UNC School of Dentistry’s  
Vendor Relations Policy  

I. Description  
This Policy provides guidelines to UNC School of Dentistry Individuals on how to engage with industry in ways that protect personal and institutional integrity. 

II. Rationale  
A. Introduction  
The UNC School of Dentistry (SOD) works to advance the goals of providing quality health care, first class dental education, and transformational research consistent with the highest principles of integrity. Interaction with Vendors can support the SOD’s mission of education, research, service and patient care, but should not compromise patient confidentiality, interfere with patient care, bias research results, or bias the education of residents, or students. 

When conducted ethically and transparently, interactions with Vendors can result in benefits to our patients and trainees. It is appropriate and oftentimes necessary, for example, for faculty members to become involved at various stages of drug and device development so that they can assist with the development of products and services that will benefit their patients and society. Appropriate contacts with industry sales representatives also provide learning opportunities about new therapeutic options, research products and other services or supplies. In all these activities, the safety and well-being of our patients and the integrity of our institution must be our foremost concern. This Policy, adopted by the SOD, is designed to enable SOD faculty, staff and students to engage with Vendors in ways that protect personal and institutional integrity and foster compliance with applicable laws and regulations. 

B. Applicability  
For purposes of this Policy, a “Vendor” is described as any business that manufactures, provides or has potential to provide services or products to the SOD. This Policy applies to all SOD employees, faculty, students and trainees, regardless of the location at which they work or are assigned (collectively, “Covered Individuals”, each a “Covered Individual.”) 

Financial relationships of family members of Covered Individuals are considered to be the same as the relationships of the Covered Individuals. These relationships are also subject to disclosure and regulation as provided under this and related policies. “Family Members” includes one’s spouse and dependent children. For the purposes of this Policy, “spouse” includes a person with whom one lives together in the same residence and with whom one shares responsibility for each other’s welfare and shares financial obligations. 

C. Applicability of Other University Policies  
This Policy supplements existing UNC System and UNC-Chapel Hill policies, including, but not limited to:  

- University of North Carolina System: Policy on Conflicts of Interest and Commitment and Regulations on External Professional Activities for Pay by Faculty and Non-faculty EPA Employees.  
- UNC-Chapel Hill Policy on Individual Conflicts of Interest and Conflicts of Commitment. 
- UNC-Chapel Hill External Professional Activities for Pay 
- SOD Accepting Technology from Vendors Policy
Covered Individuals should also be aware of two Federal laws that relate to individual and school activities with Vendors.

1. The Physician Payments Sunshine Act (the “Sunshine Act“):
   http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html?q=sunshine+act+final+rule In March 2010, the Sunshine Act was passed as part of the Patient Protection and Affordable Care Act (the “ACA”). The stated purpose of the Sunshine Act is to increase transparency of financial relationships between manufacturers of health care products and certain healthcare providers and to allow the public to identify potential conflicts of interests.

2. The Federal Anti-Kickback Statute is enforced by the Federal Department of Health and Human Services Office of Inspector General (“OIG”).
   http://www.ssa.gov/OP_Home/ssact/title11/1128B.htm. The Anti-Kickback Statute is a criminal law that prohibits the knowing and willful payment of “remuneration” (anything of value) to induce or reward patient referrals or the generation of business involving any item or service payable by Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients). Remuneration can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies. Taking money or gifts from a drug or device company, or a durable medical equipment (“DME”) supplier may implicate the Anti-Kickback Statute.

   a. The OIG has issued a compliance program guidance regarding permissible and suspect interactions between manufacturers of products or services reimbursed by Federal payers (e.g. Medicare/Medicaid) and healthcare professionals:
      http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf.

   In addition, several professional and trade associations have published guidelines that similarly discuss permissible interactions between industry and clinicians, including:

   1. The AdvaMed Code of Ethics on Interactions with Health Care Professionals
      http://www.adea.org/InteractionGuidelines/Pages/ADEAGuidelinesforEthicalAcademicandIndustryInteractions.aspx

   This Policy is intended to be consistent with the foregoing policies, laws, regulations and guidance documents, and should be interpreted in light of these authorities.

