CHAPTER 2

Research Ethics

Learning Objectives

2.1 Define research ethics.

2.2 Differentiate between the three ethical principles outlined in the *Belmont Report* and apply these principles in conducting research.

2.3 Develop and implement ethical research studies.

2.4 Differentiate between the different types of institutional review board (IRB) reviews.

2.5 Take the Collaborative Institution Training Initiative (CITI) test.

Competency Covered	Learning Objectives	Dimension
Competency 1 *Demonstrate Ethical and Professional Behavior*	2.2 Differentiate between the three ethical principles outlined in the *Belmont Report* and apply these principles in conducting research. 2.3 Develop and implement ethical research studies.	Skills

PBL Case 2

Can I Really Conduct This Research Study?

By responding to the questions related to this case, you will be able to determine what ethical issues you must consider before conducting a research project.

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You are doing your internship at Pine Valley Community Mental Health Center. The center is dedicated to providing comprehensive mental health services including, but not limited to, individual, family, and group treatment; substance use treatment; treatment for anxiety and depression; and crisis management to those who reside in Bucks County and surrounding communities. Staff are trained in a variety of treatment modalities and use evidence-based treatments to alleviate the distress of their clients. Services are provided to children, adolescents, and adults regardless of their socioeconomic status, race/ethnicity, religious backgrounds, sexual orientation, and so on.

You have been co-leading a group for pregnant and parenting adolescent girls. You notice that many of them have mentioned that they were abused during their pregnancy by the father of their child or other relatives. Based on what you have learned from the girls, you think you should conduct a study on the effects of abuse during pregnancy on maternal attachment.

In thinking about your study, you recall hearing on the news that a parent was suing a school district because researchers administered a survey to her child, who was an adolescent, without her knowledge. You begin to wonder if the study you are proposing may raise concerns from the parents of these adolescents.

At this point, take a few minutes to think about the case example and do the following:

1. Identify the problem.
2. Determine what you already know about the problem.
3. Determine what information you need to solve the problem.
4. List the questions needed to be answered related to the information you need to solve the problem.

Please write down your responses to each item. You will need to refer to them while reading this chapter.

During your weekly supervision with your field supervisor, Ms. Porter, you mention that you are interested in conducting a research study with the adolescents in your group and possibly with the adolescents in the other groups. You further state that your study will focus on understanding the effects of abuse during pregnancy on maternal attachment. Ms. Porter tells you that she believes that this study would be interesting, and perhaps the findings could lead to modifying what is done in the groups. She goes on to say that prior to conducting the study you need to provide her with a research proposal, as she needs to submit it to the board of directors of the agency, as they need to approve any research that will be conducted at Pine Valley Community Mental Health Center.

Introduction

In this chapter, you will learn about ethical practices that should be followed while conducting research, including the guidelines specified in the Council on Social Work Education (CSWE) Educational Policy and Accreditation Standards (EPAS) and National Association of Social Workers (NASW) standards that apply to research ethics. A brief history of research ethics is provided. The *Belmont Report*, an important document that provides the framework to guide the resolution of ethical problems arising from research involving human participants, is described. You will also learn how Institutional Review Boards (IRBs) ensure that the rights and welfare of individuals are protected when they are involved in research.

A Brief History of Ethical Practices in Research

The need to consider ethics in research is the result of several experiments that occurred and were egregiously unethical. One of the most infamous cases of unethical research occurred during Nazi rule of Germany in World War II. In December 1946, 23 Nazi medical professionals went on trial in Nuremberg, Germany, because of the atrocities performed—in guise of medical treatment, on Jewish persons in concentration camps. As a result of the Nuremberg Trial, the Nuremberg Code developed in 1949 was the first internationally recognized guideline for conducting research in an ethical manner. The code focused on ensuring the rights and welfare of human subjects. The Nuremberg Code established that participation in research is voluntary, informed consent must be obtained, participants have the right to withdraw from treatment at any time, and it is the responsibility of the researcher to obtain informed consent. Codes related to the conducting of research have continued to be developed over the years. For example, the Declaration of Helsinki (1964) provided guidelines for physicians involved in clinical research, established the need for researchers to assess the risk and benefits of participation, and emphasized participants' privacy. This declaration has been revised several times since its adoption, with the last time being in 2013.

