

Ethics in Audiology Today

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Learning Outcomes

After this course, participants will be able to:

- Identify 4 key terms important in a discussion of ethical conduct
- List 3 examples of ethical risk or dilemmas in clinical practice
- Define what is meant by "conflict of interest"

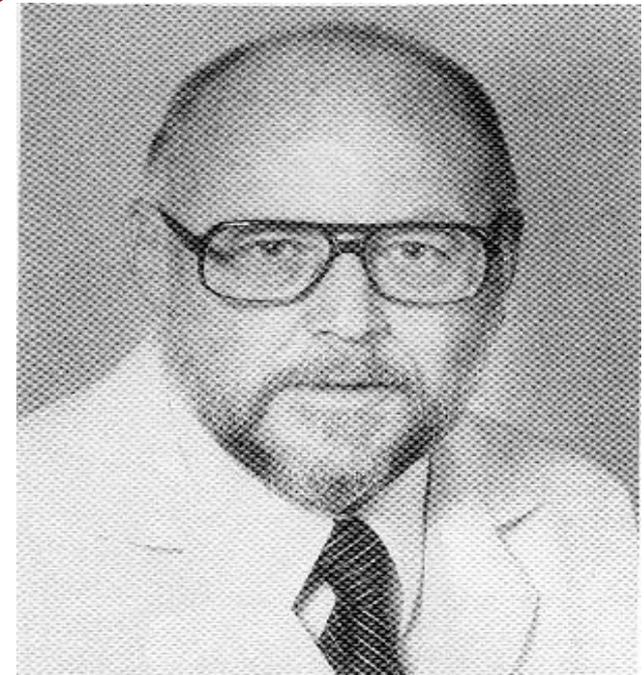
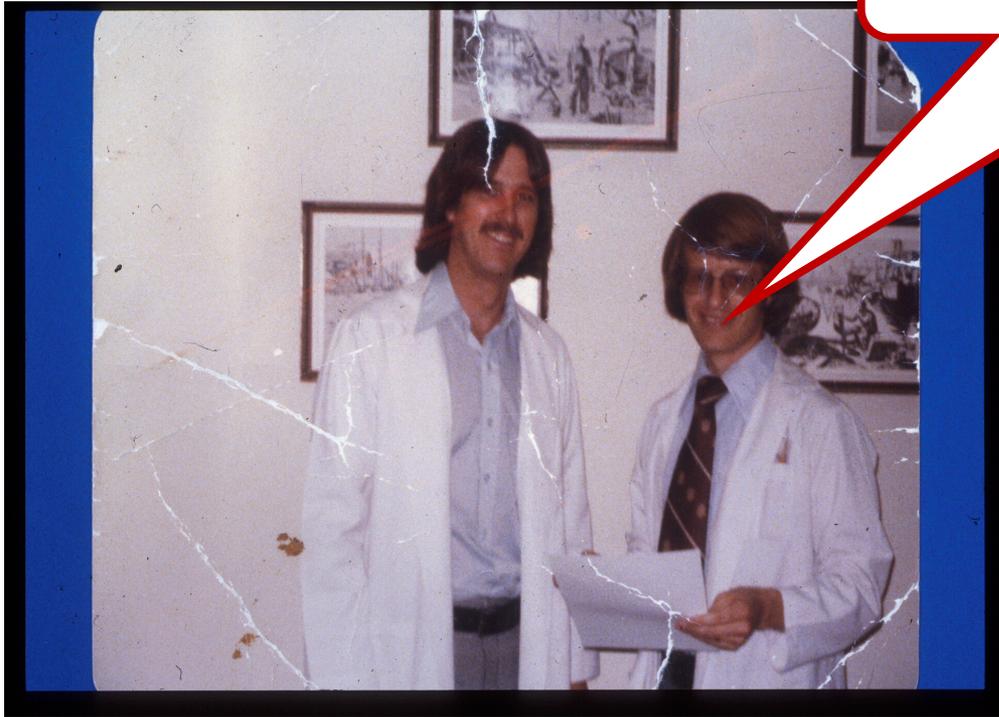
Time Ordered Agenda

- **Introduction to Ethics** (0 – 5 mins.)
- Review of Principles and Terminology (6 – 15 mins.)
- General Guidelines for Ethical Conduct (15 – 25 mins.)
- Ethics in Audiology Education (26 – 30 mins.)
- Ethics in Audiological Practice (31 – 40 mins.)
- Ethics in Auditory Research (41 – 45 mins.)
- Ethical Decisions and Dilemmas (46 – 55 mins.)
- Summary, Questions, Answers (56 – 60 mins.)