III. Policy

A. Reporting of Financial Relationships

For purposes of this Policy, a “Financial Relationship” shall be the possession or receipt by Covered Individuals or a Family Member of:

- Income, in any form and in any amount and for any purpose, received from a Vendor.
- Ownership, in any form (including stock options or warrants) other than through a mutual fund in a Vendor.
- In-kind compensation from a Vendor such as the provision of goods, travel, or lodging.
- Royalties, including royalties received through the University, originating from a Vendor.
- Gifts made for the benefit of a Covered Individual by a Vendor to the University, or any affiliated foundation.

A financial relationship may exist whether the Covered Individual is paid directly or whether compensation is routed through another legal entity, such as a limited liability company or non-profit organization.

The reporting requirements of this Policy are supplemental to and are required in addition to any
reports required under the University’s “Policy on Individual Conflicts of Interest and Commitment”, “Institutional Conflicts of Interest”, and/or “External Professional Activities for Pay”.

Covered Individuals are required to report a financial relationship at least annually and more often as needed to disclose new relationships through the entities’ online reporting structure https://apps.research.unc.edu/air/. For employee (i.e. faculty and staff) disclosures, this information will be reviewed and approved by the departmental chair or supervisor. For student and trainee disclosures, this information will be reviewed by the appropriate faculty advisor, graduate program director, or departmental chair. As noted above, such arrangements can be subject to scrutiny under fraud and abuse regulations. Failure to disclose financial relationships as required under this Policy may result in disciplinary action up to and including dismissal. Contact the SOD Dean’s Office, as applicable, for any questions related to financial relationships. Covered Individuals are also required to confirm annually all financial relationships, if any, previously disclosed during the year through the entities’ online reporting structure.

The financial information reported under this Policy shall become part of the personnel or education record of the Covered Individual, as applicable. Access to the information disclosed under this Policy will be limited to those who need to know for business purposes, which includes the appropriate supervisors, departmental chairs, faculty advisors, or graduate program directors of Covered Individuals who must review proposed activities prior to initiation; provided, however that the SOD may additionally be required to provide such information to other individuals or third parties pursuant to a valid court order or subpoena.

B. Contracting with Vendors

Contracting with Vendors on behalf of the SOD must be accomplished through the appropriate Purchasing Department and not directly by Covered Individuals. Covered Individuals are generally prohibited from participating in the SOD’s or UNC-Chapel Hill’s negotiations with any Vendor with whom such Covered Individuals have a personal interest, a financial interest, or personal or family relationship. Covered Individuals may, however, provide professional advice to the SOD or UNC-Chapel Hill persons reviewing specific goods and services, provided that they disclose any potential conflict of interest to those whom they are advising.

C. Vendor Support for Educational Activities

“Educational Activities” are activities, conferences, or meetings organized at or through the University by the SOD and primarily dedicated to promoting scientific and educational activities and to furthering the knowledge of the attendees on the topic being presented. Educational Activities include Continuing Dental Education (“CDE”) events. Covered Individuals must adhere to any American Dental Association Continuing Education Recognition Program (ADA-CERP) Recognition Standards and Procedures, this Policy and other University and UNC System Policies when organizing, holding or presenting an Educational Activity.

Vendors may sponsor Educational Activities by making a donation or educational grant to the SOD and/or The Dental Foundation of North Carolina, but the Educational Activity should be independent, free of commercial bias, and beyond the control of the Vendor. In no case may a Vendor dictate or control the selection of speakers, topic, or educational material presented. Rather, the SOD must have responsibility for the selection of content, presenters, educational materials, and venue, and the Vendor’s input (if any) must be limited to ensuring the scientific accuracy of the description and use of its product according to regulatory guidelines and approved label specifications (if such product is discussed during the Educational Activity). Further, if a Vendor’s specific products are discussed, the discussion must be done in a non-biased manner, should include comparable product options from which a healthcare professional may choose, and should be drawn from evidence-based scientific research, rather than from a Vendor’s materials.
Speakers should disclose any associations that they have with the Vendor, consistent with the Sunshine Act and institutional policy, and should include such disclosures in printed materials distributed at the Educational Activity and at the beginning of any presentation. Support provided by the Vendor to the SOD should also be fully disclosed and should not be related to the past, present, or anticipated volume or value of purchases made by the SOD. No *quid pro quo* should exist or be expected by the Vendor for future interactions with the SOD. A written agreement between the sponsoring Vendor and the SOD and/or The Dental Foundation of North Carolina, as applicable, is encouraged as a means of creating appropriate documentation of the parties’ intent and expectations.

