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CHAPTER 2

Ethics

Chapter Objectives

By the end of this chapter, the student will be able to:

1. Define the basic ethical principles.
2. Summarize the ethical violations of the U.S. Public Health Service Syphilis Study at Tuskegee.
3. Examine ways to maintain confidentiality of medical records and research data.
4. Explain the function of the institutional review board.

KEY TERMS

beneficence
institutional review board
justice
respect for persons

INTRODUCTION

This chapter provides an overview of ethics. After providing a brief historical background of ethical issues, the historical landmark case of the U.S. Public Health Service Syphilis Study at Tuskegee, which involved unethical practices in public health research, is described. Then the basic principles of scientific research ethics are defined. This discussion is followed by how these principles are applied to the role of the institutional review board (IRB), development of informed consent documents, and consideration of special populations. The chapter ends with a discussion of the ethical principles and challenges as applied to evaluations.

HISTORICAL BACKGROUND OF ETHICAL PRINCIPLES

In 1949, following the Nazi Nuremberg Trial in Germany after World War II, the U.S. National Institutes of Health, Office of Human Subjects Research issued the Nuremberg Code: Directives for Human Experimentation. The following bullets summarize the Nuremberg Code:[1]

- Voluntary consent is required.
- Research must be of societal value.
- Previous studies justify the need of the research.
- Research must avoid physical and mental suffering and injury.
- No research may be conducted if prior knowledge suggests the occurrence of death or disability.
- Risk must not exceed humanitarian benefits.
- Research planning must protect subjects from injury, disability, or death.
- Research may only be conducted by qualified researchers.
- Individuals participating in research may withdraw at any time.
- Researchers must end the research if there is cause for concern of subjects regarding their safety.

Later, the U.S. Department of Health and Human Services' Office for Human Research Protections (OHRP) was created for the protection of the rights of individuals involved in research, to provide clarification, guidance, and advice; distribute educational information; and maintain

regulatory oversight.[2] In 1979, the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research wrote the Belmont Report to describe the ethical principles that apply to human subject research. In 1981, the U.S. Department of Health and Human Services and the Food and Drug Administration revised the Belmont Report to be compatible with current statutes.[3]

It is important to review the U.S. Public Health Service Syphilis Study at Tuskegee. This historical landmark case involved unethical practices in public health research that have shaped scientific medical practices in the United States.

Syphilis is a sexually transmitted infection of great importance to public health as it may not present symptoms for years, increasing chances of it being spread among people before being treated. Syphilis causes many health problems, including painful lesions and sores, and, if left untreated, dementia in later life. Syphilis may also be passed from an infected mother to her newborn child. In 1932, the U.S. Public Health Service started a research study about the progression of syphilis in Macon County, Alabama near Tuskegee. Of the 600 impoverished African American males in the study, 399 had syphilis and 201 did not have syphilis. The men were never told that they were involved in a research study, and they did not receive proper medical care to treat syphilis. For study participation, the men received free medical exams, meals, and burial insurance; however, they were never allowed to quit participating in the study. In 1936, the study's first clinical report was published. In 1947, penicillin was available to effectively treat syphilis, yet the men never received treatment. During World War II, 250 men in the study registered for military service, were diagnosed with syphilis, and obtained treatment for syphilis. After 40 years, in 1972, the Assistant Secretary for Health and Scientific Affairs announced the end of the Tuskegee Study, and an advisory panel declared the study to be unethical. By the time the study ended, 74 men were alive. Of the original 399 men, 28 had died of syphilis, 100 had died of related complications, 40 wives had been infected, and 19 children had been born with congenital syphilis. In 1973, a class action lawsuit was filed on behalf of the men and their families. In 1974, an out-of-court settlement was reached for $10 million plus lifetime medical benefits and burial services to all living participants. In 1975, the benefits were extended to wives, widows, and children. The last study participant died in January 2004, and in 2009 the last widow receiving benefits died. There are 15 remaining children receiving medical and health benefits. The Tuskegee Study left a legacy of mistrust among the African American community of the medical establishment and many public health efforts.[4] On May 16, 1997, after 65 years, President Clinton apologized for the government's syphilis study in Tuskegee, Alabama.[5]

BASIC ETHICAL PRINCIPLES

From this historical background, let's move into a discussion of basic ethical principles. Regardless of the discipline or field of study, ethics can be defined as a system of moral principles and values applied to all aspects of evaluation and research that involve contact with human subjects. To understand ethics, it is important to learn basic terminology. The basic ethical principles are respect for persons, beneficence, and justice. After learning the definitions, it becomes apparent that each principle is understandable on its own. However, when several ethical principles are considered jointly, the overlap leads to contradiction.

