

Opinion on Ethics and Professionalism

Ethics in Health Research in Orthopaedic Surgery

An AAOS Opinion on Ethics and Professionalism is an official AAOS statement dealing with an ethical issue, which offers aspirational advice on how an orthopaedic surgeon can best deal with a particular situation or circumstance. Developed through a consensus process by the AAOS Ethics Committee, an Opinion on Ethics and Professionalism is not a product of a systematic review. An AAOS Opinion on Ethics and Professionalism is adopted by a two-thirds vote of the AAOS Board of Directors present and voting.

Issues raised

What are the general ethical issues involved in the conduct of health research in orthopaedic surgery?

Definitions

Orthopaedic surgeons conduct basic science, translational and clinical research. “Health research” is a broad term encompassing all research designed to contribute to our understanding of how best to care for our patients. Health research covers various types of research, including clinical research (defined by the AMA as “a part of a systematic program competently designed, under accepted standards of scientific research, to produce data that are scientifically valid and significant”), basic science research, research on animals as precursor to human research, outcome studies research, psychosocial research, and demographic and economic studies. In this Opinion on Ethics and Professionalism, unless otherwise noted, the broad term “health research” will be used.

Ethical considerations

According to the Academy’s *Opinion on Ethics and Professionalism on Continuing Medical Education*, upon completion of orthopaedic residencies or fellowships, orthopaedic surgeons assume an ethical and professional obligation to stay abreast of developing knowledge in the musculoskeletal sciences. Many orthopaedic surgeons have chosen to go beyond this basic obligation to assist in the advancement of musculoskeletal knowledge and its dissemination.

Orthopaedic surgeons who conduct health research have an ethical responsibility to ensure that any research performed meets all of the standards which have been developed to protect their research subjects while furthering our medical knowledge. Failing to ~~de-se~~ follow internationally accepted practices related to human and animal research is unethical and may also be illegal. Results obtained from unethical practices will not become part of the body of scientific

knowledge nor will it be accepted for presentation or publication. In addition, failure to perform well designed studies without appropriate ethical considerations may impede or delay progress in learning about the musculoskeletal sciences and will damage the credibility of all health researchers, thereby harming not only the research community, but also the greater orthopaedic community and the patients whose care depends on the results of research.

The Academy believes the ethical tenets described below constitute reasonable guidelines to assist health researchers in orthopaedics. These guidelines include the following:

The purpose of health research: Health research should be designed and conducted to develop new or confirmatory knowledge that promotes health, prevents diseases and injuries, and improves diagnosis and treatment of diseases and injuries. Research involving human subjects is only appropriate when the potential risks to the research participant are reasonable in relation to the potential benefits to the participant or to future patients and are sensible because of the importance of the knowledge which might be gained.

Examples of unethical conduct:

- Designing and conducting research with the primary purpose of discerning methods of causing injury, illness or suffering;
- Designing or conducting research that is repetitious or redundant with the primary intent of advancing individuals or specific groups financially or professionally;
- Designing or conducting research that is not intended to produce new or confirmatory information that is valid or significant; and
- Purposefully stating, reporting or misinterpreting (by omission or commission) data to arrive at a pre-determined theory or opinion.

Support of sponsorship of research: Most financial support for health research comes from the federal government, industry, philanthropic organizations, or is self-funded. Each source of funding presents a potential conflict of interest.

Three primary parties have distinct interests when corporations fund health research:

1. the researcher;
2. the research institution;
3. the corporation funding the research.

The relationships among these groups may vary substantially, and the goals of the research projects are not necessarily aligned.

In the most frequent type of relationship, the funding corporation develops a Request for Proposal (RFP) or presents a research protocol to the researcher and funds the researcher for carrying out the protocol. This essentially creates a fee-for-service arrangement.

Reimbursement for additional resources and the time devoted to complete the investigation are appropriate. Many research institutions have created structures that allow for funded research to be negotiated in a manner that attempts to eliminate any potential conflicts in the negotiations between the research and the sponsoring industry. Generally, the Office of the Vice-President for Research or the Dean for Research understands the ethical guidelines to minimize conflicts of interest and will be a valuable source in the development of an ethical and legal contract.

A second type of relationship involves the researcher submitting an unsolicited research proposal directly to the funding corporation.¹ The researcher would benefit by obtaining funds for needed equipment and supplies and the funding corporation would benefit by the possibility of expanding its market potential for a given product. This arrangement also may be viewed as ethically appropriate and mutually beneficial, assuming the proper conduct of science ensues and full disclosure is maintained.

