Guidelines for Ethical Practice in Research for Audiologists

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Protection of Human Subjects

The explosion of biomedical and behavioral research in the last half of the twentieth century has brought about scrutiny of the ethical principles by which investigators should be guided. The Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, released in 1979, describes three basic ethical principles that should guide research. These are 1) *Respect for Persons* (the choices of autonomous persons are to be respected and those with diminished autonomy should be protected); 2) *Beneficence* (an obligation to secure the well being of persons by not harming them and by maximizing the benefit-to-risk ratio); and 3) *Justice* (an equality in the sharing of risk and benefits). The Belmont Report is noteworthy for its breadth, addressing many concerns that trouble investigators and others today. Many academic institutions cite it as the ethical standard to be applied in approving research under their jurisdiction. Internationally, the Declaration of Helsinki is often the standard by which human-subjects research is judged, although it is specific to medical as opposed to behavioral, research.

In 2000, the Office for Human Research Protection (OHRP) was established under the Department of Health and Human Services. The OHRP oversees and regulates all aspects of federally funded human research in the U.S. Research institutions involved in federally funded research must have oversight by a local Institutional Review Board (IRB) and must have written "Assurance of Compliance" approved by OHRP. Other institutions can obtain "federal-wide" assurance of compliance by promising to follow general rules and guidelines. In either case the research must comply with the Common Rule, the regulation that governs nearly all federally funded research. Some research, whether or not conducted at institutions that receive Federal support, is subject to other regulations. Many studies of diagnostic and prosthetic devices are subject to FDA regulations, which are very similar to the Common Rule. The Privacy Rule, a HIPAA regulation, governs the use of health information in research.

Individuals with clinical expertise and experience often perform research in audiology. It is incumbent on everyone involved in research to insure that they are appropriately trained to conduct the research in which they are involved. If they have not had formal research training, it is their responsibility to collaborate with other trained researchers to insure compliance with all ethical and legal guidelines as well as use good research design and analysis. Investigators cannot always rely exclusively on their IRB for guidance; the investigator has the obligation to insure the ethical and legal conduct of the study. IRBs vary widely in the expertise and training of their members, so that IRB approval may not be sufficient assurance that the study conforms to ethical and legal standards. Finally, some research is not subject to Federal regulation, and the investigator must assume sole responsibility to assure that it is conducted with proper regard to accepted ethical standards.

Audiologists may be involved in activities that are not generally regarded as research but which involve many of the same ethical concerns. Academy members involved in these activities may not even appreciate the need to consider ethical issues. One example is the published case report. Such reports may not be considered research by some, but these reports have the potential to expose patients' identities, for example if a case report features unusual and/or easily recognized situations. Ethical concerns may arise when a clinician acquires familiarity with a new diagnostic test or device by using it with patients who have little prospect of benefit, or when tests are administered because the clinician anticipates their value in a future research presentation or publication, rather than from clinical necessity.

Existing provisions of the *Code of Ethics* of the Academy are relevant to many of these issues. **Principle 1** ("..honesty and compassion...respect") states important principles underlying human research. **Principle 3** (confidentiality) is clearly relevant. **Principle 4** ("Members shall provide only services...in the best interest") addresses unnecessary services, such as tests that are not clinically indicated. However, this principle raises the potential for ethical dilemmas among clinical researchers who, in controlled clinical trials, may not only act in the best interest of the patient. In these cases, the appropriate consent process is necessary to clarify the risk/benefit ratio to the prospective subject. **Principle 5** ("Members shall provide accurate information...") embodies the requirement of informed consent, and is the only principle that explicitly addresses research. **Principle 8** already addresses the need to comply with government regulation ("Rule 8b: Individuals shall not engage in...illegal conduct"). However, the Code quite naturally focuses on the conduct of members in providing professional services. It is nearly silent as to the special obligations of members engaging in human-subjects research.

Authorship in Publication and Presentation of Research

Rapid publication of scientific findings as well as peer review of such manuscripts for quality was born from a need to properly acknowledge credit for scientific discoveries as well as controlling publication quality. Scientists establish credit for their scientific discoveries by publishing them in peer-reviewed journals. The order of authorship carries great importance for establishing relative contributions to the work, including the original ideas. Because there are no hard, fast rules that govern authorship assignment (although guidelines have been published by a variety of sources), the current system is open to abuse.

Research audiologists and hearing scientists often work in groups. For that reason, they must develop rules for deciding how to determine the relative contribution and value of each contributor when assigning authorship to publication and presentation of research. Persons who participate in audiologic research should be appropriately recognized with authorship. Similarly, authorship should not be given to a person who has made little or no contribution to the work, and/or without their consent. In the latter instance, the scientist appears to endorse research about which s/he may have little involvement or knowledge. In other instances, persons may attempt to use their position of authority (department head, section chief, etc.) to secure authorship without actually contributing to the research in a substantial way.

Ethical problems may arise when potential conflicts of interest are not fully disclosed by an author of a research article or presentation.

When private companies fund research, such sponsorship must be clearly acknowledged in publications and presentation of the data. Such disclosure should contain details on degree and type of support for specific projects, or general laboratory support.

Authorship and inventorship is highly valued and can be the basis for professional advancement or continued funding of research. Employment, promotion and tenure at universities depend upon an active record of publications and patents. Publications and patents are the signs of achievement for any scientist. Such value in authorship and inventorship can lead to significant abuse. Guidelines on determination of authorship vary somewhat across fields and across institutions or laboratories. Generally the first author is given highest credit and others follow in order. In some groups, the research group leader is last author. In some laboratories, the supervisor's name never appears in the title list and in others it always appears.

According to the International Committee of Medical Journal Editors, authorship should be based on the following criteria: 1) Substantial contribution to conception and design of the research, and/or analysis and interpretation of data and 2) drafting the article or revising its critically important intellectual content and 3) final approval of the version to be published. Accordingly, gift or unwanted authorship is discouraged.

ADEQUACY OF RESEARCH DESIGN AND PROTECTION OF DATA

It is the responsibility of those involved in clinical research to insure that sound experimental design is used and to seek additional training, assistance or collaboration if necessary and appropriate. If a study fails to achieve its objectives because of inadequate sample size, poorly matched controls, or other deficiencies, the potential benefits of the study and the advancement of knowledge are reduced. This, in turn, increases the risk to benefit ratio thus compromising the human subjects in the study. In the worst case, inaccurate conclusions are drawn from poorly designed studies leading to misinformation to clinicians and inconvenience or even harm to patients.

Regardless of outward intent, bias can be reflected in conclusions drawn from research. Given the nature and purpose of the enterprise, science should be objective. The primary interest of scientists should be the discovery of truth. However, when conflicts of interest exist, scientists can be susceptible to protecting their self-interests at the expense of objective science. Outcomes may be assumed prior to the collection and analysis of data. The actual collection and analysis, not to mention the written conclusions, can be biased toward outcomes that are favorable to the author's point of view. Even without intent to manipulate conclusions, poor research methodology can lead to incorrect conclusions. The implications of biased or poor science on a healthcare profession go beyond the introduction of misinformation into the body of knowledge that comprises a discipline. Rather, it can result in the eventual clinical mismanagement of the patients whom the profession exists to serve.

Adhering to established standards when conducting and presenting research is part of the ethics of science. Adherence to the scientific method does not guarantee that research will be error free. Yet, mistakes can be minimized when scientists carefully follow basic scientific principles and accepted practice.

- **Replication.** One important principle of science is to report methodology in a way sufficient to allow for a body of research to be replicated. It is imperative that results hold up to scrutiny at the level of replication, if the truth is to be determined and believed. Scientists must include explicit detail on research design and analysis methodology. In this way other scientists will be able to prove or disprove conclusions by being able to repeat experiments.
- **Standard design, methods and analysis.** Research must be designed, executed, and analyzed to minimize bias or incorrect results. When comparing two clinical techniques, for example, it would be important for the scientist to ensure that each technique is optimized for the particular clinical application before the comparison is made. To do otherwise biases the comparison. Double-blind, cross-over, and other designs that help to eliminate bias, should be employed whenever possible. Data analyses must follow accepted statistical standards and practices. Appropriate education in statistics, as well as consultation with statisticians when appropriate, is recommended for all researchers.
- **Accurate data collection and analysis.** During data collection, meticulous record keeping is essential. Carefully controlled experimental methodology, including documentation and data management following established techniques, are required for the conduct of research. These procedures serve to insure that the scientific and clinical communities will accept the research findings.