In 1974, the U.S. Congress passed the National Research Act that established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This commission was created after the public outrage over the Tuskegee Experiment conducted by the U.S. Public Health Service (PHS). This study began in 1932, when there was no known treatment for syphilis, and continued through the time period when it became known that penicillin was effective in treating syphilis, which was in 1947. A total of 600 African American males, mostly sharecroppers, were told that they would receive free treatment for their "bad blood," a term used at the time for a variety of ailments. Doctors from the U.S. PHS diagnosed these men as having syphilis and never provided them with treatment for their disease; they merely documented the progression of the

disease. Initially this study was to last six months, but it actually lasted 40 years. For more information about the Tuskegee Experiment, go to https://www.history.com/news/the-infamous-40-year-tuskegee-study. This commission was charged with developing guidelines to be followed when conducting biomedical and behavioral research on human participants. Moreover, this commission wrote the *Belmont Report* (1979), which you will read about later in this chapter.

What Is Research Ethics?

Research ethics is a set of guidelines developed by one's profession that state the standards for conducting research with human participants. For social work, both CSWE and NASW have developed standards related to the ethical conduct of research by social workers. CSWE's Competency 1, *Demonstrate Ethical and Professional Behavior*, states that "social workers make ethical decisions by applying the standards of the NASW Code of Ethics, relevant laws and regulations, models for ethical decision-making, ethical conduct of research, and additional codes of ethics as appropriate to context" (CSWE, 2015, p. 7). In other words, social workers must engage in the ethical conduct of research in all stages of the research process. The *NASW Code of Ethics: Evaluation and Research Standards* (Section 5.0.2) outlines the guidelines for conducting program and practice evaluation and research. These ethical standards can be viewed by going to https://www.socialworkers.org/about/ethics/code-of-ethics.

Application Checkpoint 2.1

Take a moment to review the *NASW Code of Ethics: Evaluation and Research Standards* (Section 5.0.2) and think about how it applies to the research study that is being proposed to be conducted at Pine Valley Community Mental Health Center.

The *Belmont Report*

It has been 40 years since the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. The report provides a federal framework that guides the resolution of ethical problems arising from research involving human participants (Department of Health, Education, and Welfare [DHEW], 1979, now referred to as the Department of Health and Human Services [HHS]). In the report, there is a distinction made between biomedical and social research and practice, three ethical principles that are used to guide research were outlined, and discussion about how these three general principles should be applied. **Practice** refers to "interventions that are designed

solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success" (DHEW, 1979, p. 2). Meanwhile "research designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships" (DHEW, 1979, p. 3).

In thinking about the distinction between practice and research and what is being proposed in the case example, would you consider this to be research? Yes, it is research because the study you are proposing would permit conclusions to be drawn. Let us say, for example, you find that adolescent females who were psychologically abused during their pregnancy are less attached to their infants than adolescent females who were never abused. Based on this finding, you can could conclude that being psychologically abused during pregnancy has an effect on maternal attachment. Your finding also allows you to make a statement about the relationship between psychological abuse and maternal attachment. The statement would be that psychological abuse is associated with less maternal attachment.

The three ethical principles are respect for persons, beneficence, and justice. The first principle, **respect for persons**, asserts that individuals are autonomous and have the right to make decisions for themselves whether or not they are willing to participate in a research study. It is the responsibility of the researcher to ensure that persons who cannot make their own decisions to participate in a research study are protected. The respect for persons principle directly leads to the practice of informed consent. **Informed consent** requires that individuals are provided information that will allow them to understand the potential risks and benefits associated with participation in the study. Additionally, this principle requires that information regarding the study's purpose and procedures should be presented in a manner that all individuals can comprehend, especially individuals whose ability to make a decision in their own best interest may be compromised, such as persons with special needs and persons who are institutionalized. The informed consent also ensures that individuals know that at no time should they be compelled in any manner to participate in the study.

The second ethical principle is beneficence. **Beneficence** refers to the researcher not conducting research that would be harmful to the participants. This includes research that would cause physical or psychological harm to the participants. Not only is the researcher responsible for not harming the participants, but he or she needs to maximize the possible benefits of the research. In other words, the research needs to be of benefit to the participants, society, and the scientific community, and yet, cause no harm to the participants. The principle highlights that any study conducted should, at a minimum, promote the *common good*. In other words, while a study's participants may not themselves receive any direct benefits for participation, others in society may benefit from the study's findings. The potential benefits should be explained to the participants. For example, while a cancer patient may not directly benefit from participation in a study, what is learned from their data may benefit future cancer patients.

Application Checkpoint 2.2

Thinking about the ethical principle of beneficence, how would the proposed research to be conducted at Pine Valley Community Mental Health Center be of benefit to the potential participants, society, and the scientific community, and yet, cause no harm to the participants?