A third type of relationship involves truly cooperative projects.¹ Often, these types of relationships are enacted in the setting of a clinical trial. Numerous advantages exist for the researcher, the research institution, and the funding corporation for the development of cooperative programs between medicine and industry. Full disclosure is essential to the success of this type of venture.

Ethical problems may arise when the researcher or the research institution have a direct financial interest in the research program. For example, researchers may hold stock or stock options in the funding corporation that manufactures the product or they may have other profit-sharing arrangements with the company. These financial interests may compromise (or give the impression of compromising) the objectivity of the researchers and cause them to downplay or suppress negative data while exaggerating favorable data. Such economic incentives may also introduce subtle biases into the way research is conducted, analyzed or reported.

The Academy believes that guidelines for circumstances in which researchers face economic conflicts of interest may be determined in reference to two ethical principles:

- A researcher ethically may share the economic rewards of his or her efforts. If a drug, device, or other product becomes financially remunerative, the researcher may receive profits that reasonably resulted from his or her contribution. The Academy's *Standards of Professionalism on Orthopaedic Surgeon-Industry Relationships* and the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* explicitly permit an orthopaedic surgeon to receive royalties. However, ethically the researcher may not reap profits that are not justified by the value of his or her actual efforts.
- Potential sources of bias in research should be eliminated, particularly where there is a direct relationship between a researcher's personal interests and potential outcomes of the research.

Several conclusions result by applying these two ethical principles. Once the researcher becomes involved in a research project for the funding corporation or knows that he or she might become involved in the research, he or she should not buy or sell the funding corporation's stock until the involvement ends and the results of the research are publicly disseminated. As long as the researcher is involved in investigating the funding corporation's product, he or she has the potential to derive profits that stem from inside information, rather than from individual effort.

Researchers may serve as consultants or may be retained to lecture on behalf of the funding corporation. However, the researcher's remuneration ethically must be commensurate with his or her actual efforts on behalf of the funding corporation.

Safeguards may be necessary to protect against the appearance of impropriety, even when ethically permissible relationships among the researcher, research institution and the funding corporation exist. Full disclosure presents the best mechanism to address doubts about the propriety of a research arrangement. Researchers should disclose all ties to corporations whose products they are investigating. For example, the researcher's participation in educational

activities supported by the corporation; participation in other research projects funded by the corporation; and consulting arrangements with the corporation must be disclosed to the research institution, to the funding corporation, to audiences who hear the research results and to journals that publish the results of the research.

Example of unethical conduct:

- Knowingly negotiating for more funding than is appropriate to support the project and related institutional and departmental overhead costs;
- A researcher's selling or purchasing stock in a company whose orthopaedic device is being tested by that orthopaedic surgeon-researcher;
- A researcher's accepting financial incentives to alter data;
- A researcher's accepting excessive remuneration by the funding corporation for evaluating or interpreting data about that corporation's products;
- A failure to disclose research or consulting arrangements with the funding corporation when reporting about research on devices manufactured by that corporation.

Use of research resources: Resources allocated by governmental agencies (federal, state or local), industry, or philanthropic organizations for the performance of specific research should be used only for that purpose unless the granting agency gives specific permission for reallocation of the resources.

Use of animals in research: The Academy believes that the appropriate and humane use of animals in research is justified to enhance the quality of life of both humans and animals. Animals should be used in research only when there are no suitable alternatives. Research projects should be designed to use the minimal number of animals possible in a manner that avoids abuse of the animals and maintains appropriate standards of animal care. Researchers should conduct animal research only with the approval of the institution's Animal Care and Use Committee and in compliance with all applicable regulations and standards. [See also AAOS Position Statement 1103 on *Animals in Biomedical Research and Education*.]

Examples of unethical conduct:

- Using methods that cause animals unnecessary discomfort;
- Failing to maintain appropriate standards of animal care;
- Using excessive numbers of animals to perform experiments;
- Using inadequate numbers of animals to allow for an appropriately powered study;
- Using inappropriate animal models; and
- Using animals when other methods of conducting the research would be scientifically valid, e.g., computer simulations, tissue culture or mathematical models.

