

School of Dental Medicine

Guidelines for Interaction with Industry

Introduction

The following guidelines were approved by vote of Dental Senate on June 18, 2013.

These School of Dental Medicine Guidelines mirror the *ADEA Guidelines for Academia-Industry Interactions (January, 2012)* which were developed through collaboration between representatives of US dental education and the dental industry.

Compliance by the School of Dental Medicine with many of the guidelines stated herein is achieved by prevailing state, university or school-specific policies and procedures established prior to June 18, 2013; for example, *State of Connecticut Ethics Policies; UCHC Consulting, Academically-Related Activity, Research Compliance, Intellectual Property Policies; UCHC and SDM Code of Conduct.*

A number of guideline items will require additional attention by the School of Dental Medicine in order to achieve compliance. Actions or suggestions for actions required to achieve compliance are stated where applicable at the end of each category of this document; see [*Additional Actions Required beyond Policies and Processes current as of June 18, 2013.* These actions will be pursued through a multi-year , long-range plan that will be established by the School of Dental Medicine.

Key leadership around these Guidelines will be provided by a new SDM standing administrative committee, tentatively named the *SDM Committee on Interactions with Industry.* This Committee will have a relatively broad charge and scope in interpreting the new Guidelines and providing recommendations to the Dean and School units on methods to achieve compliance.

SDM Acclamation

The SDM endorses the goals and principles described in the *ADEA Guidelines for Academia-Industry Interactions (January, 2012).*

Category I. Educational Grants and Trainee Scholarships

The SDM will ensure that:

- *Funds are provided directly to the institution and not to faculty, staff, or students, and comply with existing state and institutional regulations, policies, and applicable laws.*
- *Grants or scholarships will not be tied in any way to past, present, or anticipated business generated with the SDM. There will be no direct measurable financial benefit to the Industry in exchange for the receipt of funding support.*
- *Grants will be awarded through a fair, open selection process based on clear criteria established by the SDM. The criteria may 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 will have a genuine, institutionally approved educational purpose, function or benefit. The recipient should use the funds for legitimate expenses that are consistent with SDM guidelines, including (if applicable) reimbursement for reasonable and moderate travel expenses. Recipients will 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 SDM exists as a means of creating appropriate documentation.*

Additional Actions Required beyond Policies and Processes current as of June 18, 2013

The Dean will charge a new administrative committee, the SDM Committee on Interactions with Industry, to review grants and scholarships of this description active in the SDM and, going forward, to consider proposals for new awards. The Committee will describe the information and reports needed and will advise the Dean on processes that should be implemented to fulfill its charge.

Category II. Consulting and Speaking Arrangements

The SDM will ensure that:

- *Policies and procedures or protocols are followed for approving consulting and speaking arrangements and the sharing of intellectual property.*
- *A signed contract exists between Industry and the SDM 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 will follow institutional policies, will be in the form of a memorandum of agreement or contract, and will 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 will be a declared value.*
- *Expenses incurred by the consultant in providing the contracted professional services will be within the Industry's travel-related expense guidelines and will be reimbursed by the Industry.*

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- *Compensation will 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).*

Additional Actions: NONE REQUIRED

Category III. Authorship and Attribution of Joint Articles, Publication and Presentations

The SDM will ensure that:

- *Professional presentations will not be “ghostwritten” by any external party for faculty, staff or students and will not cite their names and credentials for work in which they were not involved.*
- *Attribution of work by faculty, staff or students will occur only for work actually performed and will 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 will be clear and comply with existing institutional regulations and policy.*
- *Articles and presentations will not include actual or implied endorsement of a specific product, technology, or technique without appropriate acknowledgements, approvals, and disclosures.*
- *The SDM writer/presenter and Industry will clearly delineate a mutual agreement describing the author’s publishing rights and any other terms and indicate 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. 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.*

Additional Actions: NONE REQUIRED

Category IV. Attendance at Industry Conferences

The SDM will ensure that:

- *Conferences will be conducted only in settings that are appropriate for the communication of information.*
- *The training staff will have the appropriate expertise to conduct the educational or training program. The presentations will be drawn from evidence-based scientific research, rather than from a specific Industry provider or manufacturer.*
- *SDM faculty, staff, and students who present at Industry conferences, if receiving sponsored travel, honoraria, or other support, will disclose that support publicly to attendees prior to their presentation.*