The third ethical principle is justice. **Justice** requires that the benefits and burdens of research be distributed equitably through the selection of participants. In other words, some group of individuals, such as persons from disadvantage backgrounds or prisoners, should not bear the *cost* of research while a different group of individuals, such as persons from upper-middle-class backgrounds, *gain the most benefit* from the study. That would be unjust. The principle of justice directly applies to how researchers select their participants for their research. This principle also calls attention to the fact that individuals from marginalized groups should not have their issues ignored by researchers. For example, there is as much of a need for research to be conducted on access to health care for transgender individuals as other gender groups.

Applying the Three Ethical Principles

As mentioned earlier, the *Belmont Report* discussed how to apply each principle. The principle of respect for persons can be applied via the informed consent process. Informed consent is the process of acquiring the research participants' consent prior to their participating in any research. The informed consent process involves (1) providing potential participants with information needed to make an informed decision about their participation in the study; (2) presenting the information about the research in a manner that the individual can understand what the research entails, what they may be asked to do, and how the research may affect them; and (3) making sure the participant is aware that participation is voluntary and that they have the right to withdraw from participating at any time, without penalty. Informed consent must be obtained and documented using an informed consent form, which each participant signs. A copy of the consent form will be given to the participant. Samples of informed consent forms should be available through your university's **institutional review board (IRB)** website or via an office for sponsored research. IRBs, which you will read more about in this chapter, are responsible for protecting the rights and welfare of individuals participating in research.

Listed below are the basic elements included in an informed consent.

1. Statement of the purpose of the research. The purpose of the study, and that it is research, must be made explicit, along with the duration of the

research should also be noted. A description of the procedures to be followed should be provided.

2. Description of risks to the participants, including physical and psychological risks.
3. Description of benefits to the participants and others.
4. A disclosure of appropriate alternative procedures, if you are conducting research on an intervention.
5. Statement about available medical treatment if research-related injury or other harm occurs.
6. Description of how confidentiality will be maintained.
7. Contact information for whom the participants should direct further questions about the research and whom to contact in the event of a research-related injury.
8. Statement that participation is voluntary and the participant has a right to withdraw from the research anytime without penalty.

There are instances where research can be conducted without documentation of informed consent. An IRB may waive the requirement for the investigator to obtain a signed informed consent form when it is culturally inappropriate to have the participants sign forms. In such an instance, an alternative method of getting informed consent must be used, such as verbal consent. When verbal consent is obtained, there must be documentation of this.

Special guidelines have been developed for the participation of **minors**, or persons under the age of 18, in research. Minors, or children, are legally unable to provide their own informed consent to participate in research; however, they might be able to give assent. **Assent** means a child's affirmative agreement to participate in research. A child's failure to object should not be considered as assent. Although a child has provided his or her assent to participate in the research, his or her parent or guardian must provide written permission. Federal regulations (§45 CFR 46.4.02 (a)) define children as individuals who have not attained the legal age for consent to be involved in treatment or research. Only the IRB can determine if parental permission can be waived.

In thinking about the case presented at the beginning of the chapter, several steps would be required in order to apply the principle of respect for others. A first step would be to look at the information on each client to determine their age. If they are of legal age for consent to be involved in treatment or research, then you would obtain their informed consent. The informed consent process typically requires meeting with potential participants to tell them about the study, the risks and benefits of their participation, and letting them know that there participation is voluntary and they can withdraw from the study at any time without penalty. Signing of the consent form is also done at this meeting.

Similarly, in an informed assent process the same information that is shared at the informed consent process is provided. Along with participants' assent, their parents or a guardian must provide written permission for the minor to participate in the study.

Again, thinking about the case example, how will the principle of beneficence be applied? Before conducting a study, researchers must take into the consideration the risks and benefits of conducting the research. A researcher should ask himself or herself the following questions: "Do the risks outweigh the benefits of the research, or do the benefits outweigh the risks to participants?"; "Is there any way to gain the knowledge about the topic or effectiveness of the intervention but with a lower risk to the participants?"; and "Does the study need to be conducted to achieve the goals and objectives of the research?" Researchers must use their best judgment to ensure the research does not harm the participants.

During the informed consent process, researchers must clearly indicate the amount of risk, as well as the type of risk. For example, an informed consent form might state, "by participating in this study, you may experience a minimal amount of distress." Contact information for whom the participants should reach in case of a research-related injury and where services can be obtained to deal with the stress associated with the research should be described on the informed consent form. Additionally, it should be noted if the participant or the researcher will be responsible for paying for these services.

