Advanced Education Committee	
AGENDA	
January 25, 2016	12:00-12:50, Deans Conference Room
Dr. Anne Williamson, Chair	Recorder: Ms. Michelle Krupp
Lunch will be served.	

Agenda Items	Responsible Individual
1. Approval of the November 16, 2015 Minutes	**Williamson**
2. Grad Admissions – Operative Issue resolution; upload documents.	**Guzman/Maia**
3. UI Electronic Course Evaluation Project	**Krupp/Southard**
4. Ms. Lee Seedorff, Senior Associate Director International Student & Scholar Services, International Programs. (30 mins)	**Seedorff**
5. Comments/Updates	**Committee**
6. Next Meeting: March 7, 2016	

Action Items			
Status	**Action to be taken**	**Responsible**	**Due Date**
Pending	Expand Combined Seminar Series	Maia/Guzman	
Pending	International Student Issues – Mr. Lee Seedorff	Williamson	Jan 2016
Pending	Centralized Administrative Support for All Advanced Education Programs	Garcia	On hold
Pending	Anticipated CODA Documentation of Competency Assessment	Garcia	Accreditation 2018

Advanced Education Committee:

Anne E. Williamson, Chair
Veeratrishul Allareddy
Howard J. Cowen
Steven L. Fletcher
Matthew K. Geneser
Sandra Guzman-Armstrong
Ryan W. Hill
Lewis A. Humbert
Rodrigo Rocha Maia
Thomas E. Southard
Ghadeer Thalji
Sherry Timmons
John J. Warren

Ex Officio:
Brad A. Amendt, Associate Dean for Research
Lily T. Garcia, Associate Dean for Education
Catherine Solow, Associate Dean for Student Affairs
Joan T. Welsh-Grabin
Michelle M. Krupp, Director, Education Development

THE UNIVERSITY OF IOWA
COLLEGE OF DENTISTRY & DENTAL CLINICS

Advanced Education Committee
Minutes – January 25, 2016

Members Present: Dr. Anne Williamson (chair), Drs. Matthew Geneser, Sherry Timmons, Trishul Allareddy, Rodrigo Maia Rocha, Galen Schneider, Lily Garcia, John Warren, Sandra Guzman-Armstrong, Lewis Humbert, Ms. Cathy Solow, & Ms. Michelle Krupp

Members Absent: Drs. Howard Cowen, Steven Fletcher, Ryan Hill, Tom Southard, Ghadeer Thalji, Brad Amendt, Marcela Hernandez, Ms. Joan Welsh-Grabin

Guests: Mrs. Lee Seedorff – Senior Associate Director International & Scholar Services

I. Approval of November 16, 2015 minutes - motion to approve the minutes passed.

II. Grad Admissions – Operative Issue resolution; upload documents – Dr. Maia
- Problems w/ graduate program uploading applications has been fixed and is resolved.

III. UI Electronic Course Evaluation Project – Ms. Michelle Krupp
- Recently piloted advanced education program evaluations with Orthodontics using the University system (ACE). After working through the initial kinks, we are now ready to include all graduate programs at the end of the spring semester. Ms. Krupp reported that each program will choose one course (clinical) that residents will evaluate all faculty. The evaluations will be open for a 2-week period in May. Residents will be automatically notified through ICON. DEOs, program directors will have access to all the faculty reports and individual faculty will have access to their own. These evaluations will occur biannually at the end of the fall and spring semesters.
- Dr. Schneider mentioned that research faculty need to be evaluated as well. Departments will then need to select a research course in the department (in addition to a clinical course) that will be evaluated to capture feedback for other faculty.

ACTION ITEM: Ms. Krupp will follow-up with program directors and DEOs regarding which courses and faculty they want to be evaluated. Will need to further explore the logistics of the research faculty evaluations in ACE (Drs. Garcia & Amendt).

IV. International Student & Scholar Services – Ms. Lee Seedorff
- Ms. Seedorff reviewed the *International Student and Scholar Regulations* handout in detail. Please see attachment. The handout provides general information and basic student rules/regulations that international students need to follow. Please review and direct any questions to Ms. Seedorff.
- Reminder that new students need to attend the orientation immigration session and do the Immigration Check-in with the office before the start of their first semester.

V. Comments/Updates - Committee
- Dr. Timmons mentioned that Dr. Phil Wertz is in the process of changing "Pass/Fail" grades to "Satisfactory/Unsatisfactory" since the "P/F" designation does not count for credit.

- The *ADEA Guidelines for Academia-Industry Interactions* were distributed. See attachment. Procedures/protocols for site access by industry representatives needs to be explored and developed for Resident Lunch-n-Learn programs.
- SUGGESTED AGENDA ITEMS:
  1) Appoint workgroup to establish industry access guidelines (Williamson/Garcia)
  2) Expand Combined Seminar Series (Maia/Guzman)

Next Meeting: March 28, 2016
Minutes recorded by Ms. Michelle Krupp

International Student and Scholar Regulations

College of Dentistry

Lee Seedorff, Senior Associate Director, International Student and Scholar Services
lee-seedorff@uiowa.edu
January 25, 2016

General Information

Two types of visas our office works with:

- **F-1** – Visa category for students (most UI international students are under this category)
- **J-1** – Visa category for both students as well as scholars. Scholars are not here to be registered students, rather come for teaching, research, observation. Students on a J usually part of an exchange program or sponsored by other groups such as Fulbright, small portion of international students are on a J.

Student Regulations

- **Registration:** 9 s.h. each fall and spring; also required to be full-time in summer if it is first session of registration – after that, summer sessions are not required by immigration regs.
- **Part-Time Registration:** Students whose registration does not show 9 s.h. must submit a special electronic form to ISSS each fall and spring. We then must make a report to federal government to verify the reason the student is enrolled below 9 hours. For many Dentistry students, the clinical program is considered full-time equivalent, but we still need to have this e-form submitted by the student each semester otherwise the system will mark them as underenrolled without approval. Other examples include PhD students who have completed coursework and are working on comps or thesis/dissertation, or grad students who have a TA/RA position and are considered full-time at 6 s.h.
- **Online Courses:** International students can count only one online/distance course toward full-time enrollment each semester. They can take more than one, but only one course can count toward the 9 s.h. requirement.
- **Retroactive Drops and Withdrawals:** Federal rules do not permit an international student to retroactively drop or withdraw; any changes to registration must be done while the semester is still active.
- **Employment:**
    - **On-Campus:** Students are limited to 20 hours/week on-campus work while the fall or spring semester is in session. Can work up to 40 hours/week during summers, winter break. No special authorization is needed from ISSS under these circumstances.

    - **Off-Campus:** Students can never work off-campus (i.e. for anyone other than the University of Iowa) without first getting permission from ISSS. Students qualify only under specific circumstances, and must be internship-type situations related to the program of study. Students may also be eligible to apply for special employment authorization to gain practical experience in their field following graduation.
- **Immigration Documents:** An international student will have either a form I-20 (for F-1 status) or DS-2019 (for J-1 status) as the immigration document issued by the University of Iowa. These documents have an end date, usually set by Admissions according to standard times to complete degree programs (4 years for undergrads, 2 for Master's, 5 for PhD programs). If a student nears the expiration date and is not yet ready to graduate because of academic reasons, they must apply for an extension with ISSS before the document expires.
- **Academic Advisor Input:** Our office is entirely paperless, and we rely on input from academic advisors for a variety of things. Our electronic "e-forms" will be routed through our iHawk system to the academic advisor whenever a student applies for a certain benefit. Advisors may see things coming in requesting input for these e-forms: part-time authorization, program extension, CPT employment application, as well as several other less common things. Understand the input is only that, and advisors are under no legal obligations. The ISSS office makes all decisions regarding student immigration situations, but information from academic advisors helps us have a more accurate picture of a student's situation before we make decisions.

Scholar Regulations

- **Scholar Categories:** Short-Term (6 months of less), Specialist (12 months or less), or Researcher/Professor (up to 5 years).
- **Scholar Background:** The scholar must have an academic background appropriate for his/her activities. Normally an advanced degree is expected of an exchange visitor, although this is not a firm rule, as experience in certain academic fields can substitute for the degree.
- **Scholar Appointments:** Must be appointed in central HR, regardless of paid or unpaid status.
- **Health Insurance:** Must maintain a UI health insurance plan; no third-party or institutional plans are accepted.
- **English Proficiency:** Per new Department of State rule in January 2015, scholar applicants must demonstrate English proficiency by one of three methods: (1) scores from exams such as TOEFL (2) documentation of study in an English language institution (3) a video recorded interview following a set of questions and rubric designed by ISSS/ESL Programs where applicants meet minimum score requirements.
- **Academic Classes:** The primary purpose of the scholar category cannot be enrollment in classes, which would instead require being on a student visa. However, scholars can enroll part-time in courses as long as it is secondary to the primary scholar activity of research, teaching, or observation. They would be responsible for all tuition and fees.

- **J-1 vs. B Status:** Generally J-1 scholar status is appropriate for anyone coming to do work with the college. If there will be any form of contractual agreement, fees being paid, a complimentary appointment in the HR system, etc. then B visitor status is not appropriate.
- **212e – Two Year Home Residency Requirement:** Some scholars on the J-1 may be subject to what is called provision 212e. The purpose of the J-1 scholar program created by the federal government is to facilitate intercultural exchange, not simply be a means to employment. The U.S. government has special agreements set up with each country, where the country determines how restrictive they wish to be for citizens coming to the U.S. on a J-1 visa. Countries may elect to choose specific fields of study/work where they require the person to return to the home country and not be able to get an employment visa or green card until they have been back in the home country for two years or received a written waiver exempting them from the requirement. This is called 212e. For example China includes all fields in this requirement, so anyone coming from China is going to be subject. Japan has very few areas on this list, so most Japanese coming on a J-1 will not be subject.
- **Intercultural Programming –** Because of the nature of the program being for the purpose of intercultural exchange, the U.S. government wants to see extra interaction where both the visiting scholar as well as the local host program benefit from sharing intercultural experiences. The federal regulations actually require institutions to provide programming for J-1's, and ISSS offers special programs to expose scholars to a variety of campus and U.S. experiences. We encourage departments to offer opportunities for interactions as well.