Respect for persons or autonomy

Respect for persons or autonomy is divided into two sections. First, each individual is treated with respect and given adequate information to make an informed decision, including having no treatment or alternative treatments. Informed decisions should be made without excessive influence of others. Second, individuals with diminished decision-making capacity require extra protection, depending on the risk of harm and the likelihood of benefit. Throughout the process of participatory involvement, autonomy should be reassessed to ensure that participating individuals maintain their self-determination and understand risks and benefits. All participants are shown respect, and no reasonable information is withheld.[3] For example, when recruiting low-income individuals for an evaluation project, their participation remains voluntary, and their poverty status should not lead to coercion or undue influence over the protocol. Questions of respect for persons or autonomy include the following:

- Does each potential participant have the personal capacity to willfully choose to participate in the evaluation?
- Is anyone feeling internal or external pressure to participate?
- Are the incentives for participation appropriate?
- Do the participating individuals understand that they are free to withdraw from the program or evaluation at any time?

Beneficence

Beneficence is aligned with the Hippocratic Oath, "do no harm," by protecting individuals from harm by maximizing possible benefits and minimizing possible risks of harm. In other words, beneficence is when the chance of possible benefit outweighs the risk of possible harm. Beneficence assumes that risks are minimized as individuals and society benefit from participation. Beneficence is often ambiguous, particularly when there is minimal risk with no definitive and measurable benefits. At this point, the participant's choice

must be free of coercion and be given all possible choices to make a completely informed decision. The evaluator is required to stop the process at any time when it becomes clear that there is a possibility that participants could be harmed.[6] Questions of beneficence include the following:

- Is the health program or evaluation providing benefits to the participants?
- Is it possible that the evaluators stand to gain more from the evaluation than the participants, such as data collection for academic publications and future grant applications to promote their personal careers?
- Are the participants protected from possible risks of harm or reprisal for participating in the evaluation process?

Justice

Justice requires a fair distribution of burden and benefits, so that every individual with the same condition, job description, geographical location, and so forth has an equal chance of being selected to participate.[7] When evaluators recruit volunteers, it is essential to justify the selection process. Volunteer participants may not be chosen simply because of their availability or compromised position in society but rather for reasons directly related to the goals and objectives of the evaluation. Justice requires that every individual have equal access to the benefits. For example, if the evaluation is conducted within a large organization, each employee should have an equal chance to participate in a focus group (burden) and receive the gift card incentive (benefit). Questions of justice include the following:

- Is there a fair distribution of burden and benefits?
- Does every individual in the target audience have the same chance of being selected to participate?
- Is random assignment being used appropriately?

Although respect for persons, beneficence, and justice are the main ethical principles, additional ethical principles of nonmaleficence, paternalism, and utilitarianism should be defined.[3]

Nonmaleficence

Nonmaleficence is defined as refraining from causing harm or from acting with malice toward a person. Questions of nonmaleficence include the following:

- Even if the participant signed the informed consent paperwork, does the participant experience anxiety when responding to personal questions?
- If an individual is involved in a longitudinal study for several years, do constant reminders to remain involved in the study feel like an invasion of their privacy over time?

Paternalism

Paternalism involves a relationship of uneven power between the recruiter and individuals being recruited. For example, it is paternalistic for an administrator to insist that all employees participate in the evaluation being conducted within their facility. In this case, the administrator is assuming a parental role while placing the employees in the role of children. Questions of paternalism include the following:

- Did the administrator treat the employee as a child?
- Was information withheld from the employee because the administrator did not think that the employee should be told about potential closing of the clinic?

Utilitarianism

Utilitarianism is the decision, behavior, or action that achieves the greatest good for the greatest number of people.[7] For example, the evaluator recruits individuals who smoke at least two packs of cigarettes per day to participate in a new smoking cessation program. Because the evaluation is funded by a pharmaceutical company, the true purpose of the program is to determine the time and place where heavy smokers are able to smoke in states with strict indoor air quality laws. By participating in this program, the evaluator is deceitful and violates utilitarianism. Although the smokers receive some information about smoking cessation, the pharmaceutical company is researching how to market a new smoking cessation nicotine product to heavy smokers. Although the evaluator argues that the end product is a new smoking cessation tool to help smokers to stop smoking (the greatest good for greatest number), the truth is that this evaluation is deceptive when participants do not know what the immediate goals of the evaluation are. The goal of this evaluation was not designed to help these current participants, but rather to design advertising materials for future smokers. This type of research design involves questionable ethics. Questions of utilitarianism include the following:

- Is the program designed to assist current or future participants?
- Is only one specific group, such as participants with low health literacy, recruited for this study?

