

The Scientific and Ethical Dimensions of Chiropractic Research Part III

ETHICAL CONSIDERATIONS IN THE CONDUCT AND REPORTING OF CHIROPRACTIC RESEARCH

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Introduction

Ethical conduct in scientific research, particularly research on human subjects, has always been of concern to the scientific community. However, recent incidents of fraudulence in reporting inaccurate or contrived data, have given rise to a new level of concern both in the scientific community and the agencies that fund research.

For example, the United States Public Health Service now requires that "each institution that applies for or receives assistance under the Public Health Service Act, for any project or program which involves the conduct of biomedical or behavioral research training, or related research activities, must complete and submit to the Office of Scientific Integrity an assurance regarding procedures for dealing with and reporting possible misconduct in science."¹ The National Institute of Health (NIH) over the years has supported research training programs in the biomedical and behavioral sciences. NIH has generally assumed that most universities and academic institutions have practices and procedures to ensure the responsible conduct of research, including: conflict of interest; data recording and retention; professional standards and codes of conduct; responsible authorship; institutional policies and procedures for handling allegations of misconduct; policies regarding the use of human and animal subjects; and formal courses on bioethics, research conduct, and the ideals of science. Recently, NIH has revised its administrative guidelines for all National Research Service Award institutional training grants to require that "a program in the principles of scientific integrity be an integral part of the proposed research training effort" in any application.²

The Importance of Ethics in Chiropractic Research

The concern for ethical behavior in chiropractic research is of particular importance for several reasons. Chiropractic research and the chiropractic research community, are still in a relatively early stage of development. Thus, the skills of doing research, and the sensitivity to ethical research conduct, vary significantly across the profession. Unlike other scientific disciplines with a long history of academic and research development, chiropractic is developing basic scientific research competence, and the ethical dimensions of chiropractic research must be reinforced and closely monitored. Second, the growing interest on the part of field practitioners to become involved in research, although desirable for the profession generally, results in further challenges to ensuring ethical investigative behavior. Unlike the more structured and organized academic setting of many of the chiropractic colleges, the field practitioner group represents a diffuse entity without the checks and balances to ensure consistent ethical conduct in chiropractic field investigations.

Lastly, the activities of entrepreneurial-oriented organizations in chiropractic, that use and abuse

the research process to promote products, ideologies, or practice-building schemes, inherently contradict the ethics of scientific research. Quite often these organizations are capable of masking their ethically bankrupt research programs through the use of research "buzz words" and public-relations materials that literally entrap well-intentioned doctors and their patients. These organizations' activities emphasize the importance for the profession to recognize and inculcate basic scientific research ethical tenets in its colleges, professional associations, funding agencies, research journals, and field practitioners.

Two major domains of chiropractic research should be considered for their adherence to ethical conduct: the conduct of research studies, including the responsibilities of the principal investigator and sponsoring institution; and the reporting of research findings, including the obligations of authors and scientific publications.

Ethical Considerations in the Conduct of Chiropractic Research

Although the emphasis of this paper, particularly in regard to the conduct of research, concerns human subjects research, note should be taken that the scientific community has also developed ethical guidelines in the conduct of animal research. The American Journal of Chiropractic Medicine (AJCM) has adequately reviewed these, and the interested reader should consult this source.³

Lo, Feigal, Cummins, and Hulley identify three basic ethical principles as guidelines for clinical research.⁴ The principle of respect for persons requires researchers to "treat subjects as autonomous individuals and obtain their informed consent to participate in the research project." This principle implies not only that subjects' welfare and rights are recognized and respected, but also suggests that subjects should understand the intent of the research study, and its potential importance to the profession and patient care. This principle is particularly important when research is conducted on patient populations or combined with professional care. As the AJCM notes, "the doctor (or investigator) can combine clinical research with professional care---only to the extent that clinical research is justified by its therapeutic value for the patient."