Resources and Statistics

ISSS Website for Departments: http://international.uiowa.edu/isss/departments

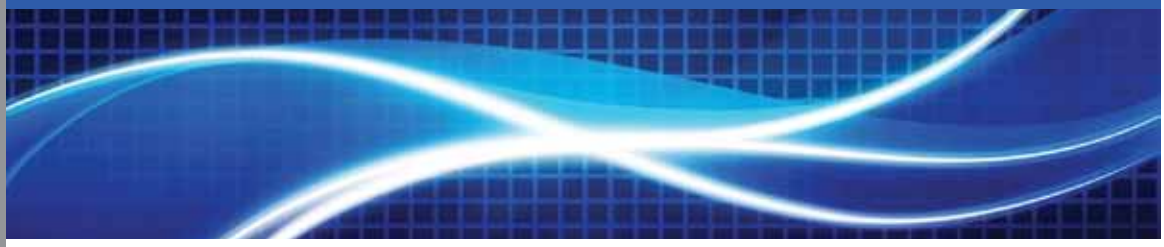
Coming Soon: Listserv for staff/faculty/departments, centered around timely reminders of immigration deadlines and policies

ISSS Statistical Report: http://international.uiowa.edu/about/annual-reports

- Fall 2015 international student population: 4540
- ISSS walk-ins for fiscal year 2014-15: almost 10,300
- Top countries of enrollment: China, India, South Korea, Taiwan, Saudi Arabia, Brazil, Turkey, Canada
- College of Dentistry: 29 enrolled + 5 engaged in post-graduation practical training

ADEA Guidelines

for Academia-Industry Interactions



A Report of the
ADEA Task Force

January
2012

ADEA
AMERICAN
DENTAL
EDUCATION
ASSOCIATION

Acknowledgments

ADEA sincerely wishes to thank AEGIS Communications for providing the broad environmental scan, the background research, and the comprehensive analysis in support of work of the ADEA Task Force on Academia-Industry Interactions.

References

To access a complete list of the references contained within this document, please visit ADEA's website at www.adea.org/InteractionGuidelines.

Table of Contents

Executive Summary

The American Dental Education Association (ADEA), The Voice of Dental Education, is committed to developing and sustaining institutional environments that foster personal, academic, and industry integrity and professionalism within the allied, predoctoral, and advanced dental education community.

Over the years, Academic Dental Institutions* (ADIs), the Dental Industry, and other industry relations (Industry) have maintained and reaffirmed the value of their professional interactions. ADIs value the opportunities for enhanced research and financial support, while Industry values access to faculty, staff, and students, as well as product evaluation and feedback.

In addition to state and federal regulations that define interactions with Industry, many ADIs must comply with local institutional policies. Similarly, Industry must follow internal industry compliance guidelines and external state and federal regulations. Both ADIs and Industry must maintain interactions that are transparent to constituents in order to help ensure the highest level of ethical behavior.

The *ADEA Guidelines for Academia-Industry Interactions* provide a framework from which the various Academia-Industry Interactions can be defined to meet the needs of the ADI, in support of education, research, patient care, and community service. These guidelines are intended to be broad so as not to be prescriptive.

In some instances, a specific guideline also models behavior for the future health professional in his or her interactions with Industry. In all instances, federal, state, and ADI policies and regulations supersede these guidelines.

In an environment of transparency and ethical behavior, the fundamental premise that both ADIs and Industry support is disclosure. Many ADIs follow conflict-of-interest and conflict-of-commitment policies through a disclosure process based on institutional policies. Disclosure is considered to be of paramount significance, and the following statement applies to each Category of interaction contained in the Guidelines:

> Full disclosure of this interaction must be made to interested parties through public declaration, visual presentation, or written statement. Communication vehicles for disclosure could include verbal acknowledgements, website statements, or brochure or program announcements.

ADIs and Industry should consider creating their own internal entity to review compliance with institutional policies and Industry guidelines or regulations and providing peer oversight of all disclosures and declared interactions.

The *ADEA Guidelines for Academia-Industry Interactions* reaffirm the importance and value of the interactions and relationships between Academia and Industry. ADEA hopes that these guidelines will be a resource to help ADIs and Industry define and manage the myriad of federal, state, ADI, and Industry policies and guidelines for protecting personal, institutional, and Industry integrity while allowing academic freedom to promote better education, research, and patient care.

These guidelines remain a constant to promote a professional, beneficial relationship between ADIs and Industry. The documents generated at the local ADI or Industry level should reflect the dynamic—i.e., ever-evolving—nature of technologies and regulations.

*Academic Dental Institution: An educational institution granting academic degrees or certification in any field of allied, predoctoral, or advanced dental study.

Category I: Education Grants and Trainee Scholarships

Definition

This category addresses financial assistance for scholarships, grants for service-based learning, grants for educational activities (e.g., journal clubs), or funds to permit faculty, staff, or students to attend educational conferences.

Intent

To help advance the ADIs' mission through the provision of financial support for the scientific and clinical education of faculty, staff, and students, whenever costs may prohibit such endeavors to occur.

To inspire and support the following for students and/or faculty: research; life-long learning; the development of new educational materials; increased familiarity with technologies, products, and materials; improved curriculum content; and enhanced patient care.

To provide an opportunity for Industry contributors to advance their social missions through public education and public awareness.

Guidance

ADIs should ensure that funds are provided directly to the institution, not to individual oral health care professionals (faculty, staff, or student), and comply with existing local and institutional regulations, policies, and applicable laws.

The grant or scholarship should not be tied in any way to past, present, or anticipated business generated with the ADI. There should be no direct measurable financial benefit to the Industry in exchange for the receipt of funding support.

Grants should be awarded through a fair, open selection process based on clear criteria established by the ADI. The criteria can be set in collaboration with the Industry sponsor, but the actual selection of awardees must be independent of the Industry funding the award.

The recipient of support must have a genuine, institutionally approved educational purpose, function, or benefit. He/she should use the funds for legitimate expenses that are consistent with institutional guidelines, including (if applicable) reimbursement for reasonable and moderate travel expenses. Recipients should be aware of expectations, stipulations, and responsibilities relating to any funding received for attendance at educational conferences or for grants and scholarships.

A written agreement or contract between the Industry sponsor and the ADI is encouraged as a means of creating appropriate documentation.