CONTINU^{ed} Ethics in Audiology Today

My First Introduction to a Professional Ethical Question

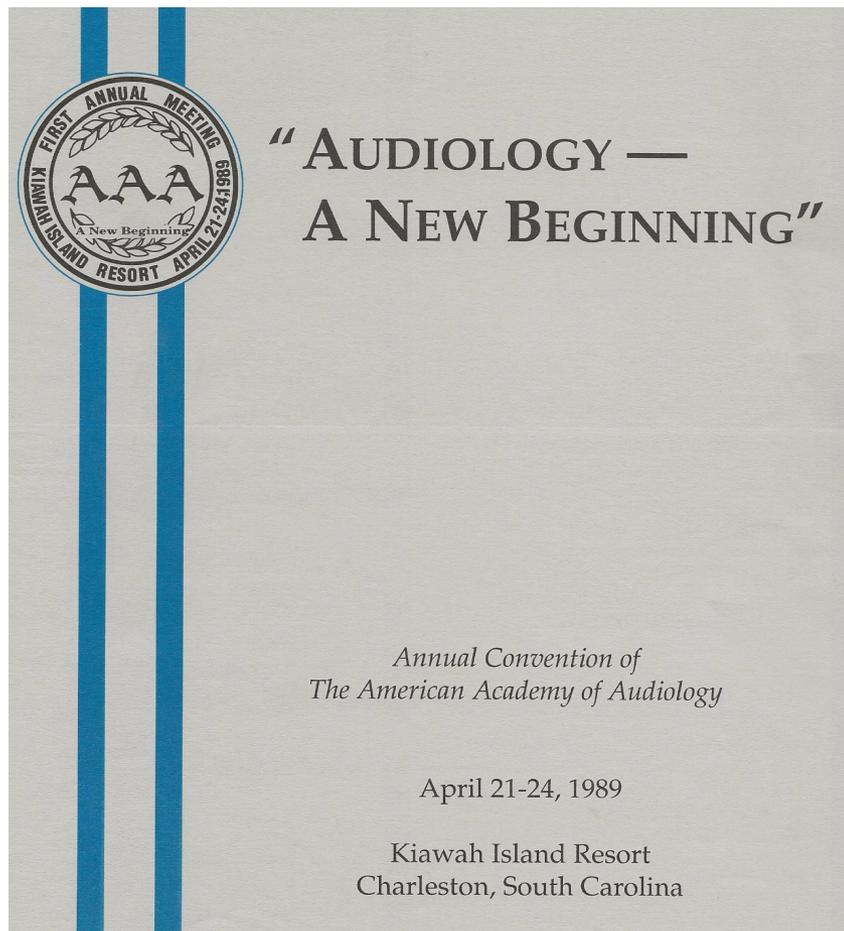
Should I accept a gift certificate from parents of a pediatric patient?



1974

James Jerger
Director, Audiology Service
The Methodist Hospital and
Baylor College of Medicine,
Houston Texas

Ethics Evolution in American Academy of Audiology



PROGRAM

Friday

Noon - 6:00 Exhibits/Poster Sessions

8:00 p.m. - Reception - Special Opening
Night Party, sponsored by
Starkey Laboratories, Inc.

- **American Academy of Audiology (2003). Ethical practice guidelines on financial incentives from hearing instrument manufacturers.**
- **American Academy of Audiology (2006). Ethics in Audiology: Guidelines for ethical conduct in clinical, educational, and research settings.**
- **AAA Code of Ethics**
- **AAA Ethical Practices Committee**

CONTINU^{ed}® **Ethics in Audiology Today**

**40+ Years of Clinical and Academic Ethics Experience
as Director of Audiology**



The promise of discovery



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General Principles

- Adhere to Code of Ethics for Audiology (e.g. AAA)
- Comply with Audiology Scope of Practice
- Follow HIPAA (Health Information Portability and Accountability Act)
- Follow FERPA (Federal Education Rights and Privacy Act)
- Practice according to ethical guidelines for your state
- Appreciate differences between ethics vs. law
- Remember: “The right thing to do is to do what is right.”
- Follow the “golden rule” in professional life
- Adhere to adage: "Integrity is doing the right thing, even if nobody is watching.”
- Would you tell your parents or patients about what you are doing?
- **When in doubt ... reach out!**

General Principles: When in Doubt ...?

- **Document your concerns**
 - Retain and maintain pertinent documents
 - Make detailed notes
- **Immediately inform your administrative superior, e.g.,**
 - Supervisor or clinic director
 - Department chair
 - Dean
 - Human resources (HR)
- **Consult with or retain legal counsel**
 - Legal department in your institution
 - Attorney representing health care professionals
 - Attorney with health care law specialty

Key Terminology (2)

- Negligence
- Professional Liability
- Professionalism
- Protected Health Information (PHI)
- Reprimand
- Sanction
- Standard of Care
- Veracity
- Violation
- Virtue



Key Terminology: Conflict of Interest (COI)

“A conflict of interest or appearance of a conflict of interest exists when a person or entity in a position of trust has a financial or personal interest that could unduly influence, or could appear to influence, decisions related to a primary interest such as patient care, student education or validity of research.” (AAA, 2017)



Examples of Possible Conflict of Interest

- **Clinical Audiology Practice**
 - Financial compensation from related industry
 - Financial interest in referral (to/from) entity
 - Financial ties to companies that are vendors for clinic
- **University Teaching**
 - Use of required authored textbook in courses
 - Teaching responsibilities at a competing institution
- **Professional Leadership**
 - Undisclosed financial interest in related industry
 - Undisclosed leadership position in another organization
 - Advisory board of company related to audiology

Disclosure of Conflict of Interest (AAA Leadership)



CONFLICT OF INTEREST, CONFIDENTIALITY & FULL DISCLOSURE AGREEMENT

1. **Conflict of Interest: Overview**

- a. Board, Committee, Task Force, subcommittee, and Working Group chairs and their membership should avoid both actual and perceived conflicts of interest that would interfere with their ability to discharge their responsibilities to the Academy.
- b. Every member of a committee or subcommittee ("committee member"), including those with responsibility for selecting speakers or topics for educational sessions at the American Academy of Audiology ("Academy") convention, AudiologyNOW! should avoid both actual and perceived conflicts of interest that would interfere with their ability to discharge their responsibilities to the Academy.
- c. Additionally, Board, Committee, Task Force, subcommittee, and Working Group chairs and their members are required to provide full disclosure of their official duties or obligations that might affect their ability to fulfill their commitment to the Academy, and to protect proprietary Academy business information from outside disclosure.