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- *Reimbursement for travel expenses will comply with institutional regulations and policies and should be for reasonable and moderate travel, meals, and meeting registration costs. Any “gifts” offered to faculty will 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 SDM is encouraged as a means of creating appropriate documentation.*
- *There is 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 SDM, 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.*

Additional Actions Required beyond Policies and Processes current as of June 18, 2013

For staff and students, these activities are appropriately monitored and approved through the UCONN Code of Conduct. To further ensure that these principles are upheld, the SDM Committee on Interactions with Industry will review industry sponsored travel for staff and students.

Category V. Complimentary Samples and/or Educational Items

The SDM will ensure that:

- A process exists 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* exists 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 are informed that the provision of the samples does not imply endorsement of the product by the SDM or its faculty, staff, and students.

Additional Actions Required beyond Policies and Processes current as of June 18, 2013

The Associate Dean for Students and the Senior Associate Dean for Education and Patient Care will formulate processes to ensure compliance.

Category VI. Industry Support for Educational Conferences and Meetings

The SDM will ensure that:

- *Support provided by the Industry is fully disclosed and not related to the past, present, or anticipated volume or value of purchases made by the SDM and that no quid pro quo exists for future interactions with the SDM.*
- *The Industry sponsor will not have any influence on the selection of awardees for attendance.*
- *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 consistent with SDM policy.*
- *Conferences will be independent, free of commercial bias, and beyond the control of Industry sponsors.*
- *In the SDM, all conferences and meetings must be approved by the Associate Dean for Students in advance and must have an internal faculty, staff or student sponsor. The sponsor must ensure that the conference or meeting will be attended by an appropriate faculty member or approved designate acting in the role of academic monitor.*
- *The conference event or activities including student “lunch-and-learns” will be held in an appropriate location and conducted in compliance with existing regulations and institutional policies (including travel and entertainment policies).*
- *Relevant financial relationships and expenditures will be available for public review and will be consistent with state and federal “sunshine act” laws that require reporting and disclosure of Industry “gifts” and donations.*
- *The SDM will have the responsibility and control over the selection of content, faculty, educational materials, and venues.*
- *Industry will 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 will be done in a non-biased manner and will include comparable product and materials options from which a professional chooses.*
- *Speakers will be required to disclose associations that they have with Industry. A full disclosure statement will be included, both in printed materials and at the beginning of any presentation.*
- *All educational programs will comply with the standards and criteria of a nationally recognized accrediting organization (ADA CERP or AGD PACE) as defined by the SDM.*

Additional Actions Required beyond Policies and Processes current as of June 18, 2013

The internal sponsor of the meeting (i.e. faculty, staff or student) will make a request to the Associate Dean of Students for approval of the presentation during eligible hours. The Associate Dean may approve or not approve based on the quality or appropriateness of the presentation, redundancy with other presentations, frequency of presentations, perceived conflict of interest or other described criteria.

Should the Industry Sponsor desire to support the conference or meeting with provision of food or materials not directly related to educational presentation, the internal (faculty, staff or student) must request approval for this as well from the Associate Dean of Students. The Associate Dean may approve or not approve based on the particular circumstance. If approved, the following process must be followed:

- The Industry Sponsor cannot provide such materials directly nor claim sole responsibility for their provision.
- Funding for approved food or materials will be derived from a pooled fund created and named for such purpose within the UConn Foundation. Industry sponsors may make contributions to this fund but will have no influence or non-restrictive authority over such funds.
- During the conference or meeting, it may be noted that the Industry Sponsor made contributions to the pooled Foundation fund/account from which support is derived to underwrite the costs of food or materials as noted.

Companies may occasionally provide items to oral health care professionals at the SDM that benefit patients or serve a genuine educational function, so 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.

