjects in federal agencies and departments is known as the "Common Rule."

Research protocols and consent forms are reviewed by IRBs. These committees are charged with responsibility for reviewing and approving prospective research protocols. They enforce regulations and oversee the protection of research subjects. Not all research projects need to be reviewed and approved by an IRB. Research

done with anonymous data (see Section 2.6.5 for an explanation of anonymous data), or studies involving the use of questionnaires or interviews may not need to be submitted to an IRB.

Before you start such a research project, it would be helpful to touch base with the Chair of the IRB at your institution and ascertain which guidelines your institution follows. Federal rules do not preempt state tort laws, and institutions and IRBs may face liability for injuries suffered by the subjects of a research project. Research that is not federally funded or regulated by a federal agency does not require the approval or oversight of an IRB. Commercially funded research conducted with no government funding is not subject to IRB procedures. HIPAA's Privacy Rule does not override the Common Rule or the FDA's regulations governing the use of human subjects.⁹⁶

2.6.5 Epidemiology

Epidemiological studies track and compare large groups of individuals over an extended period of time. It is a research method used to describe the occurrence of disease in populations and to identify the causes of disease. The study group may include an entire population, or it may involve randomly selected members of the population selected on the basis of special characteristics. Research projects may be retrospective or prospective.

Confidentiality and privacy play important roles in epidemiological studies, and are ensured by the use of anonymous identifiers. Personal health information can be used for epidemiological studies under HIPAA rules. The information must be created in a form that is not individually identifiable by "de-identifying" it. This can be done by removing 18 specific identifiers. The list of identifiers includes the following: name; street address; city; county; precinct; ZIP code; Social Security number; date of birth (except year alone); admission and discharge dates (except year); age over 89 (including date of birth and year of birth alone); telephone, fax, medical record, insurance and account numbers; e-mail address; certificate/license number; vehicle identifiers and serial number (including license plates); device identification and serial numbers; URLs and Internet Protocol address number; biometric identification (including finger and voice prints); full face and profile photographs; and any other unique identifying number, characteristic or code.

2.7 Trainees

Many genetic counselors participate in the clinical component of genetic counseling training programs. When I was a trainee, there was very little I was expected to do in my clinic placements. The role of genetic counseling interns has been better defined and is now more participatory.

As a supervisor, I have worked with trainees of all levels of capability. Some

need close supervision, while others have the skills needed to conduct a counseling session independently. Some trainees have no confidence, while for others it is possible to anticipate a future successful professional career. Before delegating responsibilities to others, you need to be sure that the individual is competent to handle them. As a supervisor of a student or trainee, you are responsible for what is said and done in a consultation.

Courts have found that a supervisor is responsible for any negligence committed by a student while that student is acting on the supervisor's behalf. The liability that is derived from your role as supervisor is called "vicarious liability". Your responsibility and potential liability for mistakes and possible harm from the care given by supervisees is proportional to the degree of your control over the trainee's actions and your knowledge of those actions. You may well be responsible for any negligent care you instruct the student to give, and for the negligent supervision of the student.

You are considered to still be practicing your specialty even while you are supervising a trainee.⁹⁷ At this time, most supervision is direct, or face-to-face. However, it is possible that some supervision can be done by telephone or written communications. The same expectations, responsibilities and standards apply to the supervisory relationship, regardless of the mode of communication you use.

Lessons Learned

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