2. **Potential Conflict of Interest Defined.** The following circumstances may potentially create a conflict of interest. A Board, Committee, Task Force, subcommittee or Working Group chair or their members:

- a. is employed by, a consultant to, or owns any financial or other proprietary interest in any entity supplying (or seeking to supply) goods or services to audiologists;
- b. receives any benefit from a third party on account of that party's past, present, or future access to participate in the Academy's convention/affairs; or
- c. receives any financial benefit from a pending decision of a committee or subcommittee of the Academy.

3. **Disclosure of the Existence of a Conflict.** If any Board, Committee, Task Force, subcommittee or Working Group chair or their membership knows, believes, or has reason to know or believe, that a conflict of interest exists with respect to any transaction involving an Academy board, committee or subcommittee, task force or working group (hereafter referred to as "organization") to which they belong or any decision of the organization, such person shall inform their organization of the existence of such conflict of interest or potential conflict of interest immediately.

4. **Effect of the Existence of a Conflict of Interest.** In the event that it is determined that an actual conflict of interest exists, and the person has made full disclosure of the facts surrounding the conflict, then the individual must withdraw from both the deliberation and vote on the proposal under consideration.

5. **Resignation.** No individual who has an actual conflict of interest shall be required to resign his or her position with the Academy's organization solely because of the existence of a conflict. In situations where the chair of the committee or task force is involved in the conflict, the President of the Academy and the committee/task force/working group's board liaison should make a fair and full evaluation of all the facts pertaining to the conflict. In the situation where a committee or

subcommittee/task force/working group's member is involved, the chair and board liaison will make a full and fair evaluation of all the facts pertaining to the conflict. If a determination that an actual conflict of interest exists and is of such a continuing nature that it would be impossible for the member to discharge the duties of his or her office, then that member will be required to submit their resignation to the committee.

CONFIDENTIALITY

I understand that accepting a position as chair or member of an Academy organization carries with it a priority obligation to commit time, effort and confidentiality to the deliberations of the organization.

I also understand that I may not represent my organization, and therefore the Academy, to groups or organizations outside the Academy without the approval of the President of the American Academy of Audiology.

I also understand that during one's term of office, audiences/readership may perceive that because I am a member of the Academy organization, my presentations or writings could be perceived as actually representing the official position of the American Academy of Audiology. Therefore if a member believes that this misperception could occur, the member should state or write a disclaimer at the beginning of their presentations or writings that conforms to the following disclaimer. *"The opinions and assertions presented are the private views of the author and are not to be construed as official or as necessarily reflecting the views of the American Academy of Audiology."*

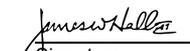
FULL DISCLOSURE

I hereby disclose the following: organization(s) where I am employed, have a consulting relationship, or have other financial interest and other organizations for which I hold a voluntary position, such as committees and task forces (chair or member), board (officer or member) include:
Lively, Inc. (unpaid advisory board member)

Salus University (paid part-time professor)

University of Hawaii (paid part-time professor)

I have reviewed the American Academy of Audiology Conflict of Interest, Confidentiality & Full Disclosure Agreement. I agree to be bound by these provisions for the duration of my appointed or elected term.


Signature
James W. Hall III

Key Terminology: Professional Liability

- **An individual who causes injury to another either intentionally or unintentionally can be held liable for the action.**
- **By virtue of advanced knowledge, training, and skill, a professional has a responsibility to conform to certain standards of conduct to protect the public from unreasonable risks.**



Key Terminology: Professionalism

Professionalism is defined as the acting out of the values and beliefs of individuals who serve those whose well-being is entrusted to them, by putting the client's [patient's] interests first.

Source: Kirk, L. M. (2007). Professionalism in medicine: definitions and considerations for teaching. *Proc (Bayl Univ Med Cent)*, 20, 13–16.



Key Terminology: Informed Consent

- **Written consent is required for a proposed course of action after the communication of adequate information regarding expected outcomes and potential risks, e.g.,**
 - **Signed by patient or parent of child before audiological assessment**
 - **Signed by patient or parent of child before audiological treatment**
 - **Signed by signed by patient or parent of child before participation as a subject in clinical trials or a research study**

Informed consent: Agreement or permission accompanied by full notice about the care, treatment, or service that is the subject of the consent. A patient must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins any such course. After receiving this information, the patient then either consents to or refuses such a procedure or treatment.

Source: The Joint Commission. 2016. Comprehensive Accreditation Manual glossary.

Key Terminology: Fraud

- **Any act, expression, omission, or concealment—the intent of which is either actual or constructive—calculated to deceive others to their disadvantage, e.g.,**
 - **False claims**
 - **Bill for services not provided**
 - **Falsifying diagnosis to justify procedures**
 - **Forging bills or receipts**
 - **“Upcoding” when billing**
 - **Accepting kickbacks for patient referrals**
 - **Billing more than co-pay**

Florida Audiologist Sentenced for Multimillion-Dollar Health Care Fraud

A Florida audiologist was sentenced to 94 months in prison recently for her role in a multimillion-dollar health care fraud and money laundering scheme.

Assistant Attorney General Leslie R. Caldwell of the Justice Department’s Criminal Division, U.S. Attorney A. Lee Bentley III of the Middle District of Florida, Special Agent in Charge Shimon R. Richmond of the U.S. Department of Health and Human Services-Office of Inspector General (HHS-OIG) Miami Regional Office and Special Agent in Charge Paul Wysopal of the FBI’s Tampa, Florida, Field Office made the announcement.

