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Protecting the rights of patients, nurses, and others participating in research

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Abstract: Clinical nurses are in a unique position to support research that studies the effects of interventions, symptom management, education, and treatment plan adherence in their patients. Nurses may also participate in research studies that aim to advance professional nursing practice. Using a quiz format, this article addresses clinical nurses' role in research, the history of federal regulation of research, basic human rights and potential violations during the conduct of research, and specific nursing actions required when research is conducted in the practice setting.

Keywords: Belmont Report, Common Rule, Declaration of Helsinki, Good Clinical Practice guidelines, human rights, human subjects protection, Kefauver-Harris Amendments, Nuremberg Code, thalidomide, Tuskegee study, Willowbrook State School study

CLINICAL NURSES are in a unique position to support research on the effects of nursing interventions, symptom management, education, and treatment plan adherence in their patients. Nurses may also participate in research studies that aim to advance professional nursing practice.

A fundamental principle of nursing practice is respect for the inherent dignity, worth, unique attributes, and human rights of all individuals.[1] Nurses who understand legal and ethical protections for human subjects can contribute to research by serving as advocates for their patients and helping to ensure that studies are conducted in an ethical, legal, and scientifically valid manner.

Test your knowledge of the clinical nurse's role in research by taking

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the following quiz, then review the discussion that follows each item to update your knowledge of basic human rights, potential violations during the conduct of research, and specific nursing actions required when research is conducted in the practice setting.

Historical events shaping protections for human subjects

Knowing why federal laws were established and what requirements must be met when conducting research can give nurses insight into the importance of their role in human rights advocacy. Which of the following events led to federal regulation of research in the US? (Choose all that apply.)
a. the Nuremberg trials
b. the thalidomide tragedy
c. the Willowbrook State School study
d. the Tuskegee study

Correct answers: a,b,c,d. All these historical events helped shape protection of the rights of human subjects when they participate in research.

• ***The Nuremburg trials.*** Some of the earliest established practice standards resulted from evaluation of evidence during the Nuremberg trials (1949–1953) regarding research performed by Nazis on prisoners of war during World War II. A result of this forum was the Nuremberg Code, which outlined essential principles for research involving human subjects.[2]

One element of the Nuremberg Code specified that persons must be able to freely volunteer for research participation without coercion and must have knowledge that they are volunteering to participate in research. Consent documents were required to include specific elements of informed consent and to be written at an appropriate reading level and language for the population being studied.

Today, the law requires that research consent forms provide a statement specifically identifying the proposed activity as "research" along with an explanation of the study's intent and procedures. Information about the study's purpose, the amount of time required for study participation, all procedures (both experimental and standard of care) involved in the study, descriptions of foreseeable risks or discomforts that may be experienced, and any anticipated benefits for study participants must be disclosed. Other elements required for informed consent include descriptions of any alternative procedures or treatments available, an explanation of how confidentiality of records will be maintained, and information about measures available to study participants if any harm results from research participation. The name of the principal investigator (PI) and his or her contact information must also be provided to study participants.

Clarifying statements include that study participation is voluntary, that the participant will experience no loss of rights or benefits if he or she chooses not to participate, and the participant can withdraw from a study at any time without penalty. The consent signature line should include a statement that the participant's signature indicates his or her decision to voluntarily participate after having read and discussed information within the consent with a study team member.[3,4]

The Declaration of Helsinki (1961) and Good Clinical Practice (GCP) guidelines are other documents developed to outline ethical principles regarding human experimentation and provide public assurance that the rights, safety, and well-being of research participants are protected.[2,5-7]

• ***The thalidomide tragedy.*** In the late 1950s and early 1960s, thalidomide was prescribed to many pregnant women to prevent morning sickness and promote sleep. Subsequently, thousands of babies were born with severe birth defects due to prenatal thalidomide exposure.[8] This tragedy spurred development of the Kefauver-Harris Drug Amendments to the federal Food, Drug, and Cosmetics Act. Enacted in 1962, these amendments required companies to conduct clinical trials to establish a drug's effectiveness before marketing and gave the FDA greatly expanded oversight authority. It also required that subjects of clinical trials provide informed consent.[9]

• ***The Willowbrook State School study***. Beginning in 1955, mentally disabled children living at the Willowbrook State School in Staten Island, N.Y., were intentionally infected with hepatitis virus as part of an ongoing experiment to test the effectiveness of various vaccines and treatments.[10,11] Public knowledge of the event led to development of federal regulations for research involving children, including informed parental/guardian consent.

