GUIDELINES FOR ETHICAL PRACTICE IN RESEARCH FOR AUDIOLOGISTS

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INTRODUCTION

An important aspect of the professional practice of audiology is clinical and laboratory research, publication of findings and related scholarly activity that addresses clinical questions and provides data and information that serve as the basis for evidence-based clinical practice. As a profession, audiology needs solid evidence to provide guidance on clinical practice that involves constantly changing technology in the areas of auditory and vestibular system diagnostics and rehabilitation strategies including those involving surgically-implantable and externally worn devices. Provision of such evidence requires that scientists maintain objectivity and ethical principles while providing information on performance of commercial property.

Audiology is a profession born out of academia. Much of audiology evolved in answer to the needs of veterans returning from WWII. Hearing-impaired veterans were seen by a wide variety of individuals with varying backgrounds. Audiology has emerged into a clinical healthcare profession. We have embraced the AuD degree as the designator for practitioners of the profession and expanded clinical training. New emphasis is placed on technology for diagnosis, prevention, and treatment of hearing disorders. Consequently the relationship between industry and audiologists has become close.

Audiologists today often are employed in private practice or specialized clinical settings. They are increasingly involved in clinical trials and studies involving human subjects, often in collaboration with or funded by industry. While collaboration with industry may be mutually beneficial and provide the most rapid development of much-needed new technologies, such relationships bring with them ethical dilemmas for the audiologist. The

Task Force on Ethics in Audiology Research (Task Force) is charged with summarizing information regarding current standards of practice in human research and ethical issues surrounding clinical research and collaboration with industry. This document also serves to remind Audiologists working in research, as well as those who are consumers of scientific information, of the ethical obligations of members of the Academy in regards to research.

This is a 2011-revision of the original document entitled *Issues and Guidelines for Ethical Practice in Research for Audiologists* published in 2003 by the Academy of Audiology's Task Force on Ethics in Audiology Research. The charge to the original task force from the Academy Ethical Practice Board was to discuss issues related to ethical research including:

- Human subjects protection
- Falsification/misrepresentation of data
- Industry sponsorship of research, conflicts of interest and ways of acknowledging conflicts of interest in presentations and publications
- Need for evidence-based research on product effectiveness
- Appropriate credit for publication.

This document contains much of the same information as the original. Many of the principles outlined in this document are supported in principle or by specific wording in the April 2011 update of the Academy's Code of Ethics (COE) and these will be incorporated into this document. This revision also includes information related to federal regulations on individual patient privacy and information security. Specifically the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act, will be highlighted in this revision.

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. Principle 1 of the 2011 COE of the American Academy of Audiology reinforces these standards, stating that "Members shall provide professional services and conduct research with honesty and compassion, and shall respect the dignity, worth, and rights of those served."

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. 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. Keeping up with current rules and regulations regarding research is the

ethical obligation of Audiologists as stated in the COE Rule 2f which reads "Individuals shall maintain professional competence, including participation in continuing education."

Audiologists who have clinical expertise and experience are often involved in audiological research either as principal investigators or as collaborators. It is incumbent on everyone involved in research to insure that they are appropriately trained in all aspects including ethical issues. If an audiologist participates in research, it is their responsibility to learn, understand and comply with all ethical and legal guidelines as well as to use good research design and analysis techniques. As stated in the COE, Rule 2a: Members shall provide only those professional services for which they are qualified by education and experience. Investigators cannot always rely exclusively on their IRB for guidance; the principal 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 yet the investigator must 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 appreciate the need to consider ethical issues. One example is the published case report. These reports have the potential to expose patients' identities, for example, if a case report features unusual and/or easily recognized situations. Academy members must familiarize themselves with HIPAA regulations described below that relate to protecting patients from having personal information divulged and should heed COE Rule 5d: "Individuals shall not carry out teaching or research activities in a manner that constitutes an invasion of privacy…"

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. Ethical standards require that any such activity, for example gathering clinical data with advance knowledge of the hope to use such data for extracting conclusions for presentation and/or publication, must have oversight by an IRB and generally include informed consent. Ethical guidelines in this area are found in the COE Rule 5c: "Individuals shall conduct and report product-related research only according to accepted standards of research practice" and Rule 5d: "Individuals shall not carry out teaching or research activities in a manner that constitutes an invasion of privacy, or that fails to inform persons fully about the nature and possible effects of these activities, affording all persons informed free choice of participation."

PROTECTION OF PERSONAL HEALTH INFORMATION

The Health Insurance Portability and Accountability Act (HIPAA) became law in 1996. HIPAA requires all healthcare providers to follow specific guidelines to safeguard the confidentiality of the protected health information (PHI) of individual patients. HIPAA regulations also provide specific information on the rules of confidentiality and protection of information regarding human, health-related research. HIPAA acknowledges the special informational needs in clinical research and provides specific guidelines for how to manage individual situations. Institutional Review Boards generally will incorporate HIPAA guidelines into their requirements for research protocols and also provide and require documentation of HIPAA training for all personnel who are associated with clinical healthcare research.

More recently, the Health Information Technology for Economic and Clinical Health (HITECH) Act (2009) standardizes emerging health information technology such as electronic medical records to insure protection of information. HITECH also strengthens privacy and security under HIPAA.

It is vitally important for Audiologists to familiarize themselves with current regulations regarding personalized health information regardless of whether they are involved in clinical practice or research. This will be particularly important for those who are working in independent clinics and offices that are not likely to receive such information from their hospital or university. More information can be found on the health and human services website listed in the reference section.

PUBLICATION, PRESENTATION OF AND CREDIT FOR RESEARCH

Authorship Rapid publication of scientific findings as well as peer review of such manuscripts 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. Audiologists and hearing scientists often work in groups. For that reason, they must develop rules to determine the relative contribution and value of each contributor when assigning authorship for publication and presentation of research. Persons who participate in audiologic research should be appropriately recognized. Conversely, authorship should not be given to a person 1) who has made little or no contribution to the work, and/or 2) 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.

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. Another method of recognizing contribution is the acknowledgment section which is appropriate for mention of technical personnel whose contribution may have been supportive but who did not participate in the development of the ideas, protocols or writing of the manuscript. Again, it is important to devise a general set of rules for determining authorship and or acknowledgement before the research is initiated and the information should be discussed with the group and have consensus.

While authorship rules are generally individualized for specific institutions, the International Committee of Medical Journal Editors has recommended guidelines. They state that 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. Abuse of authorship principles may be considered a violation of the COE Rule 6b which states **"**Individuals' public statements about professional services, products, or research results shall not contain representations or claims that are false, misleading, or deceptive" or Rule 7b: "Individuals shall inform colleagues and the public in an objective manner consistent with professional standards about products and services they have developed or research they have conducted."

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, for example, inadequate sample size, poorly matched controls, or other deficiencies, the potential benefits of the study and the advancement of knowledge are compromised. 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. Following the scientific method does not guarantee that research will be error free. Yet, mistakes can be minimized when scientists adhere to basic scientific principles and accepted practice. Several rules in the COE refer to these principles including Rule 5c: "Individuals shall conduct and report product-related research only according to accepted standards of research practice," Rule 6b: "Individuals' public statements about professional services, products, or research results shall not contain representations or claims that are false, misleading, or deceptive" and Rule 8b: Individuals shall not engage in dishonesty or illegal conduct that adversely reflects on the profession. Some specific

examples of good scientific methodology follow.

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 trained 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

Conflict of Interest (COI) Disclosure: 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 provide any level of support for research, such sponsorship must be clearly acknowledged in all publications and presentation of the data. Such disclosure should contain details on degree and type of support for specific projects, or general laboratory support. The COE asserts this premise in Principle 4c stating "Individuals shall

not participate in activities that constitute a conflict of professional interest." Further clarification on potential COI issues related to clinical practice in audiology can be found in the recent Academy document entitled "Ethical Practice Guideline for Relationships with Industry for Audiologists Providing Clinical Care."

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, such research was conducted primarily in university settings by independent faculty scientists with limited or no industry involvement. 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. 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. Consequently, the number of audiologists/clinical researchers employed by manufacturers increased, and several researchers in independent laboratories became engaged in manufacturer-sponsored product efficacy studies.

The FDA no longer requires hearing aid manufacturers to obtain pre-market approval of benefit claims, at least for the present time. 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 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, conflict. 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 or to misrepresent the data 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 regarding the benefits of a particular product. The ethics of this issue is clearly stated in COE Rule 5c: “Individuals shall conduct and report product-related research only according to accepted standards of research practice”.

• ***Audiologists and Auditory Scientists Whose Work Is Sponsored by Manufacturers***. Increased sponsorship by manufacturers of product efficacy studies in independent laboratories over the past 10-15 years also presents potential COI for 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 certain 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 and disclosed openly. Audiologists who contract with industry to perform clinical research studies should negotiate written contracts prior to entering into any agreements that spell out precisely what is expected from each party. Particular interest must be paid to how data analysis will be conducted, appropriate acknowledgement of all parties participation, who will make decisions regarding publication of the data, authorship on publications and presentations, etc. and audiologists must be satisfied with agreements. It is not necessarily wrong to not publish data that shows a product in a negative light but if it is published, the scientists must be assured that they have control of data analysis procedures and conclusions drawn. The scientists must be able to defend the conclusions drawn.

Payment to audiologists for research services by industry must not be excessive (should be in line with other funding agencies and based on the actual costs of the study) and must be agreed to prior to the start of the work to insure that COI is avoided. No excessive gifts or payments should be made by industry to research or clinical facilities without a clear reciprocal agreement for provision of services.

Notwithstanding any financial dependence on manufacturers, it is unethical for Academy members who conduct product efficacy studies to in any way bias the results 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.

A summary of ethical expectations regarding industry sponsored research follows.

a. *It is considered unethical for a member to conduct research in a manner that does not provide an honest, fair, accurate and complete evaluation of the product, device, or procedure.*

b. *Members should disclose financial relationships between the researcher and the sponsor in all written and verbal research reports.*

c. *Members should avoid agreements with industry sponsors that limit the dissemination of research results.*

d. *Members should only enter into explicit research contracts with specific deliverables restricted to scientific issues and should not accept "no strings attached" grants and gifts.*

e. *Members should disclose any financial relationships between the researcher and the sponsor in any public written or verbal reports of product evaluation activities.*

f. *Members who conduct industry-sponsored research and who also utilize that company's products clinically should disclose that relationship to their patients in writing.*

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.

Useful Websites

(Active at the time of writing: October, 2011)

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"

http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html Health & Human Services. Links to the Belmont Report, the Common Rule (45 CFR 46), as well as educational and guidance documents.

http://www.wma.net/en/30publications/10policies/b3/index.html "The Declaration of Helsinki of the World Medical Association."

https://www.aamc.org/initiatives/coi/ 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.

http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html . “Health Information Privacy published by US Health and Human Services.”