Terri L. Schneider, 57, of Lakeland, Florida, was sentenced by U.S. District Judge Steven D. Merryday of the Middle District of Florida, who also ordered Schneider to pay \$2,512,460.27 in restitution, joint and several. In December 2015, a jury in Tampa found Schneider and co-conspirator David Brock Lovelace guilty on all charges, which included conspiracy to commit health care fraud and wire fraud, health care fraud, conspiracy to commit money laundering, money laundering and aggravated identity theft. On March 7, Lovelace was sentenced to 174 months in prison and ordered to pay \$2,512,460.27 in restitution, joint and several.

According to evidence presented at trial, from approximately June 2010 through approximately May 2014, Schneider and her co-conspirators used three purported medical clinics in Florida, Cornerstone Health Specialists, Summit Health Specialists and Coastal Health Specialists, to submit approximately \$12,351,046 in false and fraudulent claims to Medicare seeking reimbursement for radiology, audiology, cardiology and neurology services. Medicare paid approximately \$2,848,424 in reimbursement on the fraudulent claims. The evidence showed that Schneider and her co-conspirators used forged and falsified documents in the Medicare enrollment process for the medical clinics that they operated under false pretenses, and billed Medicare for services that had not been rendered by physicians. The co-conspirators also paid illegal kickbacks in exchange for access to Medicare patients and Medicare patient information used in the fraud scheme, the evidence showed.

Key Terminology: Protected Health Information

- Names
- Geographical identifiers smaller than a state
- Dates (except year) related to patient
- Email address (s)
- Relevant Numbers, e.g., phone, fax, social security, account, medical record, health insurance, device serial numbers, any other unique number
- Biometric identifiers
- Full face photographic images



Key Terminology: Standard of Care

- **Standard of care is the degree of prudence and caution required of an individual who is under a duty of care.**
- **The level of care which an average practitioner would practice, and how a similar qualified practitioner would manage their patient's care under similar circumstances.**
- **Medical malpractice claims must establish the standard of care and show that the standard has been breached.**
- **Evidence-based practice as defined in clinical guidelines meets criteria for standard of care.**

CONTINU^{ed} Ethics in Audiology Today



Ethics

Law

- Moral philosophy guiding human conduct
- Right versus wrong
- Good behavior
- May be abstract
- Individual and professional guidelines
- Violations not usually punished

- Rules governing society
- Based on ethics
- Codification of certain ethical values
- Government administered
- Written in laws and regulations
- Punishable with fines or imprisonment
- Intent is to maintain peace and order in society

Legal versus Ethical Issues

Law

Ethics

Power/Influence

Felony -----> Misdemeanor
Bribery
Blackmail

*Abuse of person or
positional power*

Money

Felony -----> Misdemeanor
Grand Theft
Embezzlement

*Financial appearance
of impropriety*

Sexual Misconduct

Felony -----> Misdemeanor
Assault
Rape

Harassment
Coercion
Unwanted contact

Criminal versus Civil Law (and Lawsuits)

The legal system in the USA addresses the wrongdoings that people commit with two different types of cases: civil and criminal.

- **Civil cases typically involve disputes between individuals regarding the legal duties and responsibilities they owe to one another. Professional liability is a good example.**
- **Crimes, on the other hand, are generally offenses against the state, although the immediate harm may be done to an individual. Criminal cases are accordingly prosecuted by the state or at the federal level.**

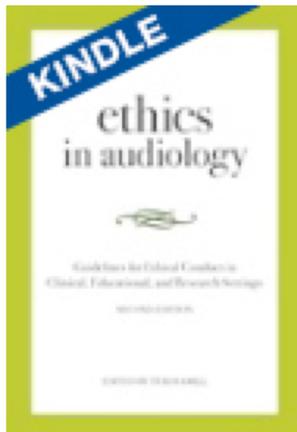
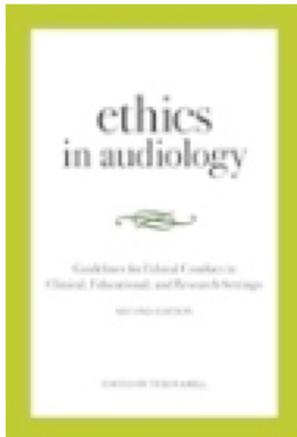
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General Guidelines for Ethical Conduct: *AAA Resources*

Ethics in Audiology (2nd ed.), 2012

- Legal and Ethical Issues in Audiology Practice; Billing and Coding
- Ethics and Professionalism
- Research Ethics and Ethics of Best Practice
- Ethics in Academia
- Ethics of Preceptorship and Supervision
- Ethical Reporting of Abuse and Neglect
- Analysis of Ethical Dilemmas
- Conflict of Interest Considerations
- The Code of Ethics and the Ethical Practice Board



General Guidelines for Ethical Conduct: *Examples of Documents and References*

- American Academy of Audiology (AAA): www.audiology.org
 - Code of Ethics
 - Scope of Practice
- State Licensure Board
 - Statutes
 - Regulations
- Institutional (e.g., University or hospital)
 - Regulations
 - Policies
 - Procedures

AAA Code of Ethics

CODE OF ETHICS OF THE AMERICAN ACADEMY OF AUDIOLOGY

PREAMBLE

The Code of Ethics of the American Academy of Audiology specifies professional standards that allow for the proper discharge of audiologists' responsibilities to those served, and that protect the integrity of the profession. The Code of Ethics consists of two parts. The first part, the Statement of Principles and Rules, presents precepts that members (all categories of members including Student Members) effective January 1, 2009 of the Academy agree to uphold. The second part, the Procedures, provides the process that enables enforcement of the Principles and Rules.