Category VII. Social Events

The SDM will ensure that:

- *A process exists for review, acceptance, or rejection and full disclosure of Industry-offered meals, gifts, entertainment, and recreation,*
- *A process exists to ensure an absence of actual or perceived quid pro quo via sponsorship of complimentary or discounted meals, recreational events, and entertainment for social purposes*
- *A process exists for review, acceptance, or rejection and full disclosure of:*
 - Meals:** *Meals and/or social interaction for the purpose of relationship building is acceptable, 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 SDM.*

Additional Actions Required beyond Policies and Processes current as of June 18, 2013

Times for industry-related social events in the SDM will be restricted to non-curriculum hours, which are defined as 6PM-8AM.

Requests for meals, gifts, entertainment, and recreation during Social Events within the School of Dental Medicine at any time must be reviewed and approved by the Associate Dean for Students. The Associate Dean may approve or not approve based on the particular circumstance. If approved, the following process must be followed:

- The Industry Sponsor cannot provide such materials directly nor claim sole responsibility for their provision.
- Funding for approved food or materials will be derived from a pooled fund created and named for such purpose within the UConn Foundation. Industry sponsors may make contributions to this fund but will have no influence or non-restrictive authority over such funds.
- During the conference or meeting, it may be noted that the Industry Sponsor made contributions to the pooled Foundation fund/account from which support is derived to underwrite the costs of food or materials as noted.

Category VIII. Site Access for Industry Representatives

The SDM will ensure that:

- *Procedures or protocols for visits from Industry officials that comply with local and institutional regulations will exist to 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.*

Additional Actions Required beyond Policies and Processes current as of June 18, 2013

The Dean's Office or the Office of the Associate Dean for Education and Patient Care will approve all visits by industry representatives to the SDM, except for those occasions described in this document wherein the Associate Dean for Students approves a social or educational event.

A representative of Industry or a Faculty/Staff/Student sponsor of an Industry visit must seek permission for the visit well in advance of the visit.

Category IX. Industry-led Training and Education

The SDM will ensure that:

- *Policies and procedures that comply with local and institutional regulations exist to ensure that there is no quid pro quo for attendance at the sessions.*
- *Attendees 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.*
- *Attendees will have a confirmed and appropriate level of training to operate devices discussed before hands-on training with the devices occurs.*
- *The meeting or session be clearly identified as commercial in nature, and those individuals leading or teaching the educational program disclose relevant financial relations to the provider and/or host.*
- *Participating attendees be monitored in some fashion for reporting back to the school and/or for receiving continuing education credit, if applicable.*
- *Industry 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.*

Additional Actions Required beyond Policies and Processes current as of June 18, 2013

The SDM Committee on Interactions with Industry will formulate a strategy in this regard. It may either: a) define criteria for approval of such events, b) designate approval authority to the Chair of the Committee or c) elect to review and approve some or all events before they occur.

Category X. All Other Industry Support or Contributions.

The SDM will ensure that:

- *Grants or donations provided by the Industry to the SDM be fully disclosed and not be related to the past, present, or anticipated volume or value of purchases made (or to be made) by the SDM and that no quid pro quo will exist for future academic interactions.*
- *When giving charitable donations or unrestricted grants for charitable or other philanthropic purposes, Industry will not have any control over how the funds are used, and all grants will comply with existing regulations and institutional policy.*

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- *“Unrestricted” grants made for educational, scientific, research, or community service will be consistent with the mission of the SDM. If funds are donated for trainee scholarships, the selection of the trainee will not be influenced by the donor.*
- *Procedures and practices will exist that promote equal access and funding opportunities within the SDM for all in Industry, to include public posting of funding opportunities and of the review process and full disclosure of award announcements.*
- *A written agreement will exist between the donating Industry and the SDM to document the grant, including what was proposed, the amount requested, and the benefits to each party.*
- *Relevant financial relationships and expenditures will be available for public review and will be consistent with state and federal “sunshine act” laws that require reporting and disclosure of Industry “gifts” and donations.*

Additional Actions Required beyond Policies and Processes current as of June 18, 2013

Funding or support by Industry to the School or any of its units (e.g. Departments, Divisions Programs) or faculty/staff/students will be reviewed annually by the SDM Committee on Interactions with Industry. The Committee will advise the Dean when potential conflicts of interest or commitment are identified. The Committee will provide recommendations on continuation of any active funding, programs or relationships and will advise on future policies and guidelines to reduce the risk of such conflicts.