ETHICAL LINKS BETWEEN RESEARCH AND EVALUATION

Building on the historical background and basic ethical principles, let's explore the ethical links between research and evaluations. Keep in mind that the purpose of research is to create new knowledge, whereas the purpose of evaluation is to improve programs. While many types of public health research do not involve human subjects (e.g., soil and water sampling, air pollution levels), most public health research is focused on

creating new knowledge for humans. Any type of research that involves collecting any type of data (interviews, tissue samples, survey completion, etc.) from human subjects must involve an ethical review to ensure safety of the human subjects. This review process is conducted by the institutional review board that is described in the next section. Now let's discuss evaluations. Even though evaluations are not creating new knowledge, like research, most evaluations involve collecting data from human subjects. Although there are differences between the purpose of research and the purpose of evaluation, the need to protect human subjects remains the same. That being said, there can sometimes be some blurring between research and evaluation on certain projects. It is possible for one project to involve both research and evaluation. For example, a funded project conducts research to develop an innovative teen pregnancy prevention curriculum for after-school programs. The same team implements the innovative curriculum and conducts the evaluation to determine if teen pregnancy rates have dropped over the 5-year longitudinal evaluation.

INSTITUTIONAL REVIEW BOARD

An institutional review board (IRB) is a committee that serves to formally approve, monitor, and review every type of biomedical and behavioral research and evaluation that involves human subjects. The purpose of the IRB is to protect the rights and welfare of the human subjects. At the national level, the U.S. Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services (HHS) oversee IRB regulations including approval, required modifications of research, and disapproval of research.[8] Keep in mind that each agency or division under the FDA and HHS has its own rules and regulations for biomedical and behavioral research. At the local level, institutions have their own IRB committees, such as universities, hospitals, clinics, health departments, and school districts. Every IRB committee performs oversight functions of all research and evaluations conducted on human subjects within its institution. In some situations, researchers and evaluators must obtain IRB approval from more than one committee. For example, if a university professor receives state funding to conduct an evaluation at a local health department clinic, the professor must receive IRB approval from the university IRB and also from the local health department IRB committee.[3]

To accomplish the purpose of the IRB, the committee members review research or evaluation protocols, informed consent documents, recruitment brochures, surveys, interview and focus group question guides, and all other materials related to the research. The IRB also reviews procedures involving previously collected personal data or secondary data, such as medical charts, lab and medical test results, prescription drug data, satisfaction surveys, financial information, and any other type of outcome data. The main objective is to assess the ethics and methods to ensure that participation is informed and voluntary and that all individuals are capable of making personal decisions. The IRB committee approves research and evaluations that provide informed consent for participants, show that the risks to the participants are balanced with potential societal benefits, and have undergone participant selection that is fair with equal distribution of risks and benefits to eligible participants.[9] Each IRB committee requires a written application the with following required components:[3]

- Research protocols and amendments/evaluation goals and objectives
- Written informed consent forms
- Participant recruitment procedures and advertisements
- Written information provided to participants
- Evaluation/research plan
- Information about availability of compensation and schedule of payments
- Safety information to accommodate any adverse conditions resulting from the research/evaluation including name and contact information of principal investigator, lead researcher, or evaluator; evidence of his or her qualifications; and names of all personnel involved with any aspect of research

Depending on the type of research, IRB committees request additional information and multiple document revisions prior to making a final approval decision. Applications of the general principles to the conduct of research or evaluation lead to consideration of the following requirements: informed consent, risk–benefit assessment, and selection of individuals.

Informed Consent

Informed consent is the hallmark of human subject research, because it reflects the individual's right to respect and autonomy. Informed consent is not a one-time encounter to obtain an individual's signature, but rather an ongoing process to assure that human subjects continue to understand that their involvement is voluntary. According to the U.S. Department of Health and Human Services,[9] the informed consent document must include the following components: full disclosure, comprehension, adequate compensation, and voluntary choice.

Full Disclosure

Full disclosure involves revealing the purpose and expected duration of the subject's participation, procedures involved, description of potential risks and benefits, appropriate alternative procedures or treatments, confidentiality of records, and a statement affirming that participation is voluntary and refusal or withdrawal will not result in a penalty or loss of entitled benefits. All informed consent forms must be written using layperson's words with simple sentence structure and presented in the preferred language of each potential human subject for maximum comprehension. In addition, informed consent documents include information on the principal investigator's name and how to contact him or her to answer questions and to explain the research participant's ability to withdraw from the study or evaluation at any time without penalty. It is important that participants understand that their participation is not required and the range of risks and benefits involved. The written informed consent document is given to each participant and orally discussed by the principal investigator. In some situations, there must be a third party present to witness the process, including the participant's and researcher's signatures.[9]

Informed consent problems arise when the data collection is likely to change the response or behavior of the participants. For example, suppose the purpose of the evaluation is to streamline the flow of patients at a local clinic by using a new computerized check-in system. One aspect of the evaluation involves observing the clinic employees as they assist patients with the new system when checking in. Because the employees know that they are being watched, their behavior is affected. Whenever data collection involves incomplete disclosure, it is essential to explain this situation in the IRB application, make sure that undisclosed risks are no more than minimal, and plan debriefing sessions along with dissemination of results. Full disclosure may never be withheld to increase recruitment or cooperation.[3]