Use of human subjects in research: The *Statement of Principles* of the American College of Surgeons provides "[t]he progress in medical care through research depends on informed partnership between patients and physicians in the development of new drugs and treatment methods. It is recognized that certain advances in the knowledge of treatment of disease can only be learned by properly conducted clinical trials during which the results of varying treatments recommended by individual doctors are carefully compared." ^{5,6,7}

Human subjects should be used in health research only when there is no reasonable alternative. Human subjects should never be exposed to unnecessary risk, embarrassment or expense and should fully understand the purpose of the research and if their participation may

benefit them (a therapeutic experiment) or is intended primarily to benefit future patients (a nontherapeutic experiment). The selection criteria of human subjects must be objective and reasonable.

Human subjects should provide **voluntary informed consent** before being included in a prospective study and should be allowed to decline to continue participation in a research program at any time without compromising their medical care. Mandatory Standards 2 and 3 of the AAOS *Standards of Professionalism on Research and Academic Responsibilities* provide:

2. An orthopaedic surgeon, or his or her qualified designee, shall present pertinent information to and obtain informed consent from the patient participating in research program or protocol, or from the person responsible for the patient.
3. An orthopaedic surgeon shall honor a request from the patient, or from the person responsible for the patient, to withdraw from a research program or protocol.

In addition, Paragraph VIII. A. of the Academy's *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* provides that "patients participating in research programs must have given full informed consent and retain the right to withdraw from the research protocol at any time." To ensure full informed consent, three elements must exist:

1. The orthopaedic surgeon must explain to the patient in terms the patient can understand the proposed treatment, its likely effect on the patient, and purpose of the research. Orthopaedic surgeons must provide at least the degree of information that is required by applicable state and federal law, which will include at a minimum information on the purpose of the research, its potential side effects, alternatives and risks of the proposed treatment as well as the method, purpose, conditions of participation and the opportunity to withdraw from the research protocol without penalty.
2. The patient must understand for what they are providing consent. The orthopaedic surgeon must ensure that the patient has understood the basic information and has engaged in rational decision-making in deciding to participate in the research; and
3. The patient's consent must be voluntary. Voluntary consent requires that the patient agreeing to participate in the project has a full understanding of all alternative treatments beyond the research protocol. The orthopaedic surgeon must believe that the patient's consent is free from undue or overbearing influences, e.g., fear of the loss of care or medical benefits if the patient declines to participate.

Human subjects participating in clinical research programs should receive the care and treatment that is in their best interest and be assured that the potential benefit of the research outweighs the risks. Researchers should conduct human subject research only with the approval of the research institution's Institutional Review Board (IRB) and any other review committees required by the institution, and in compliance with all applicable regulations and standards, including the Health Information Portability and Accountability Act (HIPAA) Privacy Rule (see below). This review and approval mechanism ensures that there is informed consent, that the rights of patients are respected, and that patients participating in the research protocol are treated with the same concern and devotion as other patients.

Sham surgery in research can be acceptable only if done for investigation of an appropriate procedure and if performed in a manner that minimizes risk to human subjects. Research protocols that utilize sham surgery should adhere to the following guidelines.²

1. There is skepticism regarding the therapeutic merits of a particular treatment.
2. There are disagreements about the perceived benefits of a particular procedure compared with the placebo.
3. Benefits might be due to the “experience of surgery” and the postoperative care regimen.
4. Risks are reduced as far as possible in the sham surgery arm without compromising trial design.
5. There is a lack of a superior therapy.

Research on populations designated by the federal government as vulnerable (including children and pregnant women) is scrutinized with special care by the IRB. Research should only be performed on these patient groups if the result of this research is directed towards the care of that vulnerable population. The vulnerable population should only be used if the study cannot feasibly be carried out on a non-vulnerable population with the same effect.³ For research involving minors, assent (by the minor) may be required in addition to parental or guardian consent. In addition, any review of any patient information, including retrospective chart and x-ray review, for any purpose other than care of an individual patient or quality improvement, must be approved by the IRB. In many cases, the IRB will grant a “chart review exemption,” but this must be obtained before initiating chart and x-ray review. Further information can be obtained from the National Institutes of Health website.

All individuals should be given access to research trials and be able to participate. Efforts should be made to prevent any specific populations from being significantly underrepresented in research.

Examples of unethical conduct:

- Failing to disclose risks (synonymous with a non-voluntary consent);
- Exposing patients who are participating in the research protocol to unnecessary risks;
- Failing to obtain voluntary, fully informed consent of adult patients or to obtain the substituted consent of the patient’s legally authorized representative when the patient lacks the legal capacity to consent (e.g., is a minor);
- Causing human subjects unnecessary embarrassment;
- Causing human subjects unnecessary expense;
- Manipulating human subject cohorts with selected medical problems or results of treatment with the intent of proving the investigator’s bias or to promote a given treatment or medical device; and
- Directly or indirectly coercing human subjects to participate in the research protocol.
- Failing to follow any IRB requirements regarding subject recruitment or research participation.

