

POLICY REGARDING RELATIONSHIPS WITH INDUSTRY

Date Issued: September 1, 2009

Authority: C.L. Max Nikias
Executive Vice President and Provost

Todd R. Dickey
Senior Vice President, Administration

1.0 **Purpose**

The purpose of this policy is to:

- Support USC's standard of maintaining a culture of ethics in its business relations and to minimize conflicts of interest and the appearance of impropriety in our relationships with pharmaceutical companies, biotechnology companies, device and medical equipment manufacturers and other healthcare suppliers ("Industry").
- Provide guidelines for USC Healthcare Professionals (defined below) for their interactions with Industry.
- Assist USC Healthcare Professionals in exercising independent clinical judgment at all times that is free from influence by relationships with Industry.
- Assist USC Healthcare Professionals in complying with federal, state and local laws and regulations, including the federal Anti-Kickback laws.

2.0 **Background**

USC recognizes that Industry possesses knowledge about the safety and efficacy of pharmaceuticals, medical devices, and medical supplies that may be of value to USC Healthcare Professionals and that may benefit their patients. In addition, USC Healthcare Professionals may have expertise that is beneficial to Industry.

However, in certain circumstances these relationships can improperly influence, or appear to improperly influence, clinical, purchasing or prescribing decisions. In addition, it is a violation of the federal Anti-Kickback laws to knowingly receive anything of value that induces a clinician to use or purchase products/services (e.g., prescription drugs or medical devices) that are paid for by government programs, such as Medicare or Medicaid.¹

¹ Attached hereto as **Exhibit A** is a summary of applicable laws and standards.

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued: September 1, 2009
University of Southern California
Page 1 of 19

Fundamentally, interactions with Industry must serve legitimate educational, research and clinical purposes, and contribute to better health care for patients. This policy establishes standards for appropriate interactions with Industry. In addition to the standards established in this policy, it is important for all USC Healthcare Professionals to comply with the university's Conflict of Interest and Ethics Policy and Procedure.

3.0 **Scope**

This policy applies to all "USC Healthcare Professionals", who are defined as:

- University faculty members (including part-time and visiting faculty), students, staff, and other employees (including residents and fellows), who interact with Industry and who have influence directly or indirectly over the prescribing, dispensing or purchasing of Industry products or services; and
- The USC affiliated faculty practice plan corporations and units listed in **Exhibit B**; and
- USC University Hospital and Norris Cancer Hospital.

The policy applies to on-site and off-site interactions with Industry.

4.0 **Types of Interactions Covered by this Policy**

This policy provides guidelines for the following types of interactions with Industry:

- A. Consulting Arrangements and Industry-Sponsored Speaking Engagements
- B. Gifts, Invitations and Free Meals
- C. Attendance at Industry-Sponsored Conferences
- D. Education Grants and Trainee Scholarships
- E. Unrestricted Grants
- F. Industry-Sponsored Research Projects
- G. Training and Education Regarding Use of Medical Devices
- H. Pharmaceutical Samples, Discounts and Other Reductions in Price
- I. Site Access by Industry Representatives
- J. Ghostwriting

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued:	September 1, 2009
	University of Southern California Page 2 of 19

K. Recusal from Purchasing Decisions

A. **Consulting Arrangements and Industry-Sponsored Speaking Engagements**

This section covers all consulting arrangements with Industry, including participating on advisory committees, giving lectures or other presentations, Industry-sponsored speaking engagements, providing training and advice or other services for payment (collectively, “Consulting Arrangements”). Special considerations for Industry-sponsored speaking engagements (e.g., speakers’ bureaus or promotional presentations) are discussed in Section A.3 below.