D. Attendance at Industry Conferences

Covered Individuals may attend conferences convened by Vendors, provided the following restrictions and/or requirements have been assured. The Vendor can help establish the guidelines for selection criteria but should not vote on, or have any other influence over the selection of conference participants. The conference should be conducted in a setting conducive to the sharing of clinical or educational information, and the presentations should be drawn from evidence-based scientific research, rather than from a specific Vendor’s materials. There should be no specific or implied *quid pro quo* for attendance at the conference, including that Covered Individuals may not be paid honoraria simply for their attendance.

Reimbursement for travel expenses should comply with this Policy and other institutional policies, and should be for reasonable and moderate travel, meals, and meeting registration costs. Vendors may not pay for travel, meals, or lodging for Family Members in conjunction with Covered Individuals attendance at such conferences.

Recreational events at conferences that are held in recreational areas should be clearly designed and identified as separate from the academic or clinical portion of the conference. Any recreational expenditures should be assumed by the Covered Individual or the SOD.

### Hypothetical:
A vendor sends out a notice to the SOD and to other schools that they have contracted with an independent group to put on an educational event on clinical research methods. Upon investigation, the program appears to be excellent and the presenters are well-known. The vendor will pay for four junior faculty members to attend, but the school must respond in three days.

### Analysis:
The SOD should ensure that the conference will be conducted in a setting conducive to sharing clinical or educational information, and that the presentations will be drawn from evidence-based scientific research, rather than from a specific Vendor’s own materials. The Vendor can’t pay an honorarium simply for attendance or for family to attend, and the Covered Individual has to pay for any recreational activities (e.g. golf) that might happen in connection with the event. The SOD (not the Vendor) would need to select which four junior faculty get to go. Absent an exception granted by the Dean’s Office, travel reimbursement must flow through the SOD pursuant to some form of written documentation with the Vendor, which needn’t be a contract and could be as simple as emails, letter correspondence, and/or itemized invoices.

E. Educational Materials

Vendors may leave educational materials regarding their products or services that may be useful to patients with the applicable department administration, but Vendors may not distribute them directly to patients. All such educational information should be reviewed and distributed (if at all) by the appropriate department. Educational materials, such as textbooks, or medical journals, may be
donated by Vendors, but only if such materials serve a genuine educational function and have a fair market value of less than $100 each. No promotional material or product information from the Vendor may be attached to any such item. Vendors may not provide any items that can be used for non-educational purposes (e.g. iPods, DVD players), even if such items may also have an educational purpose.

F. Samples

No actual or implied quid pro quo should exist when accepting complimentary drug, device or other product samples. No service, right, or license may be given to the donor in conjunction with the gift of the sample except through a written contract signed by an authorized official of the University or The Dental Foundation of North Carolina. The personal information of all recipients of product samples should be protected as per local, institutional, and federal laws and policies. In no event may the distribution of samples to patients be accompanied by any of the Vendor’s marketing materials or any affirmative messaging that implies endorsement of the product by the SOD or its faculty, staff, and students.

Hypothetical: SOD students participate in required community rotations as part of their curriculum. Some students also go to international sites for rotations. Many students solicit dental supplies from Vendors to be used as part of their international community experiences. Is this okay?

Analysis: Students can accept these donated supplies, however, there can be no quid pro quo (e.g. product promotion) to the Vendor for the free samples, the students must protect the identity of all patient recipients (e.g. not share such information with the Vendor), and students cannot accompany distribution of the samples/supplies with any of the Vendor’s marketing materials or any implied endorsement of the Vendor’s product(s).

G. Gifts

“Gifts” is defined broadly to include anything offered free of charge or consideration, but does not include educational materials, which are discussed separately in the “Educational Materials” section of this Policy. Covered Individuals may not receive gifts that, individually or in the aggregate, have a retail value of more than $25 from Vendors. Examples of gifts may include tote bags, electronic appliances (e.g., iPods), food, wine, flowers, chocolates, gift baskets or holiday gifts, cash or cash-equivalents (e.g., gift certificates), or any item that can be used by Covered Individuals (or their Family Members) for non-educational or non-patient-related purposes.

Hypothetical: A Vendor wishes to donate medical instruments to an organization of a student’s choice.

Analysis: This scenario is not directly addressed by the Policy. If the recipient of the medical instruments is a person or entity other than the SOD, a Covered Individual, or a Covered Individual’s Family Member (and assuming no financial relationship between such entity/persons and the external recipient), directing a donation in this way is acceptable under this Policy.

Hypothetical: A vendor wishes to create custom diaphragms with an image honoring a deceased student and give one to each of the student’s classmates as a form of remembrance.

Analysis: Although a touching offer, if the value of the diaphragms in the aggregate would exceed $25, they would constitute a prohibited gift.
H. Industry Led Training, Education and Product Evaluation

This section addresses Covered Individuals’ attendance at Vendor-sponsored training sessions and meetings, often including a “hands-on” component, lectures, and demonstrations. The types of activities discussed in this section are distinguishable from “Educational Activities” (discussed further in the “Educational Activities” section of this Policy) in which the Vendor can have no control over content.

At the University
For such Vendor-organized, -sponsored or -provided training and education to take place at the SOD, the Dean’s Office of the SOD must ensure that the information presented is valuable to the school and consistent with its mission of research, education and quality patient care. Examples of the types of presentations that would meet this standard include opportunities to assess the scientific evidence supporting a particular product’s usefulness, safety, directions for use, and claims of results. These sessions could additionally provide a good opportunity to teach students how to critically assess the evidence presented.

The selection or approval of Vendors to provide training, education or informational sessions on-site at the SOD must not relate in any way to the present or future volume or value of such Vendors’ products purchased by the SOD or its Dental Faculty Practice. Any remuneration proposed to be paid by a Vendor to the SOD or Covered Individuals in connection with an on-site training, education or informational session must be carefully reviewed by the SOD for compliance with this Policy and applicable laws. Covered Individuals may not be paid an honorarium simply for their attendance of the event. Vendors’ proposed distribution of samples at such sessions are subject to the “Samples” section of this Policy, which prohibits (among other things) any quid pro quo for the Vendor.

Vendors 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) and for the conduct of the training or educational session. Vendors must enter into an agreement approved by the SOD’s Dean’s Office and the Office of University Counsel before leaving behind any capital equipment or other multiple use product brought on-site for evaluation, training or education.

Hypothetical: A department invites a Vendor in for a lunch-time presentation of their products as an educational experience for dental students, residents, and faculty. The Vendor proposes to provide lunch for the attendees and will leave some samples so the attendees can try them out on their own. Okay?

Analysis: This Policy would allow the presentation if the Dean’s Office has determined that the information presented is valuable to the school and consistent with its mission of research, education and quality patient care. The selection of which Vendor comes to present cannot be based on the volume or value of the products/services they provide to the SOD. If this activity is approved as consistent with the SOD’s mission, the Vendor can offer lunch. And this Policy would allow the Vendor to give samples / single-use products, but only to the extent reasonably necessary for the adequate evaluation of the product(s). The same analysis would apply to “Vendor Day.”
External Locations
Any off-site training activities must also be consistent with the SOD’s mission of education, research and patient care. As set forth more fully in “Work-Related Travel” section of this Policy, a Vendor may pay the SOD for reasonable travel, modest meals, and travel-related expenses for off-site training or product evaluation activities, and the SOD may, to the extent applicable, reimburse Covered Individuals for such expenses, provided such reimbursement is consistent with this Policy and institutional procedure. Covered Individuals may not be paid an honorarium simply for their attendance of the event.

Whether these training and education sessions occur on-site at SOD or off-site, Covered Individuals attendees should have a confirmed and appropriate level of training to operate the medical devices or products discussed during the session 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 instructional program should disclose relevant financial relations.

Hypothetical: A vendor contacts faculty members indicating that they want to hold a CE Course that involves “hands on” activities. They want to have the course at their facility, and they will pay for all supplies for the course, as well as for transportation, housing, food, and honoraria. The Vendor does not prescribe the content of the presentation. How would this be handled?

Analysis: The course would need to be vetted as consistent with the SOD’s mission of education, research and patient care, the attendees would need to be adequately trained to participate in any hands-on activities, and the travel reimbursement would need to be paid to the SOD pursuant to some written documentation. The SOD could in turn reimburse the Covered Individual for the travel expenses, consistent with UNC’s travel policies. For CE credit to be extended the course would have to comply with ADA-CERP requirements.

I. Other Vendor Support or Contributions

This section addresses all other Vendor support or contributions including the provision of financial resources by Vendor to the SOD for the following purposes: research grants, publication grants, critical needs, capital improvements, and capital campaigns.