Critical Thinking Question 2.1

Consider the case example. Identify at least two potential risks and benefits of conducting this study.

In your estimation, would the risks outweigh the benefits or would the benefits outweigh the risks to participants? Would there be another way to gain the knowledge about the topic of interest? In your opinion, does this study need to be conducted to achieve the goals and objectives of the research?

Finally, in thinking about the case, how will the principle of justice be applied? This principle is implemented through the procedures and processes for selecting the study's participants. Researchers should not be biased in the way they select their participants. That is, researchers should not select participants from vulnerable groups (e.g., pregnant women and prisoners) just because they have access to them or they perceive them to be easily manipulated. Do you see that it would be equally unethical if researchers were to select participants from advantaged groups in order to make the study results appear to be more effective? Researchers need to make sure that they are selecting their participants based on the inclusion criteria for their study and excluding individuals based on the exclusion criteria for their

study. **Inclusion criteria** "are a set of predefined characteristics used to identify (participants) to be included in a research study" (Velasco, 2010b, p. 589). On the other hand, **exclusion criteria** "are a set of predefined definitions that is used to identify subjects who will not be included or who will have to withdraw from a research study after being included" (Velasco, 2010a, p. 438). Both inclusion and exclusion criteria are used to establish who is or is not eligible to participate in the research study.

The principle of justice clearly states that researchers should not select participants from vulnerable groups merely because they have access to this population. Think about the case example again. Because you are working with and therefore have access to pregnant adolescents should not be the primary reason for conducting the proposed study. It is important that an inclusion criteria and exclusion criteria be developed. For example, the inclusion criteria for the study proposed in the case example could be as follows: Only those adolescent females who have experienced psychological abuse during pregnancy by the father of their baby will be included in this study. The exclusion criteria would be as follows: Adolescent females who have experienced psychological abuse during pregnancy by persons other than the father of their baby are not eligible to participate in this study. Additionally, adolescent females who have experienced any other type of abuse besides psychological abuse by the father of their baby will not be eligible to participate in this study.

Other Considerations for Conducting Ethical Research

Ethical research is dependent on implementing the three ethical principles set forth in the *Belmont Report*; however, there are other considerations for a researcher when conducting research that is ethical. In particular, the safety of participants is of paramount importance. The researcher is responsible for identifying all the potential risks associated with the study and weighing these risks against the benefits of the study. Once the study is underway, as a researcher, you must continue to monitor the ongoing research to determine if any participants experience an unanticipated **adverse event**. An adverse event is any behavioral, medical, physiological, psychological, or social event that is undesirable or unintended. Prior to the study being implemented, you need to have a plan to address the possibility of the participants being exposed to an adverse event or experiencing distress. In devising the plan to respond to an adverse event, the researcher must decide whether participants will pay for the services needed to address such distress. Moreover, you need to be prepared to stop the research if your participants have been put at risk.

Along with safety, researchers are responsible to protect participants' privacy and confidentiality. Researchers must think through such decisions as who will have access to the data, how and where the data will be stored, the process for destroying the data, and how to prevent disclosure of the participants' personal information.

Institutional Review Board

Federal regulations require that all universities and other entities that receive federal funding must have an IRB. IRBs register with the federal government's Office of Human Research Protection. All research studies are required to be vetted by the IRB, which is responsible for ensuring that the rights and welfare of participants are protected. An IRB has a number of responsibilities. The IRB reviews, approves, disapproves, and requests modifications to all research (whether funded or not) involving human participants, prior to it being conducted. Once the research has been approved, the IRB is responsible for conducting continuous review of the research, suspending approved research in the case of adverse events, and enforcing the informed consent and research procedures.

An IRB committee is made up of at least five members; of these five, it is federally mandated that one of the committee members should not be affiliated with the university, one whose primary concerns are in a scientific area, and one whose primary concerns are not in a scientific area. Both men and women must be members of the IRB. When members of the IRB review research, they take into consideration the three ethical principles outlined in the *Belmont Report* and make a determination if the research fits the U.S. Department of Health and Human Services (HHS) Federal Policy for Human Subjects regulations at 45 CFR part 46, also known as the "Revised Common Rule," definition of research involving human participants. The Revised Common Rule defines research as follows: (1) a systematic investigation designed to develop or contribute to knowledge (45CFR 46.102 (d)), (2) involves obtaining information from living individuals (45 CFR 46.102 (f)), and (3) involves an intervention or interaction with individuals (45 CFR 46.102 (f)). If the IRB determines that the research meets the Revised Common Rule definition, then it considers if the research involving human participants is covered by the regulations. If the research is covered by the regulations, the IRB will determine if the research can be approved for an **exemption** (also referred to as an **exempt review**). In other words, the IRB is determining if your research can be exempt from a full review by the IRB. Studies that may qualify for an exempt review are described in Table 2.1.