Legally, only competent adults can provide informed consent. However, the American Academy of Pediatrics recommends obtaining *assent* from children as young as 7 years depending on the child's age, maturity, and psychological state.[10,12,13] Assent is an ongoing process involving the child, parents, and members of the healthcare team in which, with parental consent, the team tells the child about the research in terms the child can understand and encourages the child to ask questions. When the team believes the child understands his or her role in the research, the child is asked to assent or dissent from participation. Unlike informed consent, assent is not required by law, although it may be required for institutional review board (IRB) approval, which will be discussed below.[13]

• ***The Tuskegee study.*** The Tuskegee Study of Untreated Syphilis in the Negro Male, commonly called the

Tuskegee study, was conducted from 1932 to 1972. In this study, researchers from the Public Health Service and the Tuskegee Institute in Alabama withheld penicillin, a known effective treatment, from study participants with syphilis in order to observe the disease's natural course. The participants were not informed about the study's purpose and did not receive treatment for their syphilis, even after penicillin became the treatment of choice in 1947.[14]

When this research came to light in 1972, the public outcry led to an inquiry by the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research. The Commission examined human rights issues of experimentation with humans and published the Belmont Report in 1979. In 1981, the Protection of Human Subjects Law was passed, providing the ethical standards followed in the US to this day.[2]

The Belmont Report heavily influenced the Federal Policy for the Protection of Human Subjects, known as the Common Rule, published in 1991.[15-17] This regulation added basic protections for participation of pregnant women, fetuses, neonates, children, and prisoners in research. The Common Rule also established requirements for voluntary consent for participation in research and obtaining written consent from persons agreeing to participate in research on a form to be approved by the IRB during the review process. Awareness of the history that led to legal requirements for conducting research reminds us of how basic human rights were violated in the past and how we can guard against similar events in the future.

The National Institutes of Health sets policies for human subjects research according to federal law.[18] IRBs require evidence of current human subjects protection training by all study team members to approve a research project. Renewal of human subjects protection knowledge is required every 3 years so researchers remain current on new laws that are developed as history evolves (for example, laws and regulations involving new technology and internet use).

Ethical principles that govern research

Which document defines the ethical principles that govern all research conducted in the US based on three basic tenets: respect for persons, beneficence, and justice?
a. the Nuremberg Code
b. the Common Rule
c. the Belmont Report
d. the Kefauver-Harris Amendments

Correct answer: c. The Belmont Report (1979) defines the ethical principles that govern all research conducted in the US based on three basic tenets: respect for persons, beneficence, and justice.[16,17] All persons who serve in the role of a study investigator are required to complete human subjects training, which includes a review of content from the Belmont Report.[3] Understanding interventions required to uphold these ethical principles when research is conducted is another important element of nursing advocacy.

The ethical principle of ***respect for persons*** acknowledges the dignity and freedom of every person and supports the requirement that voluntary informed consent be obtained before involving a human subject in research. In relation to the conduct of research, this principle addresses a person's ability to independently and autonomously volunteer for participation in a study. It also supports the mandate that persons be fully informed regarding study procedures and risks and benefits, and that they cannot be pressured or coerced to participate in research. All study opportunities must include provisions that give research participants the freedom to withdraw from a study at any time without penalty.[2,3,17,18]

The principle of ***beneficence*** requires researchers to maximize benefits and minimize risks for research subjects. PIs must weigh the benefits and risks of a research project by conducting a risk assessment that considers both physical and nonphysical harm. Minimal risk is defined as the probability that harm or discomfort will not be greater than that experienced in ordinary daily life. Study participants may not directly benefit from study participation; however, future benefits may be described as those that may be gained by society as a result of knowledge gained through research.[2,3,17,18]