The principle of beneficence requires "investigators to design protocols that will provide valid and generalizable knowledge and to ensure that the benefits of the research are proportionate to the risks assumed by the subjects." This principle dictates that the researchers must try to minimize the risks and maximize the benefits of participation in the study. Related to this principle is the obligation of the investigator to anchor a study's methodology or treatment interventions in the current state of scientific knowledge or clinical practice consensus. Some latitude must be given in research studies that also involve professional care -- the doctor-investigator may be free to use new treatment procedures if in his or her professional judgment there is significant probability of saving a life or restoring health. However, in any research study, the investigator is obligated to terminate an investigation that is harmful to a subject, or for which any potential therapeutic benefit is negated by immediate threats to safety or life.

The principle of justice requires that "the benefits and burdens of research be distributed fairly." The most obvious implication of this principle is that no particular group of individuals should be asked to assume a disproportionate share of the risk of experimentation. However, the converse of this implication is equally important: no particular group or individual should benefit disproportionately from the results of a study. This latter point speaks directly to the motivations for engaging in scientific research, i.e., the pursuit of new knowledge for the common good.

Beyond these general ethical issues, several specific ethical guidelines and behaviors must be

monitored diligently by the chiropractic profession, as it matures in its development as a scientific-based, health care profession. (1) A research protocol should always be submitted to peer review prior to implementation. In academia, it is customary for an institutional review committee or board (IRB) to review a research proposal prior to its submission for funding consideration or initiation. This process constitutes the use of peer review to ensure that a study design adheres to accepted scientific and ethical principles, that proper procedures have been followed to guarantee the rights of human subjects (including informed consent) or the humane treatment of animals, and that the proposal does not contain misrepresentations (for example, documentation of an investigator's credentials, validity of pilot data, accuracy of references, etc). A general axiom of scientific research is that the proper use of peer review is the most effective mechanism for scientific and ethical self-regulation. All chiropractic colleges that engage in research should have this mechanism in place, and many appear to have made an attempt to do so. However, college administrators must assume responsibility for the diligent use of this review process, and the appropriate composition of the review committee to ensure the most rigorous review of proposed research. So too, field practitioners who wish to engage in research must submit their protocols to review prior to implementation. (2) A principal investigator must be scientifically competent and qualified to effectively design, implement, and manage a research project. Although this may appear to be an obvious assumption for the conduct of scientific research, it should not be taken for granted. The concept is especially germane to chiropractic and its research community. Although interest in research in chiropractic is abundant, the necessary competence to conduct a scientific study is not always as apparent. The role of principal investigator should be assumed by one who can demonstrate the general knowledge, technical skills, experiences, and overall scientific "track record," which are consistent with the scope of a proposed research study, and which can ensure the scientific and ethical conduct of the research. Junior-level researchers, students, or field practitioners can participate in an investigation, but must be properly supervised by the principal investigator. Hence, the principal investigator is ultimately responsible for the conduct of an individual associated with the study, and the day-to-day management of the project. (3) An investigator must recognize, and effectively resolve, conflicts of interest that may arise during a study. For example, an investigator who is also the personal physician for a patient must appreciate that what may be best for a patient's health care may conflict with what is most desirable for the research study. A serious breach of ethics can arise when an investigator has a financial interest in the treatment procedure or measurement system under investigation. Such financial interest can easily lead to the abuse of research subjects' rights and welfare, and the biased collection and reporting of research data. The chiropractic profession must be particularly wary of conflicts of interest in its research programs, as more individuals with limited research and scientific training become involved in clinical investigations.

Ethical Considerations in Reporting and Publishing Chiropractic Research

It should be obvious that scientific research depends to a great extent on implied trust in an investigator's integrity, coupled with adequate, but not necessarily intrusive, external mechanisms to monitor scientific conduct. This is no more apparent than in the processes related to the reporting and publishing of research findings. Again, because of the relatively nascent stage of chiropractic scientific research, the profession and its research leadership must pay close attention to the ethical principles associated with reporting and publishing research data. Both investigator, in the role of author, and journal editor, in the role of publisher, must confront ethical issues.