All research activities, including but not limited to the use of investigational drugs and devices, must be conducted pursuant to University policies and procedures concerning research, including the University’s Policy on Conflict of Interest and Commitment, and may require the involvement of the Office of Sponsored Research, the Office of Clinical Trials, the Office of Industry Contracting, and/or the University’s Institutional Review Board. It is the obligation of the Covered Individuals to learn about the applicable policies and procedures before beginning any research projects. Promotional activities by Vendors may not be performed under the guise of research.

Grants or donations provided by the Vendor to the SOD or the University should be for bona fide research or educational purposes, 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 SOD. No quid pro quo should exist for future interactions with the Vendor donor. SOD should consult with the relevant SOD or University development officers, the Office of Sponsored Research, the Office of Industry Contracting, and/or the Office of University Counsel regarding the proper structuring of Vendor-proffered grants.

Vendors may make charitable donations or grants for charitable or other bona fide philanthropic purposes consistent with the SOD’s mission, so long as permitted by applicable laws. The donating Vendor may not have any control over how the funds are used, including if funds donated are for trainee scholarships or endowed professorships, and the selection of the trainee or professor must not
be influenced by the Vendor. All donations must comply with existing law and institutional policy. SOD should consult with the relevant SOD or University development officers and/or the Office of University Counsel regarding the proper structuring of Vendor-proffered charitable donations.

In all cases, a written agreement should exist between the donating Vendor and the SOD to document the grant or donation, including the amount transferred and the intent of the parties. Such grants or donations may also be subject to a conflict of interest review if the support for the benefit of the professional activities of a Covered Individual or connected to a research project.

J. Ghostwriting and Speakers’ Bureaus

Participation in speakers’ bureaus and publication and delivery of ghostwritten works for compensation are considered types of external professional activities for pay.

For purposes of this Policy, “ghostwriting” is the practice of allowing someone other than the named author to write a paper or presentation delivered or reported to be written by the named author. Covered Individuals are not allowed to engage in ghostwriting under any circumstances.

For purposes of this Policy, “speakers’ bureaus” are defined as panels of experts who deliver talks or papers for compensation in any form for the promotion of a product, service, or device manufactured or marketed by the entity directly or indirectly providing such compensation. Covered Individuals are not allowed to participate in speakers bureaus under this Policy.

The conditions of any other speaking engagement will govern the decision as to whether the activity is acceptable under this Policy.

Covered Individuals may participate in speaking engagements that are sponsored by a Vendor(s) where:

- the Covered Individual retains full editorial control and authority over the content of the presentation;
- the content of the lecture is educational, free from commercial influence, and is not designed to recommend specific drugs, devices, or other commercial products or services;
- the content of the lecture is based on best available evidence and reflects a balanced assessment of the current science and treatment options;
- the event sponsor does not provide honoraria to the attendees;
- any required attestations are made at the beginning of the presentation that disclose all funding and editorial relationships with the Vendors, including an attestation of receipt of honorarium for providing the talk to the program attendees;
- the Covered Individual makes a disclaimer that the views expressed are not necessarily those of the University or the SOD;
- the slides do not contain any logos or names of the Vendor that sponsored their production, except as required in the attestation;
- in the estimation of the reviewing supervisor, departmental chair, faculty advisor, or graduate program director authorized to approve the speaking activity, any honorarium and travel expenses paid for the speaker’s participation are reasonable; and
- the activity is permitted/approved as an EPAP, as set forth more fully in the “External Work” section of this Policy.

While prior review of the presentation by a Vendor is acceptable, Covered Individuals should NOT allow a Vendor to influence the content of the presentation. If the reviewing supervisor, departmental chair, faculty advisor or graduate program director has concerns about possible overreaching by a Vendor in conjunction with a specific presentation, that supervisor, departmental chair, faculty advisor or graduate program director may require that he or she review and approve the slides prior to the presentation.
K. Meals and Other Hospitality

Covered Individuals may not accept meals or other hospitality from Vendors, except in the following circumstances:

- Meals that are served as part of a general professional conference or meeting supported in whole or in part by Vendor(s) and included in the event registration (e.g., annual meetings of academic societies where lunch is served to all registered attendees).
- Meals provided in conjunction with off-site activities as part of EPAPs approved per the “External Work” section of this Policy.
- Meals provided in conjunction with training and education sessions approved per the “Industry-Led Training, Education and Product Evaluation” section of this Policy.