Finally, the principle of ***justice*** requires a PI to develop a valid research protocol and fairly administer it. Justice requires that recruitment and selection of research subjects be equitable, with all participants being treated fairly during the conduct of a study. The PI should distribute burden and benefits among population groups by considering who bears the burden and risk of research participation and who benefits from the research findings. Study subjects should be selected fairly and equitably without exploiting a group that will not benefit from the study results.[2,3,17,18]

Conducting research according to ethical and legal standards requires nurses to:

- protect vulnerable research participants. Vulnerable participants are those with diminished autonomy who are less able to defend themselves in a given setting or situation.[17-20] In considering autonomy, two elements must be addressed: mental capacity or the ability to understand and process information, and voluntariness or freedom from the control or undue influence of others.[17] When some or all participants are likely to be vulnerable to coercion or undue influence,

additional safeguards must be included to protect their rights and welfare.[17-20] Nurses have a role in identifying vulnerable subjects and verifying that their rights are being protected when research is conducted.

Study participants may be vulnerable because of age, legal or mental incompetence, terminal illness, or confinement to an institution.[17,20] Examples include infants and children, human fetuses, prisoners, pregnant women, physically or mentally disabled persons, economically or educationally disadvantaged persons, and workers. The latter category may include employees of the facility in which the research is being conducted or any other participant who may face employment-rated risks. IRB approval requires justification for the inclusion of vulnerable subjects as study participants and the protocol should include a description of measures taken to protect their rights.[19,20]

Research involving special populations should not exceed a minimal risk level. The US Department of Health and Human Services and the FDA provide additional guidance on the concept of participant research vulnerability.[21-23]

• adhere to federal regulation of research activity. In 1974, Congress passed the National Research Act as Public Law 93-348 and established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.[2] The Commission identified that all research proposals involving human subjects should be based on ethical principles and be approved in advance by an IRB. The IRB is the recognized authority for determining whether a project is research or a quality improvement (QI) initiative (see *Is it research or QI?*).

In the early 1980s, these regulations were revised and published as Title 45 Code of Federal Regulations Part 46, Protection of Human Subjects (45CFR46), which includes a category of Special Protection of Children, Mentally Ill, or Special Populations.[24] Nurses should be aware that because research conducted in the US is subject to all federal regulations identified in 45CFR46, an organization can lose the right to conduct research if 45CFR46 requirements are violated.

Two government agencies oversee research conduct: the Office for Human Research Protections and the FDA.[24,25] Hospitals, universities, and other organizations receiving federal research funding enter into an agreement, called an assurance, regarding the ethical conduct of research. As discussed below, the agreement specifies that an IRB functioning in accordance with 45CFR46 reviews and approves all research proposals involving human subjects that will be conducted within the organization.

Is it research or QI?[31-33]

Research is defined as a systematic or scientific investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. *Quality improvement (QI)* is an organizational strategy involving analysis of process and outcomes data and systematic initiatives designed to improve performance in a particular healthcare setting. Both research and QI projects can involve data collection from human subjects; however, not all interactions with humans or data collected from humans is considered research under IRB rules. For example, purely QI projects such as data collection for internal administrative purposes do not require IRB approval. But because QI projects can overlap with research, many organizations require all project proposals to be submitted for IRB review.

The IRB is the recognized authority for determining whether a project is QI or research. The IRB review process assures human subjects protection for all proposed project work.

Understanding the role of IRBs

Which statement about an IRB is ***not*** *true?*

a. The primary responsibility of an IRB is to protect the welfare and rights of human subjects.

b. Federal regulations require an IRB to be comprised of a minimum of twelve members from diverse occupations and backgrounds, with one member from outside the organization.

c. IRB members are responsible for reviewing a protocol to assess the balance of risks and benefits and determine that risks to subjects do not outweigh the benefits or knowledge to be gained.

d. IRBs conduct an initial review of all proposed research studies, continuing reviews, and quality assurance audits.

Correct answer: b. The minimum number of members required for an IRB is 5, not 12.

An IRB's primary responsibility is to protect the welfare and rights of human subjects. Many IRBs are institutionally based programs. IRBs conduct an initial review of all proposed research studies and then conduct a continuing review, at least annually, for studies in progress for more than 12 months. The IRB also conducts quality assurance audits.[3]

Federal regulations require an IRB to be comprised of at least five members from diverse occupations and backgrounds, with one member from outside the organization. Typical IRBs are comprised of physicians, nurses, other healthcare specialists, chaplains, ethicists, and at least one community member.[3] IRB members are responsible for reviewing a research protocol to assess the balance of risks and benefits, and to determine that risks to subjects do not outweigh the benefits or knowledge to be gained. IRB members also evaluate ethical components to determine that basic

human rights are not being compromised, selection of subjects is fair and equitable, informed consent will be obtained, and confidentiality of study data will be protected.[26]

Five basic human rights

Which basic human right is violated when people become research subjects and/or are exposed to research treatment without their knowledge or when participants are misinformed about the purpose of the research?
a. self-determination
b. privacy and dignity
c. anonymity and confidentiality
d. fair treatment
e. protection from discomfort and harm

Correct answer: a. The right to self-determination is violated when people become research subjects and/or are exposed to research treatment without their knowledge or when participants are misinformed about the purpose of the research.

Nurses engaged in research must address all five of these basic human rights as they develop a study protocol.[27]

- The *right to self-determination* addresses freedom to choose without external control and is founded on the ethical principle of respect for persons.[28] When conducting research, participants must be treated as autonomous agents with the right to choose to participate or to not participate, and the freedom to withdraw from a study at any time without penalty. Potential violations can result when participants perceive a threat of harm or when excessive rewards are offered to ensure study participation. Other violations would occur when people become research subjects without their knowledge or when participants are misinformed about the purpose of the research. A researcher includes information in the informed consent and data collection procedures of a protocol to describe how this basic right is being protected.
- The *right to privacy and dignity* addresses freedom of a person to determine the time, extent, and circumstances for sharing private information and is based on the ethical principle of respect for persons.[28] When conducting research, the PI must inform participants that they may choose to decline to answer questions and decline to allow measurements, such as vital signs or lab specimens, to be collected by the researcher. The PI must also tell participants how their study data will be managed and shared. Violations may occur if invasive questions are asked that may result in loss of job, friendships, or dignity, or that may create embarrassment or emotional distress. A violation could also occur if participants are not notified that their study information will be shared with others. The researcher includes information to explain how this basic right is being protected in the intervention (if applicable), instrument description, consent, data collection, data treatment, and dissemination sections of a protocol submitted for IRB review.
- The *right to anonymity and confidentiality* involves measures to assure that a subject's identity cannot be linked, even by the researcher, with his or her individual responses. Individual identities of subjects cannot be linked to research responses and cannot be publicly divulged. This right is based on the ethical principle of respect for persons.[28]

A researcher must describe how study data will be deidentified or collected in a manner that will protect the identity of all study participants. Violations can occur when the researcher, by accident or direct action, allows an unauthorized person to gain access to study data that contains identifiers or creates a harmful situation. The researcher includes descriptions of all measures taken to protect anonymity and confidentiality in the instrument, data collection, data treatment, and risks and benefits sections of a protocol.

- The *right to fair treatment*, which means that all persons should be treated fairly and should receive what they are due/owed, is based on the ethical principle of justice.[28] The PI makes plans to ensure equitable selection of subjects and their treatment when conducting research, confirms that subject selection is directly related to the research question, and assures that risks and benefits are distributed fairly. Potential violations may involve injustices with subject selection that occur as a result of social, cultural, racial, and/or gender biases. The researcher addresses these elements in the sample, setting, eligibility (inclusion/exclusion criteria), and risks and benefits sections of a protocol.
- The *right to protection from discomfort and harm* requires the researcher to take an active role to promote good and prevent harm; this aligns with the ethical principle of beneficence.[28] The researcher must design a study to minimize risks for social, physical, economic, or psychological discomfort or other harm. Violations may occur if the researcher knows in advance that harm, death, or disabling injury will occur and/or that the benefits do not outweigh the risks. Violations also can occur when measures are not included to minimize or manage potential study risks.

Risk exposure in research

Safety of human participants in research involves addressing categories of risk exposure during study participation. Which statement about risk exposure in research is true?
a. Research risk does not include nonphysical injury, such as concerns about loss of confidentiality, psychological distress, legal implications, employment issues, or social embarrassment.

b. Study participants are not exposed to risk when research procedures involve data collection using surveys/questionnaires or retrospective data collection from medical records.
c. All research studies involve some level of risk.
d. A researcher does not need to define measures taken to minimize risk within the study protocol if a study is categorized as "minimal risk."

Correct answer: c. Because all research studies involve some level of risk, the safety of human participants in research involves addressing categories of risk exposure during study participation. The term *risk* is used to describe potential injury or damage that may result from study procedures. In the US, control of research risk is centered within federal law 45CFR46.[24,28]

When developing a protocol, nurses sometimes mistakenly assume that no risk will be involved with certain research projects. Nurses need to be aware that all research studies involve some level of risk because risk in research is defined broadly and is not limited to physical injury.

Examples of research-related physical injury may be associated with an investigational device, experimental procedure, or medication. Nonphysical injury may involve loss of confidentiality, psychological distress, legal implications, employment issues, and/or social embarrassment.

In general, research subjects should not suffer undesirable effects from their research participation.[3] Because all research involves some degree of risk, a researcher must justify the risk and assure that the prospective benefits of the research proposal outweigh the risks a participant may be exposed to. All measures taken to minimize risk should be defined within the study protocol.[29]

Examples of minimizing risk may include use of a study design with adequate safeguards to protect the confidentiality of information collected, and inclusion of a data management plan. A data management plan could describe who is in control of collected data; where data will be securely stored; who will be authorized to access, use, or disseminate study data; how use of data will be disclosed to a study participant; whether personal identifiers will be used; and whether study results will be included in employee personnel files or patients' medical records. In addition, plans for the future uses of samples, identifiers, and data obtained from the samples must also be provided, along with a description of how long study data will be maintained and how study data will be destroyed. A researcher addresses these elements in the method, intervention (if applicable), data treatment, and risks and benefits sections of a protocol.

Key takeaways for nurses

The American Nurses Association Code of Ethics for Nurses–Provision 7 states that the nursing profession should engage in scholarly inquiry to identify, evaluate, refine, and expand the body of knowledge that forms the foundation of its discipline and practice.[1] Ongoing scholarly activities are essential to fulfilling a profession's obligations to society. Provision 7 identifies that nurses working alone or in collaboration with others can participate in the advancement of the profession through the development, evaluation, dissemination, and application of knowledge in practice. Magnet® organizations deliberately integrate evidence-based practice (EBP) and research into clinical and operational processes and educate nurses about EBP and research to explore the safest and best practices for patients and to generate new knowledge.

All nurses should learn the policies and procedures of their organization related to three areas: human subjects' protection (informed consent and the role of the IRB), requirements of study participation, and procedures for reporting conflicts between protection of a patient and requirements of study participation (see *Clinical nurse's role: Four examples*).[26] Remember that all proposed data collection from human subjects (including employee records and patients' medical records) should have some form of review. In addition to IRB approval, an organization may require other review processes for projects and studies that will be conducted by nurses or other employees. Nurses should identify the recognized body for determining if a proposal is research or QI within their practice setting and confirm that required human subjects review procedures were completed before data collection begins.

When a patient is admitted, clinical nurses should ask whether the patient is currently a subject in a research study. If the patient responds yes, the nurse should confirm that the patient has signed a consent form and ask for a copy of the consent form to be included in the medical record. However, the nurse cannot obtain consent for a research study unless he or she is a part of the study team, has received education about the study, and has competed human subjects' protection training. In addition, nurses should not obtain informed consent to participate in research from their assigned patients to prevent patients from feeling coerced or compelled to participate in order to receive quality care.[26]

Nurses must be aware that clinical care and research have different goals, procedures, and ethical considerations. The nurses' role when caring for a patient who is serving as a study participant is to recognize and report conflicts that can occur.[30]

Clinical nurse's role: Four examples

Review these clinical scenarios and choose the correct responses based on the discussions in this article.

1. When admitting a patient, the nurse learns that the patient is currently participating in a research study. What steps should the nurse take? (Choose all that apply.)

a. Confirm that the patient has signed a research consent form and ask for a copy of the consent form to include in the medical record.
b. Confirm that the study's PI knows about the hospital admission so he or she can provide information about the study procedures and any requirements that may have bearing on the patient's treatment plan.
c. Obtain information from the PI on all study requirements and any changes in the standard of nursing care (for example, additional vital sign measurements, phlebotomy, or patient teaching).
d. Notify the patient's healthcare provider and unit manager/director/supervisor.

Correct answers: a,b,c,d. The admitting nurse should take all of these steps.

2. A nurse coworker on the unit is the PI for a study she plans to conduct as part of her graduate program requirements. She asks all nurses on the unit to let their patients know about the study and obtain consent from patients who want to participate. The clinical nurse should:

a. Support the PI conducting the study so she can fulfill her school program requirements.
b. Recruit only those patients who are directly assigned to the nurse.
c. Tell the PI that a nurse cannot obtain consent for a research study unless the nurse is a part of the study team, has received education about the study, and has competed human subjects' protection training.
d. Discuss the study opportunity with patients, have patients sign the research consent form if they agree to participate in the study, and place the signed consent form in the medical record.

Correct answer: c. Nurses should not participate in recruitment unless they are authorized to do so as members of the research team. Nurses authorized to recruit should not recruit patients in their care to protect patients from feeling coerced by a caregiver.

3. Which of the following statements about clinical nurses' participation in research is true?

a. IRB review and approval of a research study proposal is not required when data are collected from nurses employed in a hospital setting.
b. Study opportunities can provide a way for nurses to contribute information that can be used to improve nursing practice and/or patient outcomes.
c. It is acceptable to forward an email study invitation to others to help the researcher reach the targeted sample size.
d. A review process is not required before collecting data from patients' medical records as long as the data collector is a hospital employee.

Correct answer: b. Study opportunities can provide a way for clinical nurses to contribute information that can be used to improve nursing practice and/or patient outcomes.

Nurses may receive email invitations to participate in a study being conducted within in their work setting. Nurses should never forward such an email study invitation to others because by doing so, the nurse would be engaging in study recruitment. Only members of the research team are eligible to recruit study participants after the IRB has reviewed the proposed recruitment and data collection procedures and has granted permission for the PI/study team to recruit participants.

4. A nurse's role in human subjects' protection involves which of the following? (Choose all that apply.)

a. Learning the policies and procedures of their organization related to three areas: human subjects' protection (informed consent and role of the IRB), requirements of study participation, and procedures for reporting conflicts between protection of a patient and requirements of study participation.
b. Serving as a patient advocate to uphold patient rights and ensure that research is conducted in an ethical, scientifically valid manner.
c. Assessing patients' ability to provide informed consent.
d. Confirming patients' knowledge regarding procedures and risks and benefits of the study they are participating in.

Correct answers: a,b,c,d. Nurses must fulfill all these responsibilities to protect human subjects engaged in research.

Examples include the incompatibility of planned treatment measures with study medications and/or interventions, adverse medication reactions, changes in mental status, breaches in confidentiality, coercion with recruitment or continued participation, or any identified healthcare risks.

To learn more about human subjects' protection, consider completing online courses such as the Collaborative Institutional Training Initiative at https://about.citiprogram.org/en/series/human-subjects-research-hsr or the National Institutes of Health web-based Training Module at https://phrp.nihtraining.com/users/login.php. ■

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INSTRUCTIONS

Protecting the rights of patients, nurses, and others participating in research

TEST INSTRUCTIONS

- Read the article. The test for this CE activity is to be taken online at **www.nursingcenter.com/CE/nursing.**
- You'll need to create (it's free!) and log in to your personal CE Planner account before taking online tests. Your planner will keep track of all your Lippincott Professional Development online CE activities for you.
- There's only one correct answer for each question. A passing score for this test is 13 correct answers. If you pass, you can print your certificate of earned contact hours and access the answer key. If you fail, you have the option of taking the test again at no additional cost.
- For questions, contact Lippincott Professional Development: 1-800-787-8985.
- Registration deadline is **June 4, 2021.**

PROVIDER ACCREDITATION

Lippincott Professional Development will award 1.5 contact hours for this continuing nursing education activity. Lippincott Professional Development is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. This activity is also provider approved by the California Board of Registered Nursing, Provider Number CEP 11749 for 1.5 contact hours, and the District of Columbia, Georgia, and Florida CE Broker #50-1223.

Payment: The registration fee for this test is $17.95.