Responsibility of the research institution: The ultimate responsibility for the ethical conduct of research resides within the institution in which the health research is conducted and/or with the Primary Investigator (PI). Research institutions should assure that rigorous scientific standards are upheld by each of their faculty, staff, and students and should extend these standards to all reports, publications, and databases produced by the institution. All medical schools and research institutions should implement guidelines for a review process for dealing with allegations of scientific misconduct, which include appropriate due process protections for

those alleged to have committed scientific misconduct. In addition, the research institution must be capable of and committed to implementing effective procedures for examining allegations of scientific misconduct.

Examples of unethical conduct:

- The research institution's failing to maintain guidelines for dealing with allegations of scientific misconduct or fraud;
- The research institution's failing to inform and educate staff and students of institutional guidelines for dealing with allegations of scientific misconduct or fraud; and
- The research institution's failing to implement and enforce institutional guidelines for dealing with allegations of scientific misconduct or fraud.

Responsibilities of the Principal Investigator: The Principal Investigator of a health research project is responsible for proposing, designing and reporting the research. In addition, the Principal Investigator is usually accountable for dispensing project funds. In designing trials, it is incumbent upon the Principal Investigator to identify clinical questions for which there exists equipoise. The Principal Investigator may have a preference or opinion regarding the clinical condition being investigated, but a clinical trial should only be pursued to answer the clinical question if there is debate in the medical community as to the optimal approach.

Paragraph VIII. C. of the Academy's *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* provides that "the principal investigator may delegate portions of the work to other individuals, but this does not relieve the principal investigator of responsibility for work conducted by other individuals." In addition, Mandatory Standard 12 of the *Standards of Professionalism on Research and Academic Responsibilities* provides "An orthopaedic surgeon shall credit with authorship or acknowledge and not exclude those individuals who substantially contributed to the proposed research, the analysis and interpretation of the data, and the drafting and revising of the final article or report."

Federal regulations under the HIPAA Privacy Rule also affect the storage and dissemination of research information. The Privacy Rule requires that personally-identifiable information designed as Protected Health Information (PHI) must be kept private. PHI includes any information which might identify an individual (social security number, address, photographs, etc.) as well as any information in a medical record, including diagnosis, treatment, and health status and test results. The Principal Investigator is responsible for following the Privacy Rule, and the IRB requires the researcher to determine the minimum amount of PHI necessary to perform the research; to obtain consent from all subjects for obtaining PHI for research, and to document how PHI for research will be stored, who will have access to PHI, and how reports including PHI will be disseminated. Additional limitations on the use of PHI for research may be imposed by the institutional IRB. Failure to adhere to the requirements of the HIPAA Privacy Rule of HIPAA may result in civil and criminal penalties.

Examples of unethical conduct:

- The Principal Investigator's failing to participate in and supervise the design or conduct of a research project;
- The Principal Investigator's failing to adequately supervise those conducting the project;
- Failure to maintain confidentiality of PHI obtained for the purposes of research by the Principal Investigator or anyone else assisting with the project; and
- The Principal Investigator's failing to critically review the results and verify the accuracy of reports.

Reporting results of research: The results of research should be reported in a timely, objective, accurate, complete manuscript. Any potential conflicts of interest should be fully reported and explained. Mandatory Standard 13 of the *Standards of Professionalism on Research and Academic Responsibilities* states: “An orthopaedic surgeon shall, in reporting on research, publicly acknowledge the source of all relevant funding or consulting arrangements.” Paragraph III. D. of the Academy’s *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* provides that when reporting on clinical research or experience with a given device or procedure, orthopaedic researchers have an ethical obligation to “disclose any financial interest in that procedure or device if the researcher or any institution with which that researcher is connected has received anything of value from its inventor or manufacturer.” In accordance with the HIPAA Privacy Rule, reports may not disclose individual PHI without the express permission of the subject. Objectives, outcome measures, and levels of significance of research should be established prior to the initiation of trials. Randomized control trials should also be registered prior to initiation of trials in order to ensure this.