CONFLICT OF INTEREST IN PRODUCT-ORIENTED OUTCOMES RESEARCH

Accurate research aimed at documenting the efficacy of hearing aids, other auditory prosthetics, and diagnostic tests and equipment is essential to the practice of audiology. Most of the research evaluating these products is generated internally by the manufacturers, or is sponsored by manufacturers. Manufacturers often employ audiologists and auditory scientists to evaluate and promote their products. In other instances, product-oriented research is sponsored by industry to be carried out in audiology clinics in a variety of settings. The American Academy of Audiology acknowledges the value of close collaboration between industry, audiologists and auditory scientists in the development and evaluation of new technology for our profession. In fact, such collaboration is felt to be indispensable. However, the employment and sponsorship of Academy members by manufacturers to conduct and report product-oriented outcomes research creates the potential for conflict of interest.

Audiology evolved from primarily an academic discipline, largely centered in educational institutions, into a healthcare profession that focuses on the delivery of clinical services to patients with auditory and balance disorders. Paralleling this evolution has been a change in where, by whom, and why product-oriented outcomes research is conducted. During the early years when audiology was largely an academic discipline, independent faculty scientists with limited or no industry involvement conducted such research primarily in university settings. Gradually, however, responsibility for conducting product efficacy clinical studies has

shifted either to the manufacturers of these products, or to independent researchers whose work may be sponsored by those manufacturers.

Although this evolution had been taking place for many years, it received substantial impetus from actions by the federal government in the early 1990's. Primarily in response to consumer complaints that advertising claims of some hearing aid manufacturers were misleading (especially with regard to speech understanding in noise), the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) charged several major manufacturers with making misleading and/or unsubstantiated claims in advertising about their products. The eventual outcome of these actions was an FDA requirement that hearing aid manufacturers substantiate and obtain pre-market approval of benefit claims in advertising. In order to obtain FDA approval, benefit claims must be substantiated by clinical studies, a portion of which had to be conducted by independent researchers. The result was that hearing aid manufacturers were obligated to conduct efficacy studies of their products within their companies and to support research studies in independent laboratories.As a result, the number of audiologists/clinical researchers employed by manufacturers increased, and several researchers in independent laboratories became engaged in manufacturer-sponsored product efficacy studies.

Within a few years after issuing their ruling requiring hearing aid manufacturers to obtain pre-market approval of benefit claims, the FDA rescinded it. Many Academy members continue to be employed by manufacturers and are involved in conducting and reporting clinical studies of hearing aids and other auditory prostheses. Others receive support for their work through contracts with industry. Additionally, the FDA continues to regulate cochlear implants and middle ear implants, thereby making it virtually certain that audiologists and auditory researchers will continue to conduct efficacy studies of these devices.

A healthcare profession such as audiology, in which the dispensing of products and the use of diagnostic equipment is central to its clinical activities, relies upon outcomes research that accurately assesses the efficacy of those products. Unlike some other professions, such as medicine in which product efficacy studies (pharmaceutical studies) are closely scrutinized by the FDA, studies of hearing healthcare products (i.e., conventional hearing aids and most diagnostic equipment) may receive little government scrutiny. Without efficacy studies that are objective, reliable and carefully executed, audiologists cannot determine which products are best suited to the needs of their patients. The involvement of manufacturers in conducting, reporting, and funding of studies to evaluate their products creates the potential for conflict of interest:

- ***Audiologists and Auditory Scientists Employed by Manufacturers.*** It is normal and expected that employees will be loyal to their employer. The financial success and security of audiologists and auditory scientists employed by manufacturers is at least partially dependent upon the success of those companies in marketing their products. Hence, it is only reasonable to expect that persons employed by manufacturers will share the commercial goals of their employers and work to achieve those goals. However, as healthcare professionals, audiologists and auditory scientists also have a responsibility always to work toward the best interests of hearing-impaired consumers. It is possible that the commercial interests of manufacturers and the larger professional responsibilities of audiologists and auditory scientists employed by manufacturers may, at times, be conflicting. Often such conflicts may be quite subtle. Nevertheless, Academy members employed by manufacturers must be aware that conflicts in loyalty and responsibility can arise. The potential for conflict of interest needs to be acknowledged. Despite their loyalty and responsibility to employers, it is unethical for Academy members to use poor research designs in clinical studies for the purpose of showing benefit of a particular product, to misrepresent the results of clinical studies of product efficacy, or to misinform/mislead fellow Academy members and/or consumers of the benefits of a particular product.
- ***Audiologists and Auditory Scientists Whose Work Is Sponsored by Manufacturers***. Although the potential for conflict of interest among Academy members who are employed directly by product manufacturers may be more obvious, audiologists and auditory scientists whose work is sponsored by manufacturers also are susceptible. The increased sponsorship of product efficacy studies in independent laboratories by manufacturers over the past 10-15 years has involved many Academy members located in academic and/or research settings.Coupled with the generally diminishing availability of intramural funds at these institutions and extramural funding from government agencies, the laboratories of many Academy scientists have become dependent to a greater or lesser extent on funding from manufacturers. With this dependence comes the potential for conflict of interest. Naturally, manufacturers are happy when clinical studies support the efficacy of their products and disappointed when the opposite occurs. Just as audiologists and auditory scientists who are employed directly by manufacturers quite naturally want to please their employers, similarly persons whose laboratories are dependent upon manufacturer funding want to please their sponsors. Again, the potential for conflict of interest needs to be acknowledged. Notwithstanding any financial dependence on manufacturers, it is unethical for Academy members who conduct product efficacy studies to use poor research designs in clinical studies for the purpose of showing benefit of a particular product, to misrepresent the results of clinical studies of product efficacy, or to misinform/mislead fellow Academy members and/or consumers of the benefits of a particular product.