Covered Individuals must pay for their own meals if attending an educational meeting or journal club organized by a Vendor as an invitation-only event and held at a restaurant or resort.

Under no circumstances may Covered Individuals accept complimentary tickets to sporting or other events from a Vendor.

Hypothetical: A Vendor is organizing a conference aboard a cruise ship for a week. Several faculty members are invited to speak. There are no restrictions on what they present as part of their topic. The time commitment would involve presenting for a total of 6 hours during the week. Vendor would pay all expenses plus an honorarium. Permissible?

Analysis: No. This Policy permits speaking engagements only where, in the estimation of the supervisor, any honorarium or travel expenses paid for the speaker’s participation are reasonable. Arguably, paying for a cruise would not meet an objective “reasonableness” standard. Further, the conference is not being conducted in a setting conducive to the sharing of clinical or educational information and there is not a clear separation of (and Covered Individual personal payment for) the recreational component attached to this “academic” event. Lastly, Vendor-sponsored meals and refreshments (which are read to also include recreation) provided in conjunction with meetings to be modest in value and subordinate in time and focus to the primary purpose of the meeting.

Hypothetical: A Vendor wants to arrange an “appreciation” dinner at a restaurant for faculty and students. Permissible?

Analysis: Only if the faculty and students pay for their own meals.

L. External Work

For purposes of this section, “Covered Individual” shall refer exclusively to employees (i.e. faculty and staff; this section shall not apply to students or trainees).

Vendors engage the SOD’s Covered Individuals to provide a wide-range of valuable, bona fide services through various types of arrangements, such as contracts to advise on product development, development and/or transfer of intellectual property, marketing, participation on advisory boards, and presentations at Vendor-sponsored training and other services. To the extent
such activities are conducted in a Covered Individual’s individual capacity, a request by the Covered Individual for approval of such proposed external professional activities for pay (“EPAPs”) is required in advance of undertaking the activities and must include the proposed compensation. An EPAP approval request is also required whether Covered Individuals are paid directly or paid through another legal entity, such as a limited liability company or a non-profit organization. EPAPs do not include services rendered pursuant to a contract between the University and the external entity for which the services are undertaken.

Covered Individuals who have received permission from their supervisors to conduct the activity as an EPAP are responsible for ensuring that the arrangement complies with, among other things, the Anti-Kickback Statute. This means that:

- Compensation for the activity must be consistent with fair market value in an arm’s length transaction for the services provided and should not be based on the volume or value of the Covered Individual’s or SOD’s past, present or anticipated business.
- The services must be provided in fulfillment of a legitimate business need on the part of the Vendor and not constitute an unlawful inducement (e.g. reward for recommending the purchase of a Vendor’s products disguised as payment for services which are unnecessary).
- The agreements should be in writing and describe all services to be provided.
- A Vendor may pay for documented, reasonable and actual expenses (such as costs for travel, modest meals, and lodging) incurred by the Covered Individuals, provided the expenses are necessary to carry out the arrangement and consistent with its educational or scientific purpose.
- Vendors may not pay for travel, meals, or lodging for Family Members in conjunction with a Covered Individual’s EPAP activity.
- The venue and circumstances for Vendor meetings with Covered Individuals in furtherance of the engagement should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.
- Vendor-sponsored meals and refreshments provided in conjunction with such meetings should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting. Vendors should not provide recreation or entertainment in conjunction with these meetings.

Further, Covered Individuals who have received permission from their supervisors to conduct the activity as an EPAP may consult for Vendors for compensation and use or prescribe those Vendors’ products in patient care only if:

- They comply with the University Policy on External Professional Activities for pay
- Their department chair or supervisor has approved, through the appropriate reporting mechanism, and they have disclosed the amount of compensation they expect to receive from the proposed activity at least ten days prior to the activity;
- Their supervisor determines that any external relationships, including projected compensation, are not excessive; and
- The supervisor determines that such activities will not interfere with the employment obligations of the affected Covered Individuals.

Any EPAP request which includes a relationship which overlaps with a Covered Individual’s research activities shall be subject to the standard review process under the University’s Conflict of Interest Policy.

It is understood that there may be changes in approved external arrangements during a given academic/fiscal year. Covered Individuals are responsible for submitting an amended EPAP request form that addresses any such changes, including changes in the amount of time or compensation involved. This amended EPAP request form must be submitted not later than thirty (30) days after Covered Individuals learn of the changes in the terms of the approved arrangement.
Failure to disclose and obtain approval for external activities prior to the engagement as required may result in disciplinary action up to and including dismissal.