PART I. STATEMENT OF PRINCIPLES AND RULES

PRINCIPLE 1: Members shall provide professional services and conduct research with honesty and compassion, and shall respect the dignity, worth, and rights of those served.

Rule 1a: Individuals shall not limit the delivery of professional services on any basis that is unjustifiable or irrelevant to the need for the potential benefit from such services.

Rule 1b: Individuals shall not provide services except in a professional relationship and shall not discriminate in the provision of services to individuals on the basis of sex, race, religion, national origin, sexual orientation, or general health.

PRINCIPLE 2: Members shall maintain the highest standards of professional competence in rendering services.

Rule 2a: Members shall provide only those professional services for which they are qualified by education and experience.

Rule 2b: Individuals shall use available resources, including referrals to other specialists, and shall not give or accept benefits or items of value for receiving or making referrals.

Rule 2c: Individuals shall exercise all reasonable precautions to avoid injury to persons in the delivery of professional services or execution of research.

Rule 2d: Individuals shall provide appropriate supervision and assume full responsibility for services delegated to supportive personnel. Individuals shall not delegate any service requiring professional competence to unqualified persons.

Rule 2e: Individuals shall not knowingly permit personnel under their direct or indirect supervision to engage in any practice that is not in compliance with the Code of Ethics.

Rule 2f: Individuals shall maintain professional competence, including participation in continuing education.

PRINCIPLE 3: Members shall maintain the confidentiality of the information and records of those receiving services or involved in research.

Rule 3a: Individuals shall not reveal to unauthorized persons any professional or personal information obtained from the person served professionally, unless required by law.

AAA Code of Ethics (2)

PRINCIPLE 4: Members shall provide only services and products that are in the best interest of those served.

Rule 4a: Individuals shall not exploit persons in the delivery of professional services.

Rule 4b: Individuals shall not charge for services not rendered.

Rule 4c: Individuals shall not participate in activities that constitute a conflict of professional interest.

Rule 4d: Individuals using investigational procedures with human participants or prospectively collecting research data from human participants shall obtain full informed consent from the participants or legal representatives. Members conducting research with human participants or animals shall follow accepted standards, such as those promulgated in the current Responsible Conduct of Research by the U.S. Office of Research Integrity.

PRINCIPLE 5: Members shall provide accurate information about the nature and management of communicative disorders and about the services and products offered.

Rule 5a: Individuals shall provide persons served with the information a reasonable person would want to know about the nature and possible effects of services rendered or products provided or research being conducted.

Rule 5b: Individuals may make a statement of prognosis, but shall not guarantee results, mislead, or misinform persons served or studied.

Rule 5c: Individuals shall conduct and report product-related research only according to accepted standards of research practice.

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.

Rule 5e: Individuals shall maintain accurate documentation of services rendered according to accepted medical, legal and professional standards and requirements.

PRINCIPLE 6: Members shall comply with the ethical standards of the Academy with regard to public statements or publication.

Rule 6a: Individuals shall not misrepresent their educational degrees, training, credentials, or competence. Only degrees earned from regionally accredited institutions in which training was obtained in audiology, or a directly related discipline, may be used in public statements concerning professional services.

Rule 6b: Individuals' public statements about professional services, products or research results shall not contain representations or claims that are false, misleading, or deceptive.

PRINCIPLE 7: Members shall honor their responsibilities to the public and to professional colleagues.

Rule 7a: Individuals shall not use professional or commercial affiliations in any way that would limit services to or mislead patients or colleagues.

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.

AAA Code of Ethics (3)

PRINCIPLE 8: Members shall uphold the dignity of the profession and freely accept the Academy's self-imposed standards.

Rule 8a: Individuals shall not violate these Principles and Rules nor attempt to circumvent them.

Rule 8b: Individuals shall not engage in dishonesty or illegal conduct that adversely reflects on the profession.

Rule 8c: Individuals shall inform the Ethical Practices Committee when there are reasons to believe that a member of the Academy may have been in noncompliance with the Code of Ethics.

Rule 8d: Individuals shall fully cooperate with reviews being conducted by the Ethical Practices Committee in any matter related to the Code of Ethics.

Signature: _____ Date: _____

PART II.

PROCEDURES FOR THE MANAGEMENT OF ALLEGED NONCOMPLIANCE

INTRODUCTION

Members of the American Academy of Audiology are obligated to uphold the Code of Ethics of the Academy in their personal conduct and in the performance of their professional duties. To this end, it is the responsibility of each Academy member to inform the Ethical Practice Committee of possible noncompliance with the Ethics Code. The processing of alleged noncompliance with the Code of Ethics will follow the procedures specified below in an expeditious manner to ensure that behaviors of noncompliant ethical conduct by members of the Academy are halted in the shortest time possible.