References

U.S. Department of Health & Human Services
Office of Inspector General (OIG)
Compliance Program Guidance for Pharmaceutical Manufacturers—April 2003 (*Federal Register* [Vol. 68, No. 86, Page 23,735]; OIG PDF document [Pages 17–21])

Pharmaceutical Research and Manufacturers of America (PhRMA)
Code on Interactions with Healthcare Professionals—January 2009 (Page 11)

Advanced Medical Technology Association (AdvaMed)
Code of Ethics on Interactions with Health Care Professionals—July 2009 (Page 10)

Eucomed
Eucomed Code of Ethical Business Practice—"Eucomed Guidelines on Interactions with Healthcare Professionals"—September 2008 (Pages 9–10)

Eve M. Brunts, Esq. (Ropes & Gray LLP), and Ann E. Lewis, Esq. (Vice President, Compliance, Americas, Bristol-Myers Squibb Company)
Managing Relationships: Manufacturers, Institutional Providers and Their Affiliated Practitioners (Page 37)

Tufts University School of Medicine
2010 Revised Policy on Industry Conflicts of Interest—April 2010 (Pages 7–8)

Johnson & Johnson
The Right Course: Everyday Health Care Compliance, an Introductory Guide for Our Employees—2009 (Page 9)

Pfizer Inc.
Global Policy on Interactions with Healthcare Professionals—May 2005 (Page 18)

Category II: Consulting and Speaking Arrangements

Definition

This category addresses various services financially supported or otherwise underwritten by Industry, including training or advice, serving on advisory committees, participating as a lecturer at Industry-sponsored events, or acting as a paid promotional speaker at events.

Intent

Both ADIs and Industry engage experts to assist in discovery, knowledge transfer, the provision/receipt of expert analysis and advice on products, technologies, techniques, and the needs of patients.

Both ADIs and Industry can provide knowledge and specialized skills that might not be available otherwise and that could provide value to each other.

Selection of a consultant should be based on scientific and health care expertise and not on input from an industry representative or on product use.

Guidance

Guided by state-specific and institutional policies, ADIs should establish procedures or protocols for approving consulting and speaking arrangements and the sharing of intellectual property.

A signed contract should exist between Industry and the academic oral health care professional clearly outlining and disclosing the scope of the individual's responsibilities, the duration of the arrangement, the terms of compensation, and the required documentation upon completion of the work.

Documentation of a financial agreement should follow institutional policies, should be in the form of a memorandum of agreement or contract, and should fall within customary or fair market value. When all or part of the compensation agreement is in the form of equity ownership (i.e., stocks), there must be a declared value.

Expenses incurred by the consultant in providing the contracted professional services should be within the Industry's travel-related expense guidelines and should be reimbursed by the Industry.

Compensation should not be offered for "time spent" attending the conference or for passive attendance, nor for the attendance at consulting assignments or meetings by spouses, children, or guests (unless qualified in their own right).

References

Pharmaceutical Research and Manufacturers of America (PhRMA)
Code on Interactions with Healthcare Professionals—January 2009 (Pages 7–10)

Advanced Medical Technology Association (AdvaMed)
Code of Ethics on Interactions with Health Care Professionals—July 2009 (Pages 5–7)

Eucomed
Eucomed Code of Ethical Business Practice—"Eucomed Guidelines on Interactions with Healthcare Professionals"—September 2008 (Pages 6–8)

Eve M. Brunts, Esq. (Ropes & Gray LLP), and Ann E. Lewis, Esq. (Vice President, Compliance, Americas, Bristol-Myers Squibb Company)
Managing Relationships: Manufacturers, Institutional Providers and Their Affiliated Practitioners (Pages 19–21)

Tufts University School of Medicine
2010 Revised Policy on Industry Conflicts of Interest—April 2010 (Pages 5–6)

University of Southern California
Policy Regarding Relationships with Industry—September 2009 (Pages 3–5)

Johnson & Johnson
The Right Course: Everyday Health Care Compliance, an Introductory Guide for Our Employees—2009 (Page 8)

Category III: Authorship and Attribution of Joint Articles, Publications, and Presentations

Definition

This category addresses articles or professional presentations that are officially credited to someone other than the writer. (Not included is transparent collaboration with attribution.) Example: Using a faculty member's name as the author of Industry-written articles or presentations to provide credibility.

Intent

To avoid "selling" one's opinion and leading readers to believe that the opinion is independent, all writing collaborations with Industry must be transparent, with the disclosure of all authors and contributors.

Guidance

Faculty, staff, or students should not allow their professional presentations to be "ghostwritten" by any party, or permit usage of their names and credentials for work in which they were not involved.

Attribution must be accepted only for work actually performed and must accurately reflect the person's actual contribution.

In the case of joint authorship of articles, publications, and presentations, the authors' contribution to content and their affiliations should be clear to the reader and comply with existing institutional regulations and policy.

Articles and presentations should not include either an actual or an implied endorsement of a specific product, technology, or technique without appropriate acknowledgements, approvals, and disclosures.

The ADI writer or presenter and Industry should clearly delineate a mutual agreement describing the author's publishing rights and any other terms and indicating which party has the first right of refusal when the scholarly activity pertains to the presentation of information that he/she does not deem medically relevant, accurate, or consistent with his/her clinical/research experiences.