The appearance of a conflict of interest may serve to discredit the work of Academy scientists, if such conflicts are not acknowledged and if appropriate safeguards are not taken to insure the integrity of the research. Clearly, it is in the best interest of hearing-impaired consumers whom we serve that Academy members be engaged in product efficacy studies, both as employees of manufacturers and in contractual relationships with industry. It is in the best interests of the Academy and its members, therefore, to implement safeguards to minimize conflicts of interest among audiologists and auditory scientists employed by manufacturers or whose work is sponsored by manufacturers to maintain scientific integrity.

SUGGESTED READINGS:

Brody BA. (1998) *T*he Ethics of Biomedical Research. Oxford University Press.

Sieber JE. (1992) Planning Ethically Responsible Research. Newbury Park: Sage Publications.

Committee on Science, Engineering and Public Policy, of the National Academy of Sciences, National Academy of Engineering, and Institute of Medicine. On Being a Scientist: Responsible Conduct in Research. National Academy Press: Washington DC, 1995.

Faden, R.R. et al.: Final Report of the Advisory Committee on Human Radiation Experiments. US Government Printing Office (Stock #061-000-00-848-9). Washington, DC, 1995. In addition to being a thorough and candid history of the radiation experiments, this is an excellent resource on the history of human research ethics and regulation. Also available at tis.eh.doe.gov/ohre/roadmap/achre/report.html.

USEFUL WEB SITES:

http://www.fda.gov/oc/ohrt/irbs/default.htm

"U.S. Food and Drug Administration Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators." Useful guidance documents, plus links to regulations and other documents. Many are of interest to investigators in clinical research, as well as to IRBs and manufacturers, including the following:

"Emergency Use of Unapproved Medical Devices"

" 'Off-Label' and Investigational Use of Marketed Drugs, Biologics and Medical Devices"

"Guidance on Significant and Nonsignificant Risk Devices"

ohrp.osophs.dhhs.gov/index.html

Office for Human Research Protections. Links to the Belmont Report, the Common Rule (45 CFR 46), as well as educational and guidance documents.

http://www.wma.net/e/policy/17-c_e.html

"The Declaration of Helsinki of the World Medical Association." This is the most recent version, which has several substantial differences from earlier versions.

http://www.aamc.org/members/coitf

Protecting Subjects, Preserving Trust, Promoting Progress-Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research. Task Force on Financial Conflicts of Interest in Clinical Research, Association of American Medical Colleges, December 2000.

The American Academy of Audiology Board of Directors accepted the recommendation of the Ethical Practices Board that the Code of Ethics be modified to include guidelines for researchers. The revised Code is available for review at http://www.audiology.org/about/code.php.

Based on recommendations of the Task Force on Ethics in Audiology Research, researchers ethical responsibilities are clearly defined. The wording of six rules and one principle were altered to specifically include research activities. One rule was added: Rule 4d "Individuals using investigational procedures with patients, or prospectively collecting data, shall first obtain full informed consent from the patient or guardian."

Rule 4d from the previous version of the code was rescinded. The rule stated "Individuals shall not accept compensation for supervision or sponsorship beyond reimbursement of expenses." This rule was stricken, as it would prevent audiologists supervising students / serving as student preceptors from being compensated in any way by the student's university. By rescinding this rule, Academy members may now accept free continuing education activities, adjunct faculty benefits or other forms of compensation from the university. Rule 4c prohibits conflicts of interest, which prevents supervisors/preceptors from accepting compensation directly from students.