PROCEDURES

1. Suspected noncompliance with the Code of Ethics shall be reported in letter format, giving documentation sufficient to support the alleged noncompliance. Letters must be addressed to:

American Academy of Audiology
 Chair, Ethical Practices Committee
 11480 Commerce Park Dr. Suite 220
 Reston, VA 20191

AAA Code of Ethics (3)

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Ethics in Audiology Education

- **Comply with FERPA (Federal Education Rights and Privacy Act)**
- **Important for educational audiologists as well as faculty and on/off campus preceptors in AuD programs**
- **FERPA classifies protected information into three categories:**
 - Educational information
 - Personally identifiable information
 - Directory information
- **Unintentional FERPA violations**
 - Overheard conversations about students
 - Discarding student records improperly, e.g., without shredding
 - Release of information to parent of student > 18 years
 - Vendor misuse of student educational records

Ethics in Audiology Education

- **Plagiarism (online plagiarism tools)**
- **Conflict of interest (many examples)**
- **Falsifying or “padding” resume or curriculum vitae (CV)**
- **Failure to acknowledge academic contributions**
- **Sexual harassment or otherwise creating a hostile or uncomfortable work or educational environment**
- **Violation of fairness and nondiscrimination policies**
- **Failure to properly report unethical conduct**



Statements from AuD Course Syllabi *(Nova Southeastern University)*

XII. ACADEMIC STANDARDS

The university is an academic community and expects its students to manifest a commitment to academic integrity through rigid observance of standards for academic honesty. The university can function properly only when its members adhere to clearly established goals and values. Accordingly, the academic standards are designed to ensure that the principles of academic honesty are upheld.

The following acts violate the academic honesty standards:

- 1. Cheating**—intentionally using or attempting to use unauthorized materials, information, or study aids in any academic exercise
- 2. Fabrication**—intentional and unauthorized falsification or invention of any information or citation in an academic exercise
- 3. Facilitating Academic Dishonesty**—intentionally or knowingly helping or attempting to help another to violate any provision of this code
- 4. Plagiarism**—the adoption or reproduction of ideas, words, or statements of another person as one's own without proper acknowledgment.

Statements from AuD Course Syllabi

University of Florida Policy on Academic Integrity

- Cheating, lying, misrepresentation, or plagiarism in any form is unacceptable and inexcusable behavior.
- University of Florida students are bound by The Honor Pledge which states, “We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: “On my honor, I have neither given nor received unauthorized aid in doing this assignment.”
- The Honor Code specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. Students are expected to act in accordance with the University of Florida policy on academic integrity (see Student Conduct Code, the Graduate Student Handbook or these web sites for more details:
- <http://www.dso.ufl.edu/sccr/honorcodes/conductcode.php>

Disclosure of Conflict of Interest (University Teaching)

University of Florida
Disclosure of Outside Activities
Disclosure Period: July 1, 201

Name JAMES W. HALL III
Title/Rank ADJUNCT PROFESSOR
Phone number 352-275-0335
Email jwhall3.phd@gmail.com
% FTE 0.25

UFID 1021-9030
Department or Unit SPEECH LANGUAGE & HEARING
College or Division PHHP SCIENCE
University Contract Period
 9 month 12 month

1. In accordance with University of Florida regulations, I report the following activity or financial interest. Please check the category or categories of the activity or financial interest as described in the Instructions to this form:

a. b. c. d. e. f. g. h. i. j. k. l. m. n.

2. Please provide the requested information on the activity or financial interest performed/proposed during the University contract period as identified above. Please use additional pages if necessary. All activities and financial interests for one entity should be disclosed on one form. Additional activities and financial interests should each be reported on separate forms.

(a) Name of entity (or person) with which the activity is to be conducted, or name of entity in which the financial interest is held, and nature of its business:

SALUS UNIVERSITY: TEACHING INTERNATIONAL COURSES
UNIV. OF HAWAII: TEACHING UNDERGRADUATE COURSES

Is the entity a for-profit entity or a not-for-profit entity ?

Does the entity or parent, subsidiary or affiliated organization of the entity sponsor your research at UF or license technology from UF you invented? Yes No

40+ Years of Clinical and Academic Ethics Experience as Director of Audiology



The University of Florida recognizes

James W Hall

for the successful completion of

**Maintaining a Safe and Respectful Campus:
Sexual Violence, Harassment and
Discrimination Awareness and Prevention**

Certificate of Completion

Salus University

James Hall

has completed

HIPAA Overview (Full Course)

Certificate of Completion

Salus University

James Hall

has completed

FERPA: Confidentiality of Records (Full Course)

Certificate of Completion

Salus University

James Hall

has completed

Title IX and Sexual Misconduct (Full Course)

Certificate of Completion

Salus University

James Hall

has completed

Discrimination Awareness in the Workplace (Full Course)

Certificate of Completion

Salus University

James Hall

has completed

General Ethics in the Workplace (Full Course)

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Ethics in Audiological Practice: Examples of Violations

- **Conflict of interest (many examples)**
- **Falsifying clinical records**
- **Sexual harassment or misconduct**
- **Billing for services not provided (fraudulent claims)**
- **Offering free hearing test as a Medicare provider**
- **Providing audiology services without license**
- **Inappropriate gifts**
 - **To or from patients**
 - **To or from referral sources**
 - **From vendors**
- **Failure to properly report unethical conduct**



CONTINU^{ed} Ethics in Audiology Today

Ethics in Audiological Practice: *Vendor or Manufacturer Related Violations*

- Inappropriate gifts exceeding limits
- Inappropriate manufacturer "incentives" (kickbacks)
 - Discounted hearing aid pricing
 - Lease of clinic space
 - Business development funds
 - Free advertising
 - Use of referral
- Inappropriate referral source relationships
 - Use of referral pads
 - Quid pro quo
 - Gifts exceeding limits



CONTINU^{ed} Ethics in Audiology Today

Ethics in Audiological Practice: *More About Manufacturer Gifts (AAA, 2017)*

- Acceptance of gifts in excess of \$50 by a member of the American Academy of Audiology from any company that manufactures or supplies products that he or she professionally uses or recommends, may compromise, or give the appearance of compromising, the audiologist's ability to make ethical decisions, and should be avoided.
- Gifts represent a conflict of interest because of the real or apparent influence they may have on audiologists' clinical decisions.
- For the purpose of this guideline, "gifts" are defined as anything of value given to individuals by industry for personal use and/or personal profit.