References

Eve M. Brunts, Esq. (Ropes & Gray LLP), and Ann E. Lewis, Esq. (Vice President, Compliance, Americas, Bristol-Myers Squibb Company)
Managing Relationships: Manufacturers, Institutional Providers and Their Affiliated Practitioners (Page 24)

Tufts University School of Medicine
2010 Revised Policy on Industry Conflicts of Interest—April 2010 (Page 5)

University of Southern California
Policy Regarding Relationships with Industry—September 2009 (Page 14)

Category IV: Attendance at Industry Conferences

Definition

This category addresses attendance at Industry-sponsored educational meetings, lectures, and conferences containing objective scientific and educational information that promotes evidence-based scientific research and patient care and for which Industry support is prominently disclosed.

Intent

These guidelines apply to educational meetings that provide the opportunity for the advancement and presentation of contemporary scientific and clinical information.

The guidelines also apply to presentations for faculty, staff, and students for their knowledge base and critical assessment of new products, technologies, and methodology integral to health education and patient care.

Guidance

The conferences should be conducted only in settings that are appropriate for the communication of information, such as clinical, educational, or conference facilities that are either commercially available or at an academic institution.

The training staff must have the appropriate expertise to conduct the educational or training program. The presentations should be drawn from evidence-based scientific research, rather than from a specific Industry provider or manufacturer.

ADI faculty, staff, and students who present at Industry conferences, if receiving sponsored travel, honoraria, or other support, should disclose that support publicly to attendees prior to their presentation.

Reimbursement for travel expenses should comply with existing institutional regulations and policies and should be for reasonable and moderate travel, meals, and meeting registration costs. Any “gifts” offered to faculty should be appropriate for use with patients or for an educational purpose, such as textbooks, educational DVDs, or three-dimensional models.

A written agreement or contract between the Industry sponsor and the ADI is encouraged as a means of creating appropriate documentation.

There should be no specific or implied *quid pro quo* for attendance at the conference. Participants’ attendance should be monitored in an appropriate fashion for reporting back to the ADI, and for compliance with American Dental Association Continuing Education Recognition Program (ADA CERP) and Academy of General Dentistry Program Approval for Continuing Education (AGD PACE) guidelines, if continuing education credit is granted.

References

Advanced Medical Technology Association (AdvaMed)
Code of Ethics on Interactions with Health Care Professionals—July 2009 (Pages 4–5)

University of Southern California
Policy Regarding Relationships with Industry—September 2009 (Pages 7–8)

Pfizer Inc.
Global Policy on Interactions with Healthcare Professionals—May 2005 (Pages 14–5)

Category V: Complimentary Samples and/or Educational Items

Definition

This category addresses product samples that are provided for patient use or items designated for patient education or the education of students and health care professionals. These samples generally should be nominal in cost, limited in quantity, and of no commercial value outside of professional responsibility and use.

Intent

The complimentary samples and/or educational items should be used only to promote faculty, staff, and student learning about new technologies and products, to facilitate and provide patient education, or to provide products in support of the ADI's service learning programs.

Guidance

ADI should have a process to evaluate and approve the appropriateness of complimentary product samples for distribution, as well as a mechanism to ensure compliance with institutional regulations and policy, including special knowledge of any billing restrictions or prohibitions for a complimentary product.

No actual or implied *quid pro quo* should exist when accepting or providing complimentary samples. The personal information of all recipients of product samples should be protected as per local, institutional, and federal guidelines.

Patients receiving samples should be clearly informed that the provision of the samples does not imply endorsement of the product by the ADI or its faculty, staff, and students. ADI must ensure patients are informed appropriately.

References

Pharmaceutical Research and Manufacturers of America (PhRMA)
Code on Interactions with Healthcare Professionals—January 2009 (Page 12)

Advanced Medical Technology Association (AdvaMed)
Code of Ethics on Interactions with Health Care Professionals—July 2009 (Page 8)

Tufts University School of Medicine
2010 Revised Policy on Industry Conflicts of Interest—April 2010 (Page 6)

Johnson & Johnson
The Right Course: Everyday Health Care Compliance, an Introductory Guide for Our Employees—2009 (Page 12)

Pfizer Inc.
Global Policy on Interactions with Healthcare Professionals—May 2005 (Page 17)

Category VI: Industry Support for Educational Conferences and Meetings

Definition

This category addresses Industry-provided financial support for educational meetings, lectures, and conferences containing objective scientific and educational information that promotes evidence-based scientific research and patient care, and for which Industry support is prominently disclosed.

Intent

These guidelines apply to education and awards programs and conferences that seek to recognize outstanding achievements of general academia, to complement professional and organizational development, and to encourage and promote innovation within the dental community via public recognition and awards.

The Industry supporter seeks to gain recognition and goodwill, to support a legitimate business interest or a particular general area of science, and to inspire academic (education and/or research) leadership and achievements by honoring a recognized leader(s) in the profession.

Industry may provide financial assistance to support specific continuing dental education programs for faculty, staff, students, or alumni to gain knowledge about technologies, techniques, and products.

The Industry sponsor appropriately may intend to advance the dissemination of scientific evidence that supports the Industry's (e.g., manufacturer's) product category.

Guidance

Support provided by the Industry should be fully disclosed and should not be related to the past, present, or anticipated volume or value of purchases made by the ADI. No *quid pro quo* should exist for future interactions with the ADI.

The Industry sponsor can help establish the guidelines for the selection criteria but should not vote or have any influence on the selection of awardees.

Professionals participating on award committees and in the planning process and recipients of awards may accept honoraria and reimbursement for reasonable and moderate travel, lodging, and meal expenses.

The conference should be independent, free of commercial bias, and beyond the control of Industry sponsors.

The conference event or activities should be held in an appropriate location and conducted in compliance with existing regulations and institutional policies (including travel and entertainment policies). A written agreement or contract between the Industry sponsor and the ADI is encouraged as a means of creating appropriate documentation.