**Hypothetical:** A faculty member is invited to participate in a Key Opinion Leader meeting sponsored by a Vendor. Travel, meals and lodging would be paid for by the Vendor in exchange for the faculty member’s time and input. There is no honorarium or expectation of product promotion. Okay? Process?

**Analysis:** Assuming the faculty member wishes to do this activity in her individual capacity (i.e. on her own time) as an external activity, she should submit an EPAP approval request, which likely would be approved given this Policy contemplates that Vendors engage the SOD’s Covered Individuals to provide a wide-range of valuable, *bona fide* services, including advising on product development and participating on advisory boards. If the EPAP is approved, the faculty member would be responsible for ensuring that any compensation for the activity is fair market value, the services fulfill a legitimate business need of the Vendor, the venue for the meeting is conducive to scientific exchange and any meals or refreshments are modest in value and subordinate in time and focus to the primary purpose of the meeting.

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**M. Work-Related Travel**

For purposes of this section, "Covered Individual" shall refer exclusively to employees (i.e. faculty and staff; this section shall not apply to students or trainees).

Covered Individuals may not directly accept from a Vendor reimbursement or sponsorship of travel or associated expenses for site visits to conduct training or to evaluate a product or service. Vendor-sponsored visits for Covered Individuals to travel to Vendor sites for training are acceptable if the cost of such training visits is itemized, expensed to the SOD and reflected in the documentation between the SOD and the Vendor. Reimbursement from the SOD by Covered Individuals should be requested through the appropriate University office. Covered Individuals may take site visits to evaluate a product or service at the Vendor’s expense, provided that:

1. All arrangements related to site visits, including selection of participants, duration of the visit, selection of travel method and accommodations, are made by the applicable department (and not by the Vendor).
2. Site visits at the expense of the Vendor may only include travel, lodging, and food expenses specifically related to the evaluation of the product or service and incurred in accordance with departmental policies regarding the appropriateness of business expenses and within spending guidelines for expenses, including per diem payments, coach class travel, and hotel accommodations. Expenses may not include any extra expenses which are personal in nature or unrelated to the evaluation.
3. All expenses will be determined and paid for by the applicable SOD Department with the reimbursement made to the Covered Individuals through the usual process. The Department will send an invoice for appropriate expenses to the Vendor for reimbursement.
In exceptional circumstances where it is determined that indirect reimbursement is infeasible or would meaningfully preclude a valuable educational, research or academic opportunity presented by the Vendor, SOD employees may request, and the Dean’s Office may grant an exception to the requirement that travel expense reimbursement flow through the SOD. Faculty employees should be aware that direct travel reimbursement from the Vendor, as permitted by the foregoing process, will require disclosure under this Policy and may result in Sunshine Act reporting.

N. Policy Violations

Covered Individuals who are aware of potential violations of this Policy should report those allegations to the SOD Dean’s Office, Conflict of Interest Program, the Office of University Counsel, or to University Compliance Hotline (1-866-294-8688).

Alleged violations of this Policy by employee Covered Individuals (i.e. faculty and staff) shall be investigated by the SOD Dean’s Office in conjunction with the applicable University offices. On finding of a violation of this Policy by a Covered Individual who is an employee, the supervisor of the Covered Individual involved will be notified in writing of the facts and nature of the Policy violation by the SOD Dean’s Office. The SOD Dean’s Office in conjunction with the applicable University Office will work with Human Resources and/or the Provost’s Office to recommend disciplinary action or other action provided under this Policy.

Alleged violations of this Policy by student/trainee Covered Individuals will be referred to the Associate Dean for Education or the Assistant Dean for Advanced Education and will be reviewed by the relevant program's Academic Performance Committee and/or the Graduate Student Attorney General, consistent with, and as outlined in the General Academic Policies and Procedures Manual of the SOD.

In addition to any sanctions specifically provided herein, Covered Individuals found to have violated this Policy will be subject to disciplinary action up to and including dismissal. All disciplinary action taken hereunder shall follow the established procedures of the University, including, without limitation, its human resources and faculty policies with respect to employee and faculty Covered Individuals, and the SOD’s General Academic Policies and Procedures Manual with respect to student and trainee Covered Individuals.

IV. Original Policy Date and Revisions

To be determined.