Examples of unethical conduct:

- Failing to provide timely, accurate reports;
- Failing to report unfavorable results;
- Providing reports that do not contain a sufficient and accurate methodology to replicate the experiments or references to where such information might be obtained;
- Falsifying reports;
- Fabricating results;
- Reporting results of uncertain or minimal significance unless clearly stated as such;
- Preparing multiple partial reports or duplicate reports of the same work to increase apparent productivity of the investigators; and
- Failing to identify potential conflicts of interest including possible financial benefits to the investigators from research reports.

Authorship and credit for scientific work: The Principal Investigator of a research study is responsible for ensuring that articles describing the research include appropriate credit for individuals contributing importantly to the research. Mandatory Standards 12 and 10 of the *Standards of Professionalism on Research and Academic Responsibilities* are relevant:

12. An orthopaedic surgeon shall credit with authorship or acknowledge and not exclude those individuals who substantially contributed to the proposed research, the analysis and interpretation of the data, and the drafting and revising of the final article or report.
10. An orthopaedic surgeon shall warrant that he or she has made significant contributions to the conception and design or analysis and interpretation of the data, drafting the manuscript or revising it critically for important intellectual content, and approving the version of the manuscript to be published.”

In addition, the authorship policy of *The Journal of the American Academy of Orthopaedic Surgeons*, states that each author must have contributed significantly to one or more aspects of the study; its design, data acquisition, analysis and interpretation of data, drafting of the manuscript; critical revision of the manuscript; statistical analysis; and/or supervision. In addition, each author should be able to defend and assume full responsibility for the content of the manuscript, regardless of the specific contributions. The sources of financial and technical support and individuals who provide important materials and information should also be acknowledged.

Examples of unethical conduct:

- Failing to credit co-workers; individuals who have designed the project or who have interpreted the data; individuals or agencies that have provided resources to fund the project; or individuals or groups that have previously performed similar research, if such research is valid and appropriate;
- Failing to credit sources of quotations;
- Plagiarizing or using others' work without attribution;
- Failing to review and credit relevant previous publications; and
- Including as authors individuals who did not make substantial contributions to the work.

Copyrights and royalties: Most research institutions maintain an intellectual property policy which encourages controlled entrepreneurial activity by research faculty. A typical structure for managing these matters involves the research institution's Committee on Intellectual Property (or similarly named group), which serves in a capacity advisory to the administrative officer overseeing the policy. These intellectual property policies have many variations peculiar to the particular institution, but in general determine distribution of rewards for researchers for developing new products and authors for writing and publishing articles and books.

Typically, the patent to devices created and the copyright to articles written belong to the Principal Investigator or his or her research institution or funding corporations. The ownership of patents, the allocation of revenues, copyright and other intellectual property interests among Principal Investigators, the research institution and the funding corporations and other important issues should be made clear either in standing policies of the research institution or in clear contracts executed before the commercial support is received. The rewards of commercialization should be fairly allocated.

It is ethically acceptable for a Principal Investigator to receive royalties from a funding corporation for using a particular device or medication the researcher has developed. However, it is unethical for an orthopaedic surgeon/Principal Investigator to be involved in an investigation of a device or medication in which he/she receives a royalty, has a financial interest in the manufacture of the device, or could have any other potential monetary payment or reward. An orthopaedic surgeon who has developed a new implant or device should delegate scientific investigation of the benefit of the new device to a disinterested third party who has no potential financial benefit from the utilization of the device. The patient should be informed of the interests of the orthopaedic surgeon/Principal Investigator; however, disclosure to the patient does not fully remove the conflict of interest of the inventor, and the results of the study would clearly be open to concerns of conflict of interest compromising the applicability of the study.

Examples of unethical conduct:

- The Principal Investigator's agreeing to always use a device he or she developed.

Research records: Accurate and complete records of research data should be maintained until there has been sufficient time for critical review. The time will vary with the type of research, but five years after publication is sufficient for most work. Most IRBs interpret the HIPAA Privacy Rule to require that the Principal Investigator specify the length of time that records will be stored and who will have access to them, the location of the records and precautions to prevent misuse.

Example of unethical conduct:

- Failing to maintain accurate complete records of research activity so that replication of the work or verification of the results is difficult or impossible.

Scientific errors; contradictory results and inability to replicate results: If errors in the proposal, conduct or reporting of research are identified, the Principal Investigator has an ethical obligation to report such errors. If the Principal Investigator or other investigators repeat an experiment and obtain results that contradict the initial report or they are unable to replicate the experiment, the contradictions or inability to replicate an experiment should be reported. If the long-term results of a health research project differ from the initial reported results, the differences should be reported. Scientific publications have a responsibility to publish reports of scientific errors, contradictory results, and failures to replicate previously reported research.