Relevant financial relationships and expenditures should be available for public review and should be consistent with state and federal "sunshine act" laws that require reporting and disclosure of Industry "gifts" and donations.

The ADI should have the responsibility and control over the selection of content, faculty, educational materials, and venues.

Industry should have limited or no influence on the conference, except to ensure the scientific accuracy of the description and use of product according to regulatory guidelines and approved label specifications for that particular product.

If specific products or materials are discussed, the discussion must be done in a non-biased manner and should include comparable product and materials options from which a professional chooses. Speakers should be required to disclose associations that they have with Industry. A full disclosure statement should be included, both in printed materials and at the beginning of any presentation.

All educational programs should comply with the standards and criteria of a nationally recognized accrediting organization (ADA CERP or AGD PACE) as defined by the ADI.

Continued on page 8

Category VI: Industry Support for Educational Conferences and Meetings, cont.

References

Pharmaceutical Research and Manufacturers of America (PhRMA)
Code on Interactions with Healthcare Professionals—January 2009 (Page 7)

Eucomed
Eucomed Code of Ethical Business Practice—"Eucomed Guidelines on Interactions with Healthcare Professionals"—September 2008 (Pages 5–6)

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Managing Relationships: Manufacturers, Institutional Providers and Their Affiliated Practitioners (Page 40)

Accreditation Council for Continuing Medical Education
ACCME Standards for Commercial Support℠—"Standards to Ensure the Independence of CME Activities"—2007 (Pages 2–3)

American Dental Association (ADA)
ADA CERP®—*Recognition Standards and Procedures*—November 2010 (Page 5)

Tufts University School of Medicine
2010 Revised Policy on Industry Conflicts of Interest—April 2010 (Pages 7–8)

Johnson & Johnson
The Right Course: Everyday Health Care Compliance, an Introductory Guide for Our Employees—2009 (Page 9)

Pfizer Inc.
Global Policy on Interactions with Healthcare Professionals—May 2005 (Pages 13–14)

Category VII: Social Events

Definition

This category addresses meals (outside of an educational meeting or presentation), gifts, and entertainment and recreation (e.g., free or discounted event tickets, trips).

Intent

The guidance for this category is intended not only to establish parameters for Industry-sponsored or Industry-supported meals, gifts, and entertainment apart from an educational meeting or presentation but also to avoid any appearance or potential misunderstanding that a gift or entertainment opportunity could influence a decision and give preferential advantage to the Industry source providing the gift.

Guidance

The ADI should have a process for review, acceptance, or rejection and full disclosure of Industry-proffered meals, gifts, entertainment, and recreation, including for "lunch-and-learns."

In order to avoid any actual or perceived *quid pro quo*, a sponsorship of complimentary or discounted meals, recreational events, and entertainment for social purposes is not acceptable, except if the sponsorship is through the ADI and follows the institution's guidelines.

Meals: Meals and/or social interaction for the purpose of relationship building is encouraged, but the expense of these meals or activities should be incurred by the individual and should not be reimbursable.

Gifts: Industry should not provide noneducational or nonpatient-related gifts or branded promotional items to oral health care professionals. Examples of such items include pens, notepads, tote bags, electronic appliances (e.g., iPods), mugs, cookies, wine, flowers, chocolates, gift baskets or holiday gifts, cash or cash-equivalents (e.g., gift certificates), or any item that can be used by the oral health care professional (or his or her family members, office staff, or friends) for noneducational or nonpatient-related purposes.

Entertainment and Recreation: Recreational events at academic meetings that are held in recreational areas should be clearly designed and identified as separate from the academic or clinical portion of the meeting. Any recreational expenditures should be assumed by the individual or the ADI.

Companies may occasionally provide items to oral health care professionals at the ADI that benefit patients or serve a genuine educational function, as long as allowed by applicable law and institutional policies. Examples of such items include textbooks, *Physicians' Desk Reference* or other similar reference works, and informational brochures.

References

U.S. Department of Health & Human Services
Office of Inspector General (OIG)
Compliance Program Guidance for Pharmaceutical Manufacturers—April 2003 (*Federal Register* [Vol. 68, No. 86, Page 23,738]; OIG PDF document [Pages 31–35])

Pharmaceutical Research and Manufacturers of America (PhRMA)
Code on Interactions with Healthcare Professionals—January 2009 (Pages 4–5)

Advanced Medical Technology Association (AdvaMed)
Code of Ethics on Interactions with Health Care Professionals—July 2009 (Pages 7–8)

Tufts University School of Medicine
2010 Revised Policy on Industry Conflicts of Interest—April 2010 (Page 4)

University of Southern California
Policy Regarding Relationships with Industry—September 2009 (Pages 6–7)

Johnson & Johnson
The Right Course: Everyday Health Care Compliance, an Introductory Guide for Our Employees—2009 (Page 7)

Category VIII: Site Access by Industry Representatives

Definition

This category addresses access of Industry representatives to various areas on the ADI grounds, their affiliated sites, and patient care areas; to faculty, staff, and students; and to programs such as "lunch-and-learns" and continuing education courses, such as those related to special expertise in these interactions.

Intent

To establish an appropriate environment for Industry interaction with faculty, staff, and students. In such an environment, faculty, staff, and students can receive education and training to increase their knowledge and experience, as well as critical thinking opportunities to evaluate Industry product demonstrations or educational workshops. In turn, Industry is provided an opportunity to introduce new treatment modalities, technologies, and products to ADIs.