Research that is not exempted from review may be considered for expedited or full review. An **expedited review** applies to proposed research that presents no more than minimal risk to the participants, meets the criteria for research being reviewed through the expedited procedure, and has measures in place to ensure the participants experience no more than minimal risk. Minimal risk, as defined in 45 CFR, §46.104 is "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (DHEW, 1979, p. 132). Expedited review may also be used when minor changes are proposed to an approved research project. Expedited review may be done by a subset of the IRB, which may include the chairperson or one or two members of the IRB designated by the chairperson.

Table 2.1 Studies That May Qualify for an Exempt Review

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (a) the information obtained is recorded by the investigator in such a manner that the identity of the participants cannot readily be ascertained, directly or through identifiers linked to the participants; (b) any disclosure of the participants' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation; or (c) the information obtained is recorded by the investigator in such a manner that the identity of the participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
3. Research involving benign behavioral interventions (are brief in duration, harmless, painless, not physically abusive, not likely to have a significant adverse lasting impact on the participant) in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (a) the information obtained is recorded by the investigator in such a manner that the identity of the participant cannot readily be ascertained, directly or through identifiers linked to the participant; (b) any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation; or (c) the information obtained is recorded by the investigator in such a manner that the identity of the participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
4. Secondary research for which consent is not required; secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (a) the identifiable private information or identifiable biospecimens are publicly available; (b) the identifiable private information about biospecimens is recorded by the investigator in such a manner that the identity of the participant cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants; (c) the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under C45 CFR parts 160 and 164, subparts A and E, for purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR; or (d) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(Continued)

Table 2.1 (Continued)

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving participants.
6. Research involving taste and food quality or consumer acceptance studies (a) if wholesome foods without additives consumed that contains a food ingredient, agricultural chemical, or environmental contaminant at or below the level found to be safe by the Environmental Protection Agency of the Food Safety and Inspection Service by the U.S. Department of Agriculture.
7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).
8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:(a) broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);(b) documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117; or (c) an IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to participants as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Source: U.S. Department of Health and Human Services (HHS).

Note: The word *participants* was substituted for *subjects* and *human subjects*.

Any research that did not qualify for the exempt status or expedited review requires a **full review** by all the members of the IRB. A full review is warranted because such research has more than minimal risk and may not adequately have safeguards in place to reduce such risk. Typically, if a researcher proposed to include vulnerable groups as participants, the study will need to undergo a full

review by the IRB. Groups that are defined as **vulnerable populations** are pregnant women, minors (children), prisoners, persons with developmental disabilities, or economically or educationally disadvantaged persons. These groups are categorized as such because they may be more vulnerable to coercion or undue influence because of their status or situation.

The IRB uses the following criteria when it determines whether proposed research will be approved:

1. Minimal risk to participants
2. Risks are adequate in comparison to anticipated benefits
3. Selection of participants is equitable
4. Informed consent will be obtained
5. Informed consent will be documented appropriately
6. Adequate provisions for data collection to ensure safety to participants
7. Adequate provisions to protect privacy
8. Safeguards in place to protect participants from vulnerable populations, if included in the research

Once a research project has been approved by the IRB, it is the researcher's responsibility to inform the IRB of any modifications that need to be made to the research and of any research-related injury a participant has experienced. Failure to do so can result in the researcher's research being suspended along with other already approved research, inability to publish the results, and termination of employment.

Critical Thinking Question 2.2

Pretend that you are a member of the IRB at your university. You and the other members have been assigned to review the proposed study mentioned in the case example. Would this study be exempted from review? Why or why not? If not, what type of review would be required? Justify your response.