Comprehension

When explaining the informed consent document, it is important that participants understand every aspect of the research. This understanding means that the document must be written in the preferred language of the individual and at an appropriate written and verbal literacy level. The time and location of obtaining consent is considered. Consent is obtained during normal business hours in a quiet location. Individuals may wish to have family members present to hear the explanation and ask questions, although the participating individual retains the final decision. For example, if the document is explained quickly in a noisy hospital waiting room, chances are that the individual will not be allowed sufficient time to make an informed choice. Obtaining the informed consent is viewed as an educational process. It is the evaluator's responsibility to ensure that participants understand and comprehend the information. As potential risks increase, so does the obligation of complete understanding prior to giving consent. Sometimes an added safeguard is used, such as asking the individual to repeat the explanation to verify understanding and comprehension. IRB committees need to make every effort to enhance the subject's comprehension. Even with the best intentions, an evaluator may communicate every aspect of the informed consent document, but the participant may fail to fully understand his or her participation. The reasons for lack of understanding may be due, but not limited to, his or her mental capability being diminished by age; physical or mental disabilities; being under the influence of medications, alcohol, or other substances; fear of reduced services; need for monetary compensation; or real or imaginary feelings of coercion. When research involves a specific medical condition, such as dementia, an individual's legal guardian is assigned to sign the informed consent, make surrogate decisions, and protect the participant from harm.[9]

Adequate Compensation

Adequate compensation for participation in research is not specifically stated in the federal regulations. The IRB committee determines the risk of possible coercion and reasonable compensation for each situation. Incentives must neither be so attractive that potential participants are blinded to the risks nor conceal accurate information for admission into the lucrative research. Compensation does not need to be a cash payment. Other types of compensation include bus tokens, travel reimbursement, babysitting services, movie tickets, or gift cards.[9]

Voluntary Choice

Voluntary choice involves an agreement to participate in research or an evaluation after individuals understand every aspect of the study. In addition, conditions must be free of coercion and undue influence. Coercion occurs when a person in power threatens harm if individuals do not agree to participate in the research or evaluation and sign the consent form. For example, a prisoner would experience coercion if the warden announces that all prisoners must participate in a study or else special privileges will be evoked. Undue influence happens when an excessive incentive is offered for participation. For example, a tobacco company is developing a new e-cigarette and wants to test their product with current

low-income smokers. They expedite recruitment of current low-income smokers by offering $1000 to every current low-income smoker who is willing to use their new e-cigarette for 7 days. Because current low-income smokers need $1000, they would sign consent forms without asking questions to receive the excessive cash payment. Undue influence also occurs when a family member is persuaded to convince the patient to participate in the study, thus removing the patient's choice. Threatening to revoke healthcare services is also a threat of undue influence.[3] Other considerations of informed consent involve observational research, active and passive consents, secondary data, and cultural diversity concerns.

Observational Research

When human behavior is observed, researchers request an informed consent waiver because subjects may act differently when observed. For example, evaluators are evaluating a bullying prevention curriculum in a high school. They gather baseline data by staging a student bullying scene in a parking lot of one of the two high schools that will receive the bullying prevention curriculum over the next 9 months. At the end of the intervention, the evaluators stage another bullying scene in the other high school parking lot to determine the change after the intervention. For this type of research, IRB committees apply common sense and consider the degree of risk for the subjects involved without their consent.

Active Consent and Passive Consent

These terms are commonly used in a school setting when a study involves noninvasive research with students under age 18 years. When a passive consent form is used, the researcher gives the students a document to take home to their parents or guardian. With passive consent, the parent or guardian may read about the noninvasive research. If the document is not returned to school, the student will participate in the research. If the parent or guardian does not wish the student to participate, the signed form must be returned to school. Because it is common that students do not give such forms to their parents, the parents are never made aware of the research. In this case, if the parent never responds for numerous reasons, the student is allowed to participate in the research. To clarify, passive consent means the student participates due to "passive" parental consent. For active consent, the researcher sends the document home with the students. The student is unable to participate unless the document is signed by the parent and returned by the student. Parents need to be "active" for their child to participate. In this case, the researchers offer incentives for students to return the signed form in a short period of time. For example, the class with the greatest number of returned signed forms by Friday receives a pizza party, or each student who returns a signed form receives a school t-shirt.