Guidance

Each ADI should establish procedures or protocols for visits from Industry officials that comply with local and institutional regulations; include privacy protections for patients (Health Insurance Portability and Accountability Act [HIPAA]) and faculty and students (Family Educational Rights and Privacy Act [FERPA]); and address professional and state credentialing requirements regarding what qualifies for certified continuing education credit.

Basic information about the purpose of the Industry visit and about the Industry representatives should be provided in advance to faculty, staff, and students.

The ADI should designate an individual or committee to approve and announce—in advance—the planned educational experience and to assess the content and, afterwards, the value of the experience, ensuring reasonable and unbiased consistency in factors ancillary to the visit, such as time and location, scheduling, and provision of food and other services.

References

Tufts University School of Medicine
2010 Revised Policy on Industry Conflicts of Interest—April 2010
(Page 6)

University of Southern California
Policy Regarding Relationships with Industry—September 2009
(Page 13)

Category IX: Industry-Led Training and Education

Definition

This category addresses faculty, staff, and student attendance at medical device manufacturer-sponsored training sessions and meetings, often including a "hands-on" component, lectures, and demonstrations.

Intent

Industry-led training and education supports and enhances faculty, staff, and student learning, clinical awareness, and competency in specific manufacturers' existing and new products and technology for the treatment of patients.

For the ADI, the purpose of this training may be to gain information on the correct use of new and existing equipment and/or medical devices in order to enable informed decisions for patient selection; understand the learning curve for technique-sensitive materials and/or equipment; assess the scientific evidence supporting the product; and be able to make appropriate decisions for research studies and/or clinical use and for purchase or lease.

For Industry, the provision of reasonable quantities or pieces of equipment at no or little charge for evaluation and/or demonstration purposes allows oral health professionals to assess the appropriate use and functionality of the product, with adherence to applicable legal regulations.

Guidance

Each ADI should establish policies and procedures for attendance that comply with local and institutional regulations, fully disclose such policies, and ensure that there is no *quid pro quo* for attendance at the sessions.

Attendees should have a mission that is valuable to the school, e.g., assessing the scientific evidence supporting the product's usefulness, safety, directions for use, and claims of results. (Note: These sessions could provide a good opportunity to teach students how to critically assess the evidence presented.) Attendees should also have a confirmed and appropriate level of training to operate devices discussed before hands-on training with the devices occurs.

The meeting or session should be clearly identified as commercial in nature, and those individuals leading or teaching the educational program should disclose relevant financial relations to the provider and/or host.

Participating attendees should be monitored in some fashion for reporting back to the school and/or for receiving continuing education credit, if applicable.

Industry may provide only the quantity of single-use products (e.g., consumable or disposable products)—at no charge—that is reasonably necessary for the adequate evaluation of the product(s).

With regard to testing or evaluation of capital equipment and other multiple use products, provision by the Industry shall not assume the transfer of title and ownership, or an implicit agreement on the part of the recipient to purchase the product. The timetable and no-charge status, as well as the intended use of the product for demonstration purposes, should be described in a written agreement between the ADI and the Industry.

It is appropriate to reimburse for reasonable travel, modest meals, and expenses for training.

References

Advanced Medical Technology Association (AdvaMed)
Code of Ethics on Interactions with Healthcare Professionals—July 2009 (Pages 3–4)

Eucomed
Eucomed Code of Ethical Business Practice—"Eucomed Guidelines on Interactions with Healthcare Professionals"—September 2008 (Page 4)

Eve M. Brunts, Esq. (Ropes & Gray LLP), and Ann E. Lewis, Esq. (Vice President, Compliance, Americas, Bristol-Myers Squibb Company)
Managing Relationships: Manufacturers, Institutional Providers and Their Affiliated Practitioners (Page 40)

University of Southern California
Policy Regarding Relationships with Industry—September 2009 (Pages 11–12)

Category X: All Other Industry Support or Contributions

Definition

This category addresses all other industry support or contributions including the provision of financial resources by Industry to the ADI for the following purposes: research grants, publication grants, critical needs, capital improvements, capital campaigns, educational programs, and attendance at educational, research, and other professional conferences and meetings.

Intent

These guidelines aim to create a process and documentation to evaluate and approve unrestricted gifts from Industry to support the mission and goals of the ADI, as well as to avoid any perception of impropriety.

While Industry may provide support to gain goodwill, there is no *quid pro quo*.

Guidance

Grants or donations provided by the Industry to the ADI, the academic health center, or the university should be fully disclosed and should not be related to the past, present, or anticipated volume or value of purchases made (or to be made) by the ADI. No *quid pro quo* should exist for future academic interactions.

Industries may make charitable donations or unrestricted grants for charitable or other philanthropic purposes, so long as permitted by applicable laws. The donating Industry may not have any control over how the funds are used, and all grants should comply with existing regulations and institutional policy.

Grants or donations made should be designated for educational, scientific, research, or community service value. “Unrestricted” grants made should be consistent with the mission of the recipient health care entity. If funds donated are for trainee scholarships, the selection of the trainee must not be influenced by the donor.

Procedures and practices that promote equal access to and opportunity for funding for all who declare their intent to apply should be in place. Such procedures and practices should include full disclosure and public posting of the application process regarding funding opportunities and of the review process and full disclosure of the outcome through award announcements.

A written agreement should exist between the donating Industry and the ADI to document the grant, including what was proposed, the amount requested, and the benefits to each party.

Relevant financial relationships and expenditures should be available for public review and should be consistent with state and federal “sunshine act” laws that require reporting and disclosure of Industry “gifts” and donations.