CITI Certification

Federal regulations require that all persons conducting research with human participants, including students and other research staff, must undergo training to ensure the protection of participants. This training must be successfully completed prior to conducting any research with human participants. An online course about the Protection of Human Subjects is offered by the Collaborative Institution Training Initiative (CITI). This training provides an overview of the

Belmont Report, the role and functions of IRBs, the types of research that qualify for the exempted, expedited, or full review, and the Revised Common Rule. After reviewing the materials, you take the CITI Certification Test. Persons who successfully complete the training, as indicated by your passing score on the test are awarded a copy of the CITI Certificate. The certificate serves as proof that the online training was successfully completed, and it must be submitted to the IRB along with the research protocol for all persons who will work with research participants during the course of the study.

Critical Thinking Question 2.3

During weekly supervision, Ms. Porter mentions that she has informed her staff and board of directors that an intern will be conducting a research study to understand the effects of abuse during pregnancy on maternal attachment. The board members asked about possible ethical concerns. Ms. Porter asked the intern to give a presentation to the board about these concerns.

Given your understanding of ethical research practices, identify the potential ethical issues. How would your presentation address these concerns? Be sure to refer to the ethical principles in the Belmont Report. Develop a short outline of what would be included in the presentation.

SUMMARY, REVIEW, AND ASSIGNMENTS

CHAPTER SUMMARY ORGANIZED BY LEARNING OBJECTIVES

LO 2.1 Define research ethics.

Research ethics is a set of guidelines developed by one's profession that state the standards for conducting research with human participants.

LO 2.2 Differentiate between the three ethical principles outlined in the *Belmont Report* and apply these principles in conducting research.

The principle of respect for persons asserts that individuals are autonomous and have the right to make decisions for themselves, if they are willing or not willing to participate in a research study.

The principle of beneficence refers to the researcher not conducting research that would be harmful to the participants.

The principle of justice requires that the benefits and burdens of research be distributed equitably through the selection of participants.

LO 2.3 Develop and implement ethical research studies.

Developing and implementing ethical research studies requires obtaining informed consent or assent, identifying the risks and benefits associated with the research studies, devising a plan to address the possibility of participants being exposed to an adverse event, and protecting participants' privacy and confidentiality.

LO 2.4 Differentiate between the different types of institutional review board (IRB) reviews.

Research that meets the qualifications specified by federal regulations may be eligible for exempt status.

Research that meets the qualifications specified by the federal regulations and involves no more than minimal risk and approved research where minor changes are being made are eligible for expedited review.

Research that has more than minimal risk and may not adequately have safeguards in place to reduce such risk are required to be reviewed by the full IRB.

LO 2.5 Take the Collaborative Institution Training Initiative (CITI) test.

Federal regulations require that all persons conducting research with human participants must undergo training to ensure protection of human participants.

KEY TERMS

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COMPETENCY NOTE

In this chapter, you were introduced to the competency below:

> Competence 1: *Demonstrate Ethical and Professional Behavior*. Social workers engage in the ethical conduct of research in all stages of the research process. Social workers apply the NASW Code of Ethics and other relevant codes when conducting research.

ASSESSMENT QUESTIONS

1. How did the information in this chapter enhance your knowledge about research ethics?
2. How did the information in the chapter enhance your knowledge about the IRB process?
3. What specific content discussed in this chapter is still unclear to you? If there is still content that is unclear, schedule an appointment with your instructor to gain more clarity.

END-OF-CHAPTER EXERCISES

1. Go to your university's IRB website and download the template for the assent form and develop the assent form for the study proposed in the case example.
2. Develop a consent form for the study proposed in the case example. Give this consent form to one of your classmates and have him or her provide you with feedback.
3. Read about the "Tuskegee Experiment: The Infamous Syphilis Study" at https://www.history.com/news/the-infamous-40-year-tuskegee-study. After reading this study, indicate if any of the ethical principles described in the *Belmont Report* were violated or not.
4. Visit the CITI (Collaborative Institution Training Initiative) online course for training on the Protection of Human Subjects. Skim the topics and take one section of the certificate test.

ADDITIONAL READINGS

Hooke, S., Hackworth, N. J., Quin, N., Bennetts, S. K., Win, H. Y., Nicholson, J. M., et al. (2018). Ethical issues in using the internet to engage participants in family and child research: A scoping review. *PLoS, 13*(9), 1–30. doi:10.1371/journal.pone.0204572

Landau, R. (2008). Social work research ethics: Dual roles and boundary issues. *Families in Society: Journal of Contemporary Social Services, 89*(4), 571–577. doi:10.1606/1044-3826

McInroy, L. B. (2016). Pitfalls, potentials, and the ethics of online survey research: LGBTQ and other marginalized and hard-to- access youth. *Social Work Research, 40*(2), 83–93. doi:10.1093/swr/svw005