Secondary Data

Common examples of secondary data include patient medical charts, birth and death certificates, traffic violations, motor vehicle records, medical billing records, school attendance records, and insurance company vehicular claims data. Most secondary data research and evaluations use aggregate data, which are defined as records that do not contain any personal or identifying information that could be linked back to a specific individual. For example, school administrators use secondary data to evaluate the impact on elementary students who change schools more than one time during any given school year by linking the data to the number of days absent and their test scores. Secondary aggregate data provide specific information about the students who changed schools more than one time during one academic year. Data are de-identified and do not include student names, addresses, or contact information. By linking the elementary students who have changed schools more than one time with their number of days absent and test scores, school administrators are able to determine the impact of changing schools. The research questions for this study are based on the health effects and stress caused by adjusting to new schools and the impact on the students' test scores. Biased data would result if the students were lost because they moved to a school outside of the county or the students were not included in the study because they moved into the county after moving several previous times elsewhere.

Cultural and Diversity Issues

IRB committees verify if the evaluation staff has appropriate cultural and diversity sensitivity training so that participating individuals are treated with respect. If participating individuals feel comfortable, they are more likely to respond honestly to personal questions. For example, even though the evaluator from one culture views the interview question as routine, the responding person from another culture may view the identical question as intrusive. Topics that may be considered sensitive in various cultures include diverse marriage and parenting attitudes, sexual behaviors, employment loyalty, loyalty to healthcare practitioners, religious beliefs and practices, use of traditional medical treatments, and so on. Researchers need to be comfortable with not only the topic, but also the potential ethical issues that may arise when recruiting individuals from various cultural backgrounds.[6]

Risk–Benefit Assessment

The risks and benefits are carefully weighed by the IRB committee, investigator, and participating individuals. Based on known data, risk is defined as the chance that harm may occur. Risk is usually viewed as high, moderate, or low. Risks may include psychological, physical, legal, social, and economic harm. Benefit is viewed as the value of positive health or welfare gained through the study. The risk–benefit ratio assessment is the probability and extent of possible harm versus anticipated benefits. In the IRB application, it is essential to clearly state known risks according to the published literature and available alternative choices. For the IRB committee, any potential risks must be justified and offset by benefits when feasible. For participating individuals, they must understand the risk–benefit ratio, have the opportunity to ask questions, and be able to withdraw their participation at any time.

Selection of Individuals and Special Populations

When IRB committees review an application, particular attention is paid to special populations that may be recruited for participation. Each category of special populations poses unique considerations related to informed consent. Special populations include individuals who are dependent on public healthcare services due to low socioeconomic status, individuals with limited English language skills, children, individuals with mental health disabilities, prisoners or institutionalized individuals, hospitalized and very sick patients with diminished comprehension due to medications or emergency treatment, the elderly population, and pregnant women. Any of these individuals may concede their rights to gain additional or faster medical benefits or to please their healthcare practitioners. If there is any doubt about consent being truly voluntary, the individual should be removed from the selection. Such individuals need protection against recruitment selection due to convenience, medical diagnosis, or socioeconomic status.[9] Overall, the researcher or evaluator and the IRB committee must be aware of the unique ethical concerns when recruiting individuals from special populations.

ETHICAL GUIDELINES FOR EVALUATORS

From the previous discussion, you learned about the importance of the institutional review board and the informed consent process. This section focuses on the ethical integrity of the profession of evaluation. The following three tables illustrate ethical guideline summaries from several professional evaluation associations. It is apparent that all three examples are similar and closely parallel the same concepts used by IRBs. For example, in 2004 the American Evaluation Association ratified their ethical principles to guide professional evaluators. See **Table 2-1**.

A second example is from the Joint Committee on Standards for Educational Evaluation. See **Table 2-2**. A third example is taken from the United Nations Development Program Norms for Evaluation. See **Table 2-3**.

CHALLENGES FACED BY EVALUATORS

After reading through the guidelines, the ethical issues seem straightforward and easy to follow. However, it is not uncommon for evaluators to find themselves in situations where the ethical guidelines become blurred. Let's explore some possible situations that illustrate some of the potential ethical challenges.

First, although it may seem like there are different ethical issues for internal and external evaluators, they face the same

TABLE 2-1 American Evaluation Association

Topic	Definition
Systematic inquiry	Conduct systematic, data-based inquiries related to the evaluation.
Competence	Present accurate and knowledgeable information to stakeholders.
Integrity and honesty	Safeguard the honesty and integrity of the entire evaluation process.
Respect for people	Respect the security, dignity, and self-worth of all individuals participating in the evaluation.
Responsibilities for general and public welfare	Ensure the diversity of interests and values to represent participating individuals and the general public.

Data from the American Evaluation Association's Guiding Principles for Evaluators. Available at: http://www.eval.org/p/cm/ld/fid=51.