References

Pharmaceutical Research and Manufacturers of America (PhRMA)
Code on Interactions with Healthcare Professionals—January 2009 (Page 7)

Eucomed
Eucomed Code of Ethical Business Practice—“Eucomed Guidelines on Interactions with Healthcare Professionals”—September 2008 (Pages 5–6)

Eve M. Brunts, Esq. (Ropes & Gray LLP), and Ann E. Lewis, Esq. (Vice President, Compliance, Americas, Bristol-Myers Squibb Company)
Managing Relationships: Manufacturers, Institutional Providers and Their Affiliated Practitioners (Page 40)

Accreditation Council for Continuing Medical Education
ACCME Standards for Commercial Support℠—“Standards to Ensure the Independence of CME Activities”—2007 (Pages 2–3)

American Dental Association (ADA)
ADA CERP®—*Recognition Standards and Procedures*—November 2010 (Page 5)

Tufts University School of Medicine
2010 Revised Policy on Industry Conflicts of Interest—April 2010 (Pages 7–8)

Johnson & Johnson
The Right Course: Everyday Health Care Compliance, an Introductory Guide for Our Employees—2009 (Page 9)

Pfizer Inc.
Global Policy on Interactions with Healthcare Professionals—May 2005 (Pages 13–14)

Appendix One: ADEA Task Force Genesis and Process

In the summer of 2010, the ADEA Council of Students, Residents, and Fellows (ADEA COSRF) requested that ADEA encourage ADIs to examine the policies related to Academia-Industry interactions that would define appropriate opportunities for students to receive an interdisciplinary and comprehensive educational experience.

At the request of ADEA's Council of Deans Administrative Board, ADEA conducted a survey in summer 2010 among ADEA's dental school deans and ADEA's Industry members to understand better how various new federal and state regulations, as well as university policies and Industry compliance guidelines governing interactions between ADIs and the Industry, were impacting the relationship between them.

Both groups were asked about their participation in partnerships between ADIs and Industry, as well as the benefits, changes, and challenges that result from emerging regulations, policies, and guidelines. The response rate to the survey was 48% from the dental school deans and 40% from the Industry members.

The survey results were presented and discussed at the 52nd Annual ADEA Deans' Conference in November 2010 as part of an educational session titled "The Changing Relationship between the Dental School and Industry." The survey shows that all replying dental schools are engaged in various forms of partnerships with the dental Industry. Dental school deans and Industry representatives both value the partnerships, but each group has its own set of goals and views regarding the value of these partnerships. Deans value the opportunities for enhanced research and financial support, while Industry values both the access to faculty, staff, and students and the product feedback received from the dental schools.

In general, both entities recognize certain challenges, agree that they value these partnerships a great deal, and are motivated to work together. The dental school deans are concerned about increasingly constrained relationships and reduced support for, and control of, supplemental educational opportunities, while Industry is concerned with the decrease in access and opportunities for collaboration and knowledge-sharing that may result.

While recognizing that all regulations, policies, and compliance guidelines are "local" (as in politics), the overwhelming sentiment at the conclusion of the Deans' Conference session was that ADEA should consider the appointment of a representative task force to develop a set of broad general guidelines to apply to relationships between ADIs and the Industry. Additionally, the ADEA COSRF has clearly articulated the need for general guidelines for student and Industry interaction, particularly as it relates to "lunch-and-learns," speakers, and vendor-sponsored educational seminars.

There is general agreement that broad guidelines would prove beneficial in supporting ongoing and new productive relationships and that these guidelines are not intended to provide specific prescriptive directions on how to manage those relationships. It was also suggested that ADEA explore working with the Dental Trade Alliance (DTA) in developing these guidelines.

In consideration of these discussions, a motion was forwarded and presented by the ADEA Council of Deans, the ADEA Corporate Council, and the ADEA Council of Students, Residents, and Fellows. The ADEA Board of Directors moved to approve the appointment of a representative task force to establish general guidelines for the interaction between Academia and the Industry.

ADEA President Dr. Leo Rouse appointed the ADEA Task Force on Academia-Industry Interactions in March 2011. The Task Force was charged by the ADEA Board of Directors with the development of guidelines for the interaction between ADIs and Industry.

The Task Force was charged with completing the development of the broad guidelines and with presenting the Task Force Report to the ADEA Board of Directors at its January 2012 meeting.

Appendix Two: ADEA Task Force Members

Chair:

Lily T. Garcia, D.D.S., M.S., F.A.C.P.
Professor
University of Texas Health Science Center
at San Antonio, Dental School

Additional Members:

Nancy S. Arbree, D.D.S., M.S.
Professor and Associate Dean of Academic Affairs
Tufts University School of Dental Medicine

Cecile A. Feldman, D.M.D., M.B.A.
Professor and Dean
University of Medicine and Dentistry of New Jersey,
New Jersey Dental School

Evelyn O. Lucas-Perry, D.D.S., M.P.H.
Dental Public Health Resident
National Institute of Dental and Craniofacial Research,
National Institutes of Health

Elizabeth Roberts, D.D.S., M.B.A.
Director, Professional Affairs – Oral Care, North America
Johnson & Johnson Healthcare Products,
Division of McNEIL-PPC, Inc.

John L. Scott
Vice President of Sales
SDS/Dental Consumables – Kerr, Pentron Clinical, Axis

Toby T. Sexton
Associate Director, Education
Zimmer Dental

Huw F. Thomas, B.D.S., M.S., Ph.D.
Professor and Dean
University of Alabama at Birmingham School of Dentistry

ADEA Staff:

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