Ethics in Audiological Practice: *Acceptable or Appropriate Gifts (AAA, 2017)*

- Uniquely compatible items provided for patient care and education, such as proprietary software, demonstration units, cables, and software needed strictly for a specific product would not be considered a “gift.”
- Additionally, pens and notepads and other small branded items (valued at \$50.00 or under) made available to all participants of a convention or meeting used to promote the primary educational purpose of the meeting would not be considered a “gift.”
- Meals and travel deemed as rewards are also considered gifts; however, provisions for necessary and reasonable meals and travel associated with legitimate and necessary product educational/training experiences are not considered gifts, thus are not prohibited,

Ethics in Audiological Practice:
Questions to Ask Yourself (AAA, 2017)

- **How might my patients feel about my relationship with industry?**
- **How might patients view my receiving gifts from industry?**
- **How would independent colleagues view my association with industry?**
- **Would I be willing to have the details of my involvement with industry made public?**
- **Could my relationship with industry be viewed as one which may influence my professional judgment in patient care?**

Ethics in Audiological Practice: Gifts



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



December 7, 2016

Office of Inspector General Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid Beneficiaries

Under section 1128A(a)(5) of the Social Security Act (the Act), enacted as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services may be liable for civil monetary penalties (CMPs) of up to \$10,000 for each wrongful act. For purposes of section 1128A(a)(5) of the Act, the statute defines "remuneration" to include, without limitation, waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. See section 1128A(i)(6) of the Act. The statute and implementing regulations contain a limited number of exceptions. See section 1128A(i)(6) of the Act; 42 CFR 1003.110.

The Office of Inspector General (OIG) expressed its interpretation of "inexpensive" or "nominal value" to mean a retail value of no more than \$10 per item or \$50 in the aggregate per patient on an annual basis.

Ethics in Audiological Practice

[ck](#)

HEALTH INFORMATION CONFIDENTIALITY STATEMENT

[Print](#)

- I acknowledge that this statement applies to all members of the University of Florida (UF) workforce who are employed by, contracted to, or under the direct control of the healthcare components of UF, including but not limited to, employees, volunteers, students, physicians, resident physicians, and third parties, whether temporary or permanent, paid or not paid, visiting, or designated as associates.
- I understand that the UF healthcare components include the Health Science Centers located in both Gainesville and Jacksonville, and all their direct support organizations and affiliated entities (affiliates) as defined in the UF Privacy Policies and Procedures.
- I acknowledge that UF has formally stated in the UF Privacy Policies and Procedures its commitment to preserving the confidentiality and security of health information, whether maintained or distributed in paper, electronic, video, verbal, or any other medium or format. I understand that I am required, if I have access to such health information, to maintain its confidentiality and security.
- I understand that access to health information created, received, or maintained by UF or its affiliates in any location is limited to those who have a valid business or healthcare need for the information or otherwise have a right to know the information. I understand that there are many administrative, physical and technical safeguards in place to protect the privacy and security of this health information, and that any attempt to bypass or override these safeguards is a violation of federal and state laws and the privacy and security policies of the University of Florida.
- I understand that anyone who is authorized to access electronic health information within UF and affiliated systems will be issued a unique user identification and password, and that any person who knowingly discloses their user ID or password to others, uses or discloses another individual's user ID or password, or accesses any electronic protected health information without authorization is subject to disciplinary action, up to and including dismissal. In addition, I understand that all UF and affiliate workforce members must comply with applicable Information Technology Security Policies.
- I understand that approved methods and purposes for access to, uses and disclosures of, and requests for, any and all protected health information, created, received or maintained by UF and its affiliates, are limited to those described in the UF Privacy Policies and Procedures. I further understand that, with the exception of purposes related to treatment, access to, uses and disclosures of, and requests for an individual's health information must, to the extent practicable, be limited to the minimum necessary to accomplish the intended purpose of the approved use, disclosure or request.

Time Ordered Agenda

- Introduction to Ethics (0 – 5 mins.)
- Review of Principles and Terminology (6 – 15 mins.)
- General Guidelines for Ethical Conduct (15 – 25 mins.)
- Ethics in Audiology Education (26 – 30 mins.)
- Ethics in Audiological Practice (31 – 40 mins.)
- **Ethics in Auditory Research** (41 – 45 mins.)
- Ethical Decisions and Dilemmas (46 – 55 mins.)
- Summary, Questions, Answers (56 – 60 mins.)