A.1 Requirements for Consulting Arrangements

A.1.1 USC Healthcare Professionals are ultimately responsible to ensure that all Consulting Arrangements:

- Are in writing; and
- Describe in reasonable detail the services provided by USC Healthcare Professionals; and
- Provide no more than fair-market compensation; and
- Require necessary and legitimate services that are actually rendered; and
- Are not entered into for longer than a one year term and with extensions being treated as new agreements requiring compliance with all sections of Section A; and
- Are not motivated (or appear to be motivated) by any improper purpose, such as to incentivize the USC Healthcare Professional to change or maintain his or her purchasing or prescribing habits; and
- Are not provided at a time when the USC Healthcare Professional is otherwise engaged in University activities, such as the provision of healthcare; and
- Comply with the USC Faculty Handbook on Outside Consulting and the USC Conflicts of Interest in Ethics Policy and Procedure; and
- Are submitted in advance for review and approval prior to agreeing to, engaging in, or accepting reimbursement for the consulting activities; and
- If the consulting arrangement is related in any way to a company where the USC Healthcare Professional is also involved in a sponsored research project, the USC

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued:	September 1, 2009
	University of Southern California Page 3 of 19

Healthcare Professional has completed and submitted a Statement of Outside Interests under USC's Conflict of Interest in Research Policy.

A.1.2 In addition, before signing a Consulting Arrangement, USC Healthcare Professionals should consider whether the request for services has originated from an appropriate unit/division within Industry. For example, Industry marketing representatives generally are not the appropriate unit to engage services that are solely scientific in nature.

A.1.3 USC Healthcare Professionals may accept meals, travel and lodging in connection with meetings for consulting services, so long as they are of "modest value" and incidental to the consulting or other services provided. See **Exhibit C** for guidelines on establishing "Modest Value."

A.2 Disclosure and Approval of Consulting Arrangements

A.2.1 All Consulting Arrangements must be disclosed to, reviewed and approved by the USC Healthcare Professional's Department Chair or Chair Designee (the "USC Approver") before consulting services can be rendered². Consulting Arrangements may also require approval of the Dean or his/her designee, as determined at the Dean's discretion. The USC Approver/s is/are responsible for the following:

- To ensure that the services provided under the Consulting Arrangement comply with this policy and do not constitute a conflict of interest or commitment as described in USC's Conflict of Interest and Ethics Policy;
- To confirm that the USC Healthcare Professional has submitted a Statement of Outside Interests if the Consulting Arrangement relates in any way to a sponsored research project;
- To maintain a copy of the Consulting Arrangement in accordance with the university's record retention policy and a copy of their written review which has been signed by the Chair; and
- To report annually in writing to his/her Dean, upon the Dean's request, all Consulting Arrangements that have been disclosed, an update of ongoing Consulting Arrangements and the outcome of the Chair's review.

² In the event that the Department Chair or Chair Designee has a conflict of interest, the Chair shall forward the agreement to the Dean or Dean's Designee for approval. In the event that the Dean has a conflict of interest, the Dean shall forward the agreement to the Provost or the Provost's Designee for approval.

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued:	September 1, 2009
	University of Southern California
	Page 4 of 19

A.2.2 USC Healthcare Professionals must disclose to their students, residents and fellows any Consulting Arrangement they may have or have had that relates to Industry products (e.g., device, product, equipment) that are being described, taught or used in an educational or instructional setting (e.g., classroom, operating room, lab).

A.3 Industry-Sponsored Speaking Engagements/Lectures

A.3.1 USC Healthcare Professionals may participate as bona fide lecturers at an Industry-sponsored conference if they:

- Comply with the Accreditation Council for Continuing Medical Education's (ACCME) Standards for Commercial Support³, the Accreditation Council for Pharmacy Education⁴ (ACPE) or the American Dental Association⁵ (ADA), as appropriate, whether or not CE credit is awarded; and
- Ensure to the extent possible that the information they present is based on the best scientific evidence available; and
- Disclose to attendees orally and/or in writing, their financial relationship with Industry and that their opinions are their own and not intended to represent USC; and
- Ensure that the requirements set forth in A.1 and A.2 are satisfied.

A.3.2 USC Healthcare Professionals are *strongly discouraged* from speaking as a paid promotional speaker at Industry-sponsored events, i.e. speaker's bureaus. To the extent a USC Healthcare Professional chooses to engage as a speaker at such Industry-sponsored events, he/she must:

- Have control⁶ of the content; and
- Ensure to the extent possible that the information presented is based on the best scientific evidence available; and
- Not present unsolicited off-label uses of FDA-approