

GUIDELINES FOR ETHICAL BEHAVIOR RELATING TO CLINICAL PRACTICE ISSUES IN NEUROMUSCULAR AND ELECTRODIAGNOSTIC MEDICINE

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ABSTRACT: The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) developed guidelines to formalize the ethical standards that neuromuscular and electrodiagnostic (EDx) physicians should observe in their clinical and scientific activities. Neuromuscular and EDx medicine is a subspecialty of medicine that focuses on evaluation, diagnosis, and comprehensive medical management, including rehabilitation of individuals with neuromuscular disorders. Physicians working in this subspecialty focus on disorders of the motor unit, including muscle, neuromuscular junction, axon, plexus, nerve root, anterior horn cell, and the peripheral nerves (motor and sensory). The neuromuscular and EDx physician’s goal is to diagnose and treat these conditions to mitigate their impact and improve the patient’s quality of life. The guidelines are consistent with the Principles of Medical Ethics adopted by the American Medical Association and represent a revision of previous AANEM guidelines.

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THE PATIENT–PHYSICIAN RELATIONSHIP IN NEUROMUSCULAR AND ELECTRODIAGNOSTIC MEDICINE

The Patient–Physician Relationship. The relationship between the patient and the physician is a key component to assure that excellent care is provided. The quality of this relationship can impact not only the success of the outcome of the interaction between

patient and physician, but also the outcome of the patient’s treatment. The physician has a fiduciary duty to first safeguard the interests of the patient. The physician must practice competently, respect patient autonomy and confidentiality, maintain patient safety, and protect the patient’s best interests.

Beginning and Ending the Relationship. The physician is free to decide whether to perform an EDx or neuromuscular evaluation on a particular patient. The physician should not decline the evaluation on the basis of the patient’s race, color, religion, national origin, gender, disability, age, or other personal characteristics. The physician also should not decline an evaluation on the basis of the patient’s known or suspected medical diagnosis. The physician should decline performance of the EDx or neuromuscular evaluation if he or she believes it to be unnecessary or not beneficial to the patient.

If possible, it is best for the EDx physician and the referring physician to concur on who should inform the patient (or designated surrogate) of the results of the EDx or neuromuscular evaluation. The physician should discuss with the patient the reason for the evaluation and the methods to be employed. The physician should advise the patient as to who will be providing the patient with the results of the test. If the patient has a diagnosis that does not require EDx or neuromuscular testing, the physician should so inform the patient and cancel the study or give the patient the right to cancel the study (see subsection “Cooperation and Communication with Healthcare Professionals”).

Once the evaluation has begun, the physician should complete the evaluation process unless the patient ends the relationship before the evaluation can be completed, or if medical contraindications to completing the evaluation become apparent during the evaluation. After completion, the physician should return the patient to the care of the referring physician. If the patient does not have a referring physician, the physician should take

Abbreviations: AANEM, American Association of Neuromuscular and Electrodiagnostic Medicine; EDx, electrodiagnostic; EMG, electromyography; FDA, Food and Drug Administration; HIV, human immunodeficiency virus; IRB, institutional review board; LAR, legally authorized representative; NCS, nerve conduction study; OSHA, Occupational Safety and Health Administration; TJC, The Joint Commission

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responsibility for urgent care of the patient until an appropriate referral can be made.

Informed Consent in Clinical Evaluation. The physician must obtain valid verbal or written consent from the patient. When the patient cannot give consent or lacks decisional capacity, a verbal or written consent must be obtained from the patient's appropriate legally authorized representative (LAR), who acts as a surrogate decision-maker. If the LAR is unavailable and the situation is urgent, the physician may proceed without consent. The physician must disclose information that the average person would need to know to make an appropriate medical decision. This information must include the benefits and risks of the proposed tests and should include the costs of the proposed tests if the patient desires this information. If the patient is referred for evaluation of a painful symptom, the physician should explain that the EDx studies are directed toward evaluation of certain measurable peripheral nerve abnormalities, not whether pain is present or absent. The patient must give consent voluntarily. If reasonable explanation fails to elicit a patient's consent to carry out the EDx examination, the physician should not undertake the evaluation. The patient may withdraw a prior consent; if this occurs at any point during testing, the physician should not continue with the examination. Physicians must comply with applicable state and federal laws governing informed consent requirements.

Federal Food and Drug Administration (FDA) and institutional review board (IRB) rules should be followed when conducting experimental or investigational studies of procedures, pharmaceuticals, or medical devices that involve human subjects (see section "Clinical Research").

Patient Communication, Comfort, and Preparation. The physician has a duty to communicate with the patient. The physician should convey relevant information in terms the patient can understand and allow adequate opportunity for the patient to raise questions and discuss matters related to a neuromuscular and/or EDx evaluation. Physicians should make every effort to ensure that patients are adequately prepared for planned neuromuscular evaluation and EDx procedures and that they are made as comfortable as possible during the examination. Physicians should be attentive to signs of patient discomfort and safety concerns and resolve them before proceeding. Physicians may decide whether to admit family members or significant others into the examination room during testing to provide support. Informing the patient of the findings of the examination should be coordinated with the referring physician (see previous subsection "Beginning and Ending the

Relationship"). Moreover, suggestions for changes in clinical management should generally be made to the referring physician rather than the patient, unless the referring physician has requested that the physician participate in the direct clinical management of the patient.

Medical Risk to the Physician. Physicians have needs and concerns that are relevant for ethical decision-making in the context of evaluation. At the same time, a physician should provide appropriate, compassionate care to all patients, including patients with infectious and other communicable diseases [e.g., human immunodeficiency virus (HIV) or antibiotic-resistant infections]. A physician should not deny care to a patient solely because of real or perceived medical risk to the physician. Physicians must utilize appropriate universal precautions during the examination of any patient to minimize their own medical risk.

Ethical Considerations and the Management of Neuromuscular Disease. Some neuromuscular disorders are progressive or debilitating and may impact a patient's autonomy or competence. Many neuromuscular disorders have limited treatments, which may lead patients to seek unproven interventions. Others may have effective but costly treatments that their insurance may not cover or which patients may not be able to afford. Still others are known to shorten a patient's life expectancy with the prospect of a challenging final few months of life, leading the patient to seek alternatives for end-of-life care. In addition, genetically diagnosed diseases may include issues that affect relatives and future decision-making and have social implications.

Discussion of Disease Implications. First and foremost, physicians must provide patients with their best diagnostic and management skills. They also have a duty to discuss openly with their patients the implications of their EDx diagnosis and related illnesses. This discussion may require a great deal of sensitivity and compassion on the physician's part, particularly if the diagnosis is one that will severely impact the patient's quality or length of life. The physician's counsel should be honest yet allow the patient to preserve some level of realistic hope. The physician has a duty to help the patient understand, decide upon, and seek reasonable treatment, should this be available, and to help avoid ineffective treatments.

Progressive Disorders. For progressive disorders the physician should provide or refer the patient to services that will help maintain or prolong the patient's autonomy and independence. When the neuromuscular diagnosis is expected to limit life expectancy, the physician has a duty to provide this information to the patient as well as to provide

a realistic estimate of life expectancy, if possible. The patient has a right to this information in order to be able to plan appropriately and address end-of-life issues. The physician should be prepared to counsel the patient regarding end-of-life care and to provide referrals as appropriate.

Treatment. Patients with neuromuscular disorders, many of whom currently have limited treatment options, may seek out or request treatments that are not beneficial or are potentially harmful. The physician is not required to provide medical treatment if the treatment is not medically beneficial, ethically appropriate, or the risks outweigh the benefits. If a physician's determination regarding medical care conflicts with the advance directive of a competent patient or the LAR, then the physician should explain his or her treatment determination and recommendations with the goal of resolving the conflict. If the conflict cannot be resolved and it interferes with the physician's care of the patient, then the physician should make a reasonable effort to find another physician to provide care for the patient.

Pain Management. Many neuromuscular disorders can result in significant acute or chronic pain in affected patients. Patients in pain have a legitimate right to access pain management. Pain management is a complex area of patient care and one that has ethical implications for physicians. Physicians who elect to manage acute or chronic pain in this population should be familiar with the various pharmacologic and non-pharmacologic modalities and options available. Physicians who choose to manage their patients' acute or chronic pain must have a solid working knowledge of the dosing schedules, side effects, and the diversion or abuse potential of the various medications available for pain management. Physicians also should be very familiar with the use of pain medication or opioid contracts, the various professional guidelines, and state or federal regulations related to the management of acute or chronic pain. Physicians who elect to not manage a patient's acute or chronic pain should refer the patient to another physician or pain management specialist for this management as appropriate.

Genetics. Novel ethical dilemmas may occur when the diagnosis of neuromuscular disease is confirmed by genetic testing. Physicians should strive to provide a balanced approach when interpreting genetic information as it relates to environmental factors and phenotypic variability. Physicians should help patients communicate findings and health implications to extended family members. Resources for genetic counseling should be offered, including

preconception and prenatal counseling. Physicians and patients should be aware of legal protections, such as the Genetic Information Nondiscrimination Act,¹ which prohibits discrimination as it relates to employment and health insurance coverage. Social risks to patients may still include increased costs of health insurance, and non-insurability for disability, life, and extended-care insurance. Physicians should seek expert consultation as it relates to the rapidly evolving field of genetic and epigenetic diagnosis.

GENERAL PRINCIPLES OF PATIENT CARE

Professional Competence. The physician should perform evaluations only within the scope of his or her training, experience, and competence. The physician should provide care that represents the prevailing standard of care for neuromuscular and EDx practice. Physicians should use only standard, well-accepted, and published techniques and methods of evaluation and interpretation. Evidence-based techniques are preferable. To this end, physicians should participate in, and keep documentation of, a regular program of continuing education. Physicians should maintain current technical skills and ensure they have adequate experience before introducing new techniques into practice. On occasion, other new or non-standard techniques may be necessary when dealing with an unusual clinical problem or a research study. If all or part of the evaluation is considered research, it must conform to the guidelines outlined in the section "Clinical Research."

Confidentiality. The physician must maintain patient privacy and confidentiality, both in performing EDx studies and the configuration of the examination areas in which they are performed, in accordance with all state and federal laws and regulations addressing patient privacy. The patient's name or other demographic information, as well as details of the patient's life or illness that would identify the patient, must not be publicized or published without written permission.

Patient Records. Physicians should keep and manage medical records that are complete, accurate, and in compliance with the Health Insurance Portability and Accountability Act (HIPAA). The physician's records should include a statement of the problem and the indications for the neuromuscular evaluation and/or the EDx study, description of the findings, assessment of normality or abnormality of these findings, and clinical correlation and diagnostic conclusions. Storing recordings of actual waveforms from nerve conduction studies (NCS) and needle electromyography (EMG) is not required. In writing reports, physicians are encouraged to follow *Reporting the Results of Needle EMG and NCS: An Educational Report*, a publication of the AANEM.²

Information within the medical records should be available only to appropriate individuals, including referring physicians, patients, and others indicated in a valid release of information signed by the patient. Urgent information should be communicated directly and promptly to the referring physician and should be appropriately documented in the physician's record.

Professional Fees. The physician is entitled to reasonable compensation for services commensurate with specified billing procedures, the comprehensive nature of the evaluation, difficulty of the study, time involved, and the number of procedures performed. The fee structure must be made available upon request to patients, referring physicians, or third-party payers. The physician should bill for and receive compensation for only those services actually rendered or supervised. The physician must not receive a fee for making a referral or give a fee for receiving a referral ("fee-splitting"). The physician should not receive a commission from anyone for an item or service ordered for a patient ("kickback").

Appropriate Services. The physician should perform a sufficiently comprehensive neuromuscular evaluation and/or EDx study that can address the issues necessary to determine or evaluate a reasonable differential diagnosis. For the EDx study the physician must be involved in the pre-test evaluation (focused history and physical examination) of the patient and the plan of the study and should perform only those tests that are medically indicated. Tests selected and procedures used should conform to published guidelines, when available.

The physician has the ultimate responsibility for NCS examinations, even if they are performed by a technologist or another physician under the physician's supervision. The physician must be readily available and must promptly review and evaluate the results of the NCS. The patient should remain in the examination room until the supervising EDx physician has reviewed the NCS results.

All needle EMG examinations should be performed by the appropriately trained neuromuscular or EDx physician, or, in the case of residents or fellows, under supervision of such a physician.

Except in unusual circumstances, the NCS and EMG examination of a single patient should be performed on the same day and by the same EDx physician, for continuity and consistency.

The evaluation and diagnosis of neuromuscular disease may require the use of a number of specialized laboratory or diagnostic tests. The physician may have the appropriate training to perform some of these specialized studies. Referral to other specialists may be necessary for some specialized

tests. Many of these tests may provide information that can pose ethical dilemmas for the physician as well as the patient.

In particular, genetic testing is increasingly used to diagnose neuromuscular disease. Advances in multiplex genetic testing, including whole genome and exome testing, present complex ethical dilemmas for physicians and patients. Physicians should strive for clear communication and shared decision-making when considering genetic testing. Pre-test genetic counseling is essential and should include traditional discussions of benefits and risks. Attention should be given to obtaining assent from minors when appropriate. Patients should be educated on the potential for normal variants, non-specific findings, phenotypic variability, and incidental findings. At present, testing, when possible, should be limited to single-gene tests or masked-multiplex tests to decrease the occurrence of incidental findings. With next generation sequencing, the ethical dilemma will be disclosure of genetic mutations and predisposition to diseases not under consideration. Post-test genetic counseling should be provided for all positive findings, including disclosure of incidental findings. In many cases, physicians must be prepared to coordinate care for the extended family as needed for carrier testing, reproductive risk counseling, and testing of undiagnosed individuals. When beneficial treatments do not exist, testing asymptomatic minors for adult-onset diseases should be delayed until the age of consent.

As the diagnosis and management of neuromuscular disease evolves, new ethical questions will continue to present themselves, especially with whole genome and exome testing delineating not only the gene in question but also other unexpected gene mutations that may suggest additional disease(s). Society's viewpoint on these topics also will continue to shift, requiring physicians to be ever vigilant.

PERSONAL CONDUCT

Respect for the Patient. The physician must treat patients with respect and honesty, with particular sensitivity to language barriers, cultural diversity concerning personal modesty (appropriate use of chaperones), physical pain, and disability. The physician must not abuse or exploit the patient psychologically, sexually, physically, or financially.

Respect for Agencies and the Law. The physician should observe applicable laws. The physician should cooperate and comply with reasonable requests from insurance, compensation, reimbursement, and government agencies within the constraints of patient privacy and confidentiality.

Maintenance of the Physician's Personal Health. The physician should strive to maintain physical and emotional health and should refrain from practices that may impair his or her ability to provide adequate patient care.

CONFLICTS OF INTEREST

The Patient's Interest Is Paramount. Whenever a conflict of interest arises, the physician must attempt to resolve the issue in the best interest of the patient. Conflicts of interest that cannot be eliminated should be disclosed to the patient. If, after discussing the conflict, the patient does not wish to proceed, the physician should not perform the examination.

Avoidance and Disclosure of Potential Conflicts. The physician must avoid practices and financial arrangements that would, solely because of personal gain, influence decisions on the types of examinations performed on patients. Financial interests of the physician that might conflict with appropriate medical care should be disclosed to the patient.

Healthcare Institutional Conflicts. The physician should advocate for his or her patient's medical interests when they are jeopardized by policies of a healthcare institution or agency. The physician should inform the patient when referral restrictions on testing would limit the validity of results.

RELATIONSHIPS WITH OTHER PROFESSIONALS

Cooperation and Communication with Healthcare Professionals. Physicians should cooperate and communicate with other healthcare professionals, including other physicians, nurses, and therapists, to provide the best care possible to patients. Written and oral communication with other healthcare professionals should be carried out in a timely and courteous manner. The terms used in the communication should be useful to the referring physician and be as responsive to the referral question as possible.

The physician may teach fellows and residents how to perform the EDx examination. Effective teaching requires close supervision of trainees during the actual testing and careful review of the report of the findings before it is sent to the referring healthcare professional.

On occasion, while evaluating a patient referred for EDx testing, the physician will determine, based on available clinical information, that the patient most likely has a medical problem that is not localized within the peripheral neuromuscular system. The physician should attempt to communicate this opinion to the referring healthcare professional with the goal of optimizing further care for the patient. Options may include not proceeding with the planned EDx testing and redirecting the diagnostic evaluation.

Referrals from other Physicians. For the most part, referrals to physicians come from other physicians. Referrals for neuromuscular evaluations and/or EDx testing may come from other healthcare professionals, or patients may refer themselves. If the referral did not come from another physician, every attempt should be made to identify the patient's primary physician so that results of the neuromuscular or EDx evaluation, with patient consent, may be sent to the primary physician. If the patient has no primary care physician, then the physician should refer the patient to a primary physician or specialist if one is needed.

If the primary care or referring physician agrees, the EDx physician may actively participate in further evaluation and treatment of the patient's neuromuscular issues and may even become the principal provider of care for these issues.

Studies Performed on One's Own Patients—Self-Referral.

Most physicians see and follow patients for clinical, diagnostic, and therapeutic reasons. In the course of providing such evaluation and management, a physician may recommend that a patient have EDx or other specialized studies, such as biopsies or ultrasound, to clarify a diagnosis or assist with treatment. Ordering and performing EDx studies, or any other specialized studies, for which the physician is appropriately trained and experienced to do, on one's own patient is not considered a "self-referral," but is instead part of the evaluation and considered to be appropriate patient care. In fact, it may be in the best interest of the patient for the physician who knows the patient to perform these studies. When considering performing EDx or other specialized studies on one's own patient, the physician must keep in mind that there must be a proper indication for the study, which is consistent with relevant guidelines. The need for and the scope of the study should be properly documented in the patient's medical record. Some neuromuscular and EDx physicians may prefer to refer their patients to other physicians for specialized or EDx testing, to avoid even the appearance of a conflict of interest. Patients also always retain the right to request specialized neuromuscular or EDx testing by an independent physician without compromising their ongoing clinical care.

Peer Review, Utilization Review, and Quality Assurance. The physician should participate in peer review, utilization review, and quality assurance activities in order to promote optimal patient care.

Competence of Colleagues and Impaired Physicians. Physicians should not knowingly ignore a colleague's incompetence or professional

misconduct, which could jeopardize the safety of the colleague's present and future patients. The physician should strive to protect the public from an impaired physician and should assist in the rehabilitation of impaired colleagues. Physicians should cooperate with peer review processes.

Expert Witness Testimony. Physicians, as an act of public interest, are encouraged to serve as impartial expert witnesses in clinical and technical matters regarding neuromuscular and EDx medicine. Expert witness testimony is opinion testimony that may relate to the standard of care, nature and extent of disability, causation of injury, clinical status of the patient, or prognosis. Physicians cannot be required to provide expert witness testimony. An expert testifies either for the person bringing the case (the plaintiff or the government in a criminal matter), the person being sued (the defendant), or the judge. It is important for physicians who act as expert witnesses to remember that transcripts of depositions and courtroom testimony are public records and subject to independent peer review.

The minimum statutory requirements for qualifications for an expert witness in a medical malpractice action should reflect all of the following:

- (a) The expert witness should have comparable education, training, appropriate certification, and occupational experience in the same field of expertise as the opposing physician.
- (b) The expert witness's occupational experience should include active medical practice or teaching experience in the same field of expertise as the opposing physician.
- (c) Some state statutes require the expert witness to be currently in active medical practice; whereas, in most states, the expert witness needs to have been in active medical practice or teaching experience within 5 years of the occurrence giving rise to the claim.

It is unethical for expert witnesses to provide services under a contingent fee arrangement or to link compensation to the outcome of the case. Compensation should be reasonable and commensurate with actual services rendered.

Physicians who provide expert medical testimony should be adequately versed in the medical and scientific issues involved in the matter and, before giving testimony, should carefully review the relevant records and facts of the case and the standards of practice prevailing at the time of the occurrence that gave rise to the claim.

Physicians should testify about the medical records, the standard of care, and any other matter related to the case fairly, honestly, and in a balanced manner.

Physician expert witnesses are expected to be impartial and should not adopt a position as an advocate or partisan in the legal proceedings.

Healthcare Organizations. The physician may enter into contractual agreements with managed health-care organizations, prepaid practice plans, or hospitals. The physician should retain control of medical decisions without undue interference. The patient's welfare must remain paramount.

RELATIONSHIPS WITH THE PUBLIC AND COMMUNITY

Public Representation. Physicians should not represent themselves to the public in an untruthful, misleading, or deceptive manner regarding qualifications, credentials, or expertise through statements, testimonials, photographs, graphics, or other means. A patient's medical condition must not be discussed publicly without his or her consent (see subsection "Confidentiality").

Duties to Community and Society. Physicians should work toward improving the health of all members of society. This may include participation in educational programs, research, public health activities, and provision of care to patients who are unable to pay for medical services. The physician should be aware of the limitation of society's healthcare resources and should not overutilize those finite resources by performing unnecessary tests. The needs of an individual patient should be given priority.

Existing Laws. The physician is obligated to obey the laws of the land and refrain from unlawful activities but is strongly encouraged to help produce change in laws that are not in the best interest of patients and society. Physicians should cooperate with legal authorities and processes. They should honor reasonable requests from insurers and government agencies, consistent with ethical and legal privacy protections required by law.

TECHNOLOGISTS IN THE ELECTRODIAGNOSTIC LABORATORY

Establishing and Maintaining the Patient-Technologist Relationship. Although the patient-physician relationship remains the core of all medical care provided, EDx technologists (referred to as technologists hereafter) are often the frontline staff with whom patients first interact. It is, thus imperative that technologists develop and maintain rapport with patients.

Technologists should treat every patient in a professional and courteous manner, regardless of the patient's race, color, religion, national origin, gender, disability, age, or other personal characteristics, and irrespective of the patient's known or suspected medical diagnosis.

Technologists should safeguard the patient's right to privacy and confidentiality and uphold all laws governing patient information.

Technologists should maintain patient safety and cleanliness and adhere to The Joint Commission (TJC) guidelines for Universal Precautions as well as the Occupational Safety and Health Administration (OSHA) law and standards.³

Scope of Practice. The technologist should always work under the direct supervision and direction of a physician fully qualified in the practice of EDx medicine. Although Medicare regulations mandate that a physician must provide a minimum of general supervision over certified technologists throughout the performance of NCS testing, it is the position of the AANEM that direct supervision, as defined by Medicare, is recommended for all NCS testing.⁴

Technologists may explain EDx testing to patients. The technologist should perform accurate and unbiased electrophysiological studies with patient comfort as their utmost priority. The technologist should keep records of studies and take part in the overall maintenance of the EDx laboratory.

Technologists cannot give results of the NCS, can neither perform nor give results of needle EMG, and cannot discuss aspects of diagnosis and management with patients.⁴

Professionalism. Technologists should demonstrate professional etiquette toward their colleagues (physicians, residents and fellows, and other healthcare professionals) irrespective of experience level, and should provide high quality, team-based, patient-centered care. Technologists may guide and teach the skills involved in NCS to other junior technologists, residents, and fellows.

Technologists are required to maintain their licensure and certification. They should keep up with the latest in medical sciences and technology. Although it is not required, technologists are encouraged to attend annual conferences and contribute to research and publications.

The technologist should utilize interpersonal and communication skills that are patient-appropriate with patients, laboratory staff, and other health professionals.

The technologist should explain test procedures to the patient in order to obtain the cooperation necessary for a complete examination.

The technologist should perform standard and advanced NCS in a highly skilled, patient-appropriate manner, recognize normal and abnormal results, and recognize and take reasonable steps to eliminate physiological and non-physiological artifact.⁵

CLINICAL RESEARCH

Informed Consent. Research is an activity designed to develop and increase generalized knowledge. All research on human subjects must be approved and in compliance with current IRB rules and regulations. Informed consent must be obtained for all research on human subjects. A full disclosure of risks, as well as potential benefits or lack thereof, must be specified. In all circumstances pertaining to research, informed consent must include a written document signed by the subject or LAR. The physician or other appropriately identified investigator is responsible for obtaining informed consent from the research subject for any research investigation or clinical trial before enrolling the subject in research. If the subject is an active patient of the physician-investigator, the physician must recognize that there is a potential for coercion because of the patient's dependent relationship/position to the physician-investigator. The patient may feel under duress to consent to the research whether or not this is expressed. To avoid any real or perceived duress, it is advised that, whenever possible, informed consent be obtained by an investigator completely independent of the patient-physician relationship. Special care should be taken with vulnerable populations, including children, pregnant women, and cognitively impaired individuals. Opting to participate or not participate in the research should not affect how care is provided to the patient.

Institutional Review. The research project should conform to generally accepted scientific principles. The physician who participates in clinical research must ascertain that the research has been approved by an institutional review board (IRB) or other comparable body, and must adhere to the requirements of the approved protocol. Any adverse events or outcomes must be documented and reported to the IRB, Data Safety Monitoring Board, and to the sponsoring and regulatory agencies.

Financial Charges to Research Subjects. Although it is acceptable to mix clinical practice and clinical research procedures in the same setting, the research procedures should be clearly identified to the research subject in accordance with the IRB-approved research protocol. Compensation for clinical research should follow applicable study guidelines and IRB approval. Physicians should not bill the patient or the insurer for services for which they have already been compensated by the study sponsor. All federal, state, and local regulations pertaining to billing for clinical care/services associated with clinical research must be observed to avoid billing the same services more than once.

Disclosure of Potential Conflicts. The physician who is paid for testing patients in a clinical research project should inform the patient of any compensation he or she receives for the patient's participation. The amount of compensation for patient testing should be reasonable.

Reporting Research Results. The physician should publish research results—both positive and negative—truthfully, completely, and without distortion. In reporting research results to the news media, the physician should make statements that are clear, understandable, and supportable by the facts. Physicians should not publicize research results until after the data have been subjected to appropriate peer review and accepted for presentation or publication.

APPENDIX AMERICAN MEDICAL ASSOCIATION PRINCIPLES OF MEDICAL ETHICS⁶

Preamble. The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self. The following principles adopted by the American Medical Association are not laws but rather standards of conduct that define the essentials of honorable behavior for the physician.

Principles of Medical Ethics.

I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.

II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.

III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements that are contrary to the best interests of the patient.

IV. A physician shall respect the rights of patients, colleagues, and other health professionals, and

shall safeguard patient confidences and privacy within the constraints of the law.

V. A physician shall continue to study, apply, and advance scientific knowledge; maintain a commitment to medical education; make relevant information available to patients, colleagues, and the public; obtain consultation; and use the talents of other health professionals when indicated.

VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.

VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.

VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.

IX. A physician shall support access to medical care for all people.

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