TABLE 2-2 Joint Committee on Standards for Educational Evaluation

Topic	Definition	Questions
Utility	Provide practical information needed by the given audience.	Is the purpose of your evaluation clear? Who needs the information and what information do they need? Will the evaluation provide relevant, useful information in a timely manner?
Feasibility	Evaluations take place in the field and should be realistic, prudent, diplomatic, and frugal.	How practical is your evaluation? How much money, time, and effort can you invest? Is the planned evaluation realistic, given the time, resources, and expertise available?
Propriety	The rights of individuals affected by evaluations should be protected.	What steps need to be taken for your evaluation to be ethical and legal? Do these steps protect the rights and welfare of the individuals involved? Do they engage those affected by the program and the evaluation?
Accuracy	Evaluations should produce and convey accurate information about a program's merit and value.	Have you documented your program clearly and accurately? What design will provide accurate, valid, and reliable information? Have you demonstrated that your measures are valid and reliable? Have you used appropriate analyses, and are your conclusions justified? Is your report impartial?

Data from Joint Committee on Standards for Educational Evaluation. Program Evaluation Standards. Available at: http://www.jcsee.org/program-evaluation-standards. Accessed September 2, 2013; and National Institute of General Medical Science. How-To Guide: Standards and Ethics for Evaluation. Available at: http://www.nigms.nih.gov/Research/Evaluation/standards_ethics.htm. Accessed September 2, 2013.

issues but differ in how they are resolved.[10] For example, an internal evaluator, Jackie, uncovers that the Department Head of Medical Records, Mr. Smith, is stealing prescription pads and is forging the physician's signature to acquire pain medications for resale. As an evaluator, Jackie has the ethical and legal obligation to report the information. However, she knows that Mr. Smith's house was recently foreclosed due to his wife being laid off as a corporate attorney. She also knows that Mr. Smith has a child with disabilities and the medical bills are quickly becoming overwhelming. If Jackie reports the evidence to the Board of Directors, Mr. Smith will lose his job. As an internal evaluator who is aware of Mr. Smith's personal circumstances, Jackie may be tempted to ignore her findings. On the other hand, the external evaluator, Ken, uncovers the same information and reports the findings immediately without regard for Mr. Smith's personal situation. In the end, both evaluators report the finding and Mr. Smith is fired; however, Jackie experiences many sleepless nights over the situation, and Ken sleeps fine without ever knowing the outcome of his reported findings.

TABLE 2-3 United Nations Development Program Norms for Evaluation

Topic	Definition
Independent	Evaluators are free from conflict of interest related to the scope, content, and recommendations of their evaluation reports.
Intentional	Purpose of the evaluation is clear and understood between all individuals at the onset.
Transparent	The credibility of evaluators is essential for the stakeholders.
Ethical	Evaluators convey personal and professional integrity, respect of institutions, keep all information confidential, maintain confidentiality of information, and value for customs, beliefs, and cultures of individuals.
Impartial	Evaluators attempt to remove potential bias and maximize objectivity to increase credibility of the final evaluation report.
Timely	Evaluators design evaluations within specific timelines and agree to deliver final reports in a timely manner.
Used	Evaluations provide information to improve quality of evidence-based decision making.

Data from Better Evaluation. Define Ethical and Quality Standards. Available at: http://betterevaluation.org/plan/manage_evaluation/ethical_evaluation. Accessed September 2, 2013.

Second, evaluators attempt to conduct evaluations that are free from political interference, but sometimes they are not shielded from the political side of the organization. For example, the administration may arrange personal interviews under the pretext of convenience for the evaluators. However, in reality, the scheduled interviews are with specific and targeted individuals, so the truth is not discovered by the evaluators. On the other hand, some key stakeholders may seek out interviews with the evaluators to press their specific agenda for the evaluation. It is not the job of evaluators to become investigative detectives, but they do need to be aware of any underlying politics that may be present. Evaluators can decrease the political discord by increasing the number and diversity of individuals at the table when designing the evaluation. In addition, if evaluators suspect that the evaluation has the potential of political overtones, the evaluators may wish to add detailed language in the contract related to how the evaluation is to be conducted. Lastly, if the evaluators question the integrity or purpose of the evaluation, it is within the rights of the evaluator to deny the opportunity to work on the evaluation process. Most importantly, evaluators never wish to obtain the reputation of conducting questionable evaluations loaded with political connotations.

Third, evaluators need to determine if and when individuals participating in the evaluation will be paid. There are times when an incentive is viewed as a bribe for participation and other times when an incentive is appropriate. For example, if the evaluator is conducting a 60-minute focus group with pregnant women regarding their satisfaction with their prenatal care, it is appropriate to provide bus tokens or taxi fare and a $10 gift card for their time. However, it is not appropriate to pay homeless individuals $300 per interview regarding their opinion of a city council vote on the need to build more shelter space. This incentive would be viewed as a bribe.[10]

Fourth, evaluators have an obligation to the individuals participating in any aspect of the evaluation. Participants need to be aware of the limits of confidentiality of the data they provide. Evaluators must guarantee that confidential data cannot be traced back to one individual.[11] Also, evaluators need to be respectful of the diversity of all participating individuals (e.g., age, gender, cultural background, disability, personal interactions, and customs). The problem with bias is that it is difficult to recognize it in your own work and writing. Therefore, it is advantageous to have several colleagues read final reports in search of potential biases that were not recognized by the author. For example, if the evaluator is not familiar with local customs common to the geographic region in which the evaluation was conducted, the final report may include some bias unknown to the evaluator. This situation could be viewed as positive (truly an external viewpoint with limited bias) or negative (lack of understanding of the acceptable practice).