Examples of unethical conduct:

- Failing to report any significant scientific error;
- Failing to report work that contradicts previously reported data or conclusions;
- Failing to report late adverse outcomes for techniques or devices which were introduced with favorable initial experience;
- Failing to report difficulties in replicating or verifying previous findings; and
- A scientific publication's failing to publish reports of scientific errors, contradictory results, and failure to replicate previously reported research.

Obligation to report scientific misconduct (versus differences in methods, interpretation and judgment): Orthopaedic surgeons have an ethical obligation to report scientific misconduct in research if they become aware of it. Mandatory Standard 6 of the *Standards of Professionalism on Research and Academic Responsibilities* states: "An orthopaedic surgeon shall report those who engage in fraudulent or deceptive research to the appropriate authorities." A spectrum of activities constitutes scientific misconduct, ranging from duplicate publication at the lower end to fraud and plagiarism at the upper end. The U.S. Public Health Service (PHS) and the National Science Foundation (NSF) broadly define "scientific misconduct" to include research fraud (including plagiarism, deception, falsification and/or fabrication of scientific data) as well as "other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research."

However, while it is clear that unequivocal scientific misconduct must be reported, members of the health research community have a concurrent responsibility to attempt to distinguish between honest error and scientific misconduct. Orthopaedic surgeons must also respect differences in scientific methods and analysis, interpretation and judgment about data.

Examples of unethical conduct:

- Failing to identify and report unequivocal instances of scientific misconduct;
- Personally attacking, verbally or in writing, other investigators, based upon differences in methods, analysis, interpretation, judgment or opinion;
- Attempting to discredit or intimidate other investigators because of differences in methods, investigation or interpretation of data;
- Attempting to restrict funding or research, publication or presentation of data because of differences in interpretation; and
- Making accusations of scientific misconduct when honest error may be as likely.

Recommendations

The American Academy of Orthopaedic Surgeons urges orthopaedic surgeons who participate in health research to review and adopt these ethical tenets, which have been developed by the Academy's Ethics Committee and Council on Research and Scientific Affairs. These tenets provide a flexible, ethical framework for the conduct and the publication of research results.

References:

AAOS Standards of Professionalism on Research and Academic Responsibilities, adopted May 12, 2006. The entire document is relevant

Applicable provisions of the Principles of Medical Ethics and Professionalism in Orthopaedic Surgery

"II. **Integrity.** The orthopaedic surgeon should maintain a reputation for truth and honesty with patients and colleagues, and should strive to expose through the appropriate review process those physicians who are deficient in character or competence or who engage in fraud or deception."

"VI. **Medical Knowledge.** The orthopaedic surgeon continually must strive to maintain and improve medical knowledge and to make relevant information available to patients, colleagues, and the public."

Applicable provisions of the Code of Medical Ethics and Professionalism for Orthopaedic Surgeons

"III. C. When an orthopaedic surgeon receives anything of value, including royalties, from a manufacturer, the orthopaedic surgeon must disclose this fact to the patient. It is unethical for an orthopaedic surgeon to receive compensation (excluding royalties) from a manufacturer for using a particular product. Fair market reimbursement for reasonable administrative costs in conducting or participating in a scientifically sound research clinical trial is acceptable."

"III. D. An orthopaedic surgeon reporting on clinical research or experience with a given procedure or product must disclose any financial interest in that procedure or product if the orthopaedic surgeon or any institution with which that orthopaedic surgeon is connected has received anything of value from its inventor or manufacturer."

"IV. A. The orthopaedic surgeon continually should strive to maintain and improve medical knowledge and skill, and should make available to patients and colleagues the benefits of his or her professional attainments."

"VIII. A. All research and academic activities must be conducted under the conditions of full compliance with ethical, institutional, and government guidelines. Patients participating in research programs must have given full informed consent and retain the right to withdraw from the research protocol at any time."

"VIII. B. Orthopaedic surgeons should not claim as their own intellectual property that which is not theirs. Plagiarism or the use of others' work without attribution is unethical."

"VIII. C. The principal investigator of a scientific research project or clinical research project is responsible for all aspects of the research, including reporting. The principal investigator may delegate portions of the work to other individuals, but this does not relieve the principal investigator of the responsibility for work conducted by other individuals."

"VIII. D. The principal investigator or senior author of a scientific report is responsible for ensuring that appropriate credit is given for contributions to the research described."

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