For the author of chiropractic research reports, several ethical issues stand out. (1) Has the author collected, analyzed, reported and interpreted data in an objective, unbiased manner? (2) Are the data accurate, and available to permit confirmation of findings by another scientist? (3) Is a study's methodology sufficiently documented to permit replication? (3) Is it understood that all the authors

of a paper accept responsibility for it, and must be able and willing to represent and defend its contents publicly? (4) Is the author guilty of redundant publication, i.e., publishing the results of the same study in two or more journals, or reporting what is essentially one study in two or more fragmented or overlapping publications? This last issue has become a major concern to the general scientific community as reflected by a recent article in *The New England Journal of Medicine*.⁵ This ethical issue should also be of concern to the chiropractic profession, given the relative scarcity of well-written scientific research papers, and the competition to publish in the ever-increasing number of chiropractic research journals. (5) Is authorship based solely on contributions to the preparation of the manuscript and collection of data? Department or division heads who approve funding or released time for research warrant acknowledgements, but not authorship? Again, the AJCM has comprehensively reviewed the ethical considerations concerning authorship of scientific publications.

Chiropractic research journal editors must recognize their ethical responsibilities to the profession, in addition to their vested interests in filling their journals' pages and succeeding financially. A manuscript's publication gives it status as "scientific" in the eyes of most readers, and so the ethical and technical guidelines followed by editors are important to the entire profession. Although the general standard for scientific journals is the use of blind peer review, this process is not sufficient to guarantee that the highest ethical standards will always be followed in the publication process. The Foundation for Chiropractic Education and Research recently established the Chiropractic Research Journal Editors Section (CRJES), which is composed of the editors of chiropractic's primary source, peer-reviewed research journals. The CRJES will meet this spring, in conjunction with the International Conference on Spinal Manipulation, to consider the challenges and issues associated with the publication process in chiropractic.

In an editorial in the *Journal of the American Medical Association*, Rennie identifies a number of significant ethics-related issues that apply to all scientific journals, including those in chiropractic.⁶ There are several that are especially salient for chiropractic research journals in their development as reputable and dependable scientific publications. (1) Are there generally accepted criteria for deciding what constitutes an original scientific research paper, and do editors ensure that these criteria are consistently used in the selection of manuscripts for publications? (2) How often are what checks made by whom to determine if the work reported in a manuscript was actually done, and should editors require assurance of a paper's veracity? (3) What institutional reviews do editors require of a manuscript prior to its consideration for publication? (4) How do editors select their editorial boards and external reviewers to obtain the most expert and objective reviews and how do editors reconcile disagreement between reviewers, and reviewers and authors? (5) What personal discretion is delegated to editors to make final decisions for publication, and are editors free of political or commercial influences in making these decisions? (6) What percentage of rejected papers are ultimately published elsewhere? Can any author find a willing journal, and what implications does this have for chiropractic's scientific and professional development?

Summary

In addition to adhering to accepted methods of research design, data collection, and data analysis, the reputable research scientist must also be attentive to basic ethical principles that safeguard the integrity and welfare of subjects, and ensure the credibility of findings and their documentation in scientific publications. Academic administrators, funding agency administrators, and journal editors must also assume some responsibility for ethical conduct in research. All involved in chiropractic research must adhere to the highest ethical standards, to provide doctors and their patients with the best that science can offer to advance chiropractic knowledge of health and chiropractic treatment of illness and disease.

References

1. NIH Guide for Grants and Contracts. November 17, 1989; 18(41): 1-2.
2. NIH Guide for Grants and Contracts. December 22, 1989; 18(45): 1.
3. The American Journal of Chiropractic Medicine. March 1988; 1(1): 4-12.
4. Lo, B.; Feigal, D.; Cummins, S.; Hulley, S.B. Addressing Ethical Issues. 151-158. Hulley, S.B.; Cummings, S.R. (ed). Designing Clinical Research. Baltimore 1988; Williams and Wilkins.
5. Angell, M.; Relman, A.S. Redundant Publication. New England Journal of Medicine. May 1989; 320 (18): 1212-1213.
6. Rennie, D. Guarding the Guardians: A conference on Editorial Peer Review. Journal of the American Medical Association. November 1986; 256(17): 2391-2392.

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