Ethics in Auditory Research

- **Institutional Review Board (IRB) approval required**
- **Approval of formal research proposal with informed consent (participant or legal representative) is required for protection of Confidentiality**
 - **Privacy**
 - **Health and safety**
- **Special precautions for vulnerable populations**
 - **Infants**
 - **Children (under age of 18 years)**
 - **Cognitively impaired participants (e.g., comatose, dementia)**
- **Special precautions for experimental**
 - **Devices (not FDA approved)**
 - **Procedures (invasive or not clinical procedures)**
- **Institutional Review Board (IRB) for Animal Research**
 - **Humane treatment**
 - **Scrutiny of animal model**
 - **Minimal risk to least number of animals**

Ethics in Auditory Research: Case Studies

AUDIOLOGY CASE STUDIES

Guidelines for Writing an Audiology Case Study

By Antony R. Joseph, AuD, PhD, and James W. Hall III, PhD

Case studies provide accurate and complete accounts of patient symptoms, history, and care, potential complications, treatment alternatives, or preventive medicine and disease avoidance. Some highlight the clinical findings in a patient with a rare disease or disorder. A published case study may be used to reinforce best practices, report alarming observations in a patient encounter, and convey important clinical knowledge. Case studies also may contribute to improving the safety of our patients. In preparation for a new section in *The Hearing Journal* that will feature audiology case studies, we outline the structure and necessary components of an audiology case study.



WHAT'S A CASE STUDY?

As far back as the 1800s, case studies (also called case reports) became established as a popular tool for medical training. At that time, the case study was intended to accumulate knowledge of clinical issues, diagnostic methods, and treatments. They were primarily written to provide an educational message about the etiology and pathogenesis of diseases and disorders, as well as improvement of patient care. Today, case studies serve the same educational functions.

Any component of a written clinical note about a patient can form the basis of a case study, such as an unusual patient complaint, atypical test findings, a rarely encountered diagnosis, or even a novel treatment plan. Fundamentally, a case study should tell a succinct story about the patient that may be readily consumed by clinicians, students, researchers, therapists, allied health personnel and, on occasion, manufacturer representatives. Although a bell curve is commonly used to represent patient outcomes on a distribution, we accept that, for various reasons, some patients lie somewhere on the tails of the curve. These outliers often become the subject of case studies.

Audiologists frequently say, "Two patients with the same audiogram do not always have the same complaints." The opposite is also true. Two patients with similar chief complaints and histories may, in fact, have very different diagnoses. These nuances may be captured in a well-presented case

study. Clearly, not every patient experiences the same progression of hearing loss, vestibular disease, or tinnitus, or the same degree, type, and pattern of hearing loss or related disorder. Large clinical-research studies are not practical for diagnosis and treatment of every clinical condition, particularly ones with multiple factors at play.¹ Controlled experimental trials usually report group-level data that may not be applied to or clinically relevant for all patients. Indeed, statistically significant findings in a large research study of people with a particular disorder may have absolutely no clinical significance to the assessment and management of individual patients with the same disorder. In contrast, published case studies are invariably clinically relevant and instructive.

HOW TO GET PUBLISHED

Another major advantage of a published case study is the modest manuscript length, especially when the subject is a single patient. In most medical specialties, published case studies are brief and about issues related to one patient. Audiology case studies tend to be more extensive with a substantial literature review. Some even include multiple patients or are included as part of a research report.

The challenge in preparing a case study is to concisely and briefly tell an adequately detailed clinical story about the patient. Overall, a case study must be no less than 750 and no more than 1,400 words. Table 1 summarizes guidelines for submission of case studies for publication in *The Hearing Journal*. This should make the task of writing the manuscript more tolerable for audiologists. Clinicians will enjoy an article that is organized, succinct, and contains a compelling educational message. To reach this goal, a case study manuscript should include some or all the components described below.^{2,3}

Published case studies are a practical and clinically useful venue for disseminating important information about the

CASE STUDY CONSENT FORM¹

Use this for a patient's consent to publication of images and/or information about them in THJ.

Medical practitioner or corresponding author(s): _____

Name of patient described in article or shown in photograph: _____

Subject matter of photograph or article: _____

Provisional title of article in which information will be included: _____

- If patient not signing this form, relationship to patient: _____
- A copy of the material has been attached to this form: Verified: YES NO
- Include a description of the photo(s), image(s), text or other material about the patient: _____

PATIENT CONSENT

I, _____ give my consent for the information about me
 [PRINT FULL NAME] /the patient to appear in a THJ publication.



Dr. Anthony, left, is an assistant professor at Illinois State University's Hearing Loss Prevention Laboratory in Normal, IL. He is a dual-degree audiologist for nearly 30 years, emphasizing early identification and hearing loss prevention. Dr. Hall is an audiologist with over 40 years of clinical, teaching, research, and administrative experience. He is a professor of audiology at Salus University and the University of Hawaii.

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Ethical Decisions and Dilemmas

- **You are requested to**
 - **Sign results for tests that you did not perform (e.g., another audiologist or a technician that is not licensed)**
- **A manufacturer vendor offers to**
 - **Take you out to dinner**
 - **Provide lunch for the audiology staff**
 - **Provide you or the clinic with a cash gift**
- **During your clinical interactions with an adult patient or parent of a pediatric patient you suspect some type of abuse of the patient**
- **You have evidence or suspicion that another audiologist is submitting fraudulent Medicare claims**
- **At least 30 hours of approved CEUs are required every two years for state license renewal. At the renewal time you have < 30 hours.**

Key References

- American Academy of Audiology Code of Ethics (www.audiology.org)
- American Academy of Audiology Ethical Practice Guideline for Relationships with Industry for Audiologists Providing Clinical Care (2017). (www.audiology.org)
- Callahan et al (2011). Ethical dilemmas in audiology. *Contemporary Issues in Communication Sciences and Disorders*, 38, 76-86
- Ng et al (2019). Clinician, student, and faculty perspectives on the audiology-industry interface: implications for ethics education. *International Journal of Audiology*, 58, 576-586

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