CONFIDENTIALITY OF PERSONAL INFORMATION

In all disciplines, it is essential to maintain the confidentiality of personal information. After obtaining informed consent from an individual, investigators are responsible for protecting every aspect of the participant's personal information, including contact information, survey responses, medical data, test results, and interview responses. The investigators are responsible for maintaining this protection according to the institutional or organization policies after the completion of the evaluation or research. It cannot be emphasized enough that all data must be secured, either through being stored in locked cabinets or in password-protected databases. More elaborate procedures are necessary when the collected data involve sensitive information such as criminal activities or sexual behaviors. When the evaluation involves assigning codes for identifiers, the evaluator must separate the actual names from the assigned codes to maintain confidentiality. For example, an evaluator working in a local high school could use a three-step process. First, the high school students are given a paper with a graphic of a telephone keypad. The evaluator would ask the students to create a 6-digit code using the first letter of their first name and the first five letters of their last name, which will become their numeric signature. The student, Kevin Williams, would select 594554 (K = 5, W = 9, I = 4, 5 = L, 5 = L, I = 4. See **Box 2-1**.

Second, the high school students are given the informed consent documents to sign with only their numeric signature. And third, the high school students that signed and returned

BOX 2-1 Creating a Confidential Identification Code

1	ABC 2	DEF 3
GHI 4	JKL 5	MNO 6
PQRS 7	TUV 8	WXYZ 9
TONE *	OPER 0	 #

the informed consent are given the survey to complete. The first line of the survey asks the high school students to enter the numeric signature created by writing the keypad graphic numbers in the boxes provided on the survey.

In all disciplines, the investigators are responsible for ensuring that their staff receives the required training on federal guidelines related to data confidentiality. For example, hospital administrators must ensure confidentiality of patient medical records just as investigators must protect data collected from participants. The most common guideline for patient and data confidentiality is the Health Insurance Portability and Accountability Act (HIPAA), which passed in 1996 under President Bill Clinton. Title I of HIPAA protects the health insurance workers and their families if they change or lose their jobs. Title II of HIPAA is known as *administrative simplification* and establishes the national standards for electronic healthcare transactions and national identifiers for providers, health insurance plans, and employers.[7] For the consumer, HIPAA provides individuals the right to determine who may read or receive a copy their medical records, add corrections to their medical records, give permission for sharing health information, and file a complaint with the healthcare provider, health insurer, or the federal government. Anyone may file a complaint at the HHS website (http://www.hhs.gov/ocr/hipaa/). The type of medical information that is protected includes information added to the individual's medical record, conversations shared between healthcare providers about an individual's care, personal medical information in computer system databases, and billing information.[12]

Whether in health care or research, evaluators, hospital administrators, and principal investigators or head researchers are responsible for ensuring that each person providing health care or working on research or evaluations must be familiar with the details of HIPAA and know how to protect the privacy of patient data, records, conversations, surveys, or any other information that is collected. Several websites offer training for HIPAA and research certification, including:

- http://research.unc.edu/offices/research-compliance-program/privacy/hipaa/
- http://privacy.health.ufl.edu/training/visitors/instructions.shtml
- http://www.hhs.gov/ocr/privacy/hipaa/understanding/training/index.html

SUMMARY

This chapter begins with a historical overview of ethics and a discussion of the basic principles of ethics. The next section describes the purpose of the institutional review board (IRB), including how to design comprehensive informed consent documents including the consideration of special populations. Then ethical guidelines for evaluators and challenges faced by evaluators are presented. Last, it focuses on the necessity of learning the importance of maintaining confidentiality of personal information collected from participating individuals.

CASE STUDY: DIAZ VERSUS HILLSBOUROUGH COUNTY HOSPITAL AUTHORITY

In 1987, Karen Perrin reported to the high-risk perinatal outpatient clinic at Tampa General Hospital with affiliation to University of South Florida in Tampa. She was looking forward to a busy day and the change of pace. Karen had worked at Tampa General since January 1986. Her normal assignment was labor and delivery, but as a part-time nurse, it was not unusual for her to fill in elsewhere. For the next 2 weeks, Karen worked at the outpatient high-risk pregnancy clinic while Sue, the clinic's head nurse, took off time for her wedding. In fact, it turned out that Karen worked in the clinic for 4 weeks. She worked in the clinic for 2 weeks, returned to her regular position for 2 weeks, and then was again temporarily assigned to the clinic for 2 additional weeks, because Sue's daughter became ill.

Among other clinic tasks, Karen cared for high-risk pregnant women who came to the clinic for amniocenteses. Amniocentesis is a procedure in which a needle is inserted through a woman's abdomen to extract amniotic fluid for testing.[13] Karen entered each patient's name, hospital number, and Medicaid or insurance number into the "amnio" record log at the desk. She took the patient's weight and blood pressure, measured her belly, and checked her urine. She set up the tray of amniocentesis needles and test tubes and labels for the tubes. She explained the procedure to the patients, offered reassurance, and asked if they had any questions.[14]

During her clinic assignment, Karen noticed something unusual. The pregnant women did not ask questions about the procedure. Karen noted that, "I kept seeing all these women having amnios. Over and over and over. I'd see them one week, I'd say, 'Why are you back again?' I'm looking in their chart and I'm seeing that this is amnio #5, amnio #6 . . ."[14] When she talked with the pregnant women, it was clear that they did not understand why they were having so many amniocenteses. Their response was always the same, "The doctor told me, if I don't do them, my baby will die," she recalls.[15]

An Inquiry

In late 1987, Karen consulted her supervisor. A meeting was schedule with the Vice President of Nursing and the Director of the Perinatal Unit. They told her that the pregnant women

were part of a medical study that had been approved by the university and hospital institutional review boards (IRBs); therefore, they considered the matter closed. Her supervisor told her to drop the issue and not pursue additional investigation into the matter. Karen did not stop because she suspected that the women were unaware of a medical study. She continued to press for further investigation. In February 1988, at a final meeting, the Vice President of Nursing made it clear that she had not taken any action nor did she intend to investigate the matter further.

The Next Step

Karen shared her concerns with a friend who happened to be a civil rights attorney, Stephen Hanlon. Under the advice of Mr. Hanlon and the American Nurses Association, Karen was instructed to gather the evidence. She went to the high-risk clinic, took the "amnio" record log, made a copy, and returned the log to the clinic drawer. She returned a few days later to copy the last few pages only to discover that "Someone had taken a razor blade and cut all the pages out of the book. The pages were gone, and they were never found again. This was our only evidence."[14] She provided the copied "amnio" record log to Stephen Hanlon. She also found the contact information for 10 women in the log who had multiple amniocenteses. She contacted them by mail and stated that their rights may have been violated and invited them to contact her. Only one woman, Flora Diaz, age 16, responded.

The Lawsuit

In January 1990, Stephen Hanlon filed a federal class action lawsuit accusing the university, the hospital, and two physician researchers of ignoring the U.S. Department of Health and Human Services regulations on informed consent. Although the lawsuit was initially filed in response to a fetal-lung study[16] involving approximately 280 women, investigation revealed some 30 studies at Tampa General involving 5000 pregnant women between November 1986 and January 1990. Because none of the women or their babies were harmed, this case is not about malpractice but rather dignitary harm. The women were used as research subjects without their informed consent.

Doctors' Perspective

Walter Morales, MD, one of two physician researchers in the lawsuit, denies any wrongdoing: "I can assure you I would never do anything to a research subject that I wouldn't do to my own wife."[17] Further, he notes that he wishes the case had gone to trial instead of being settled because he does not believe that the facts would show the patients were coerced into signing the forms.[15] Further, the results of the study were published in the *Journal of Obstetrics and Gynecology* and, as a result, the combined use of corticosteroids and thyrotropin-releasing hormone is now common practice in many hospitals.[18]

The Settlement

After almost 10 years of litigation, the case was settled out of court. Under the agreement, the university and the state of Florida paid $2.7 million, and Tampa General Hospital paid $1.14 million.[19] In addition to the cash payment, the hospital and university agreed to revise record keeping so that information on study participants was easily accessible in a database. Tampa General Hospital and the University of South Florida also agreed to apply a standard readability test to their consent forms before submitting future projects to the IRB.

A Postscript

Karen Perrin, whistle-blower in this case, was removed from patient care and laid off from the hospital in September 1990.[20] The hospital made attempts to revoke her nursing license, but she successfully defended her actions with the assistance of the American Nurses Association.[21] Karen completed her master's in public health in 1990 and her PhD in 1996 from the College of Public Health at the University of South Florida. Currently, she is an associate professor at the University of South Florida and lectures on medical ethics.[14] Dr. Perrin is the author of this text.

Case Study Discussion Questions

1. What other actions could the nurse have taken?
2. What is the role of the medical residents in this case?
3. What is the role of the nurse supervisor?

STUDENT ACTIVITIES

1. Write a 200-word case study describing a violation of an ethical principle related to a proposed program plan design and evaluation.
2. Obtain two examples of IRB applications from a local hospital, health clinic, school district, or university. Compare and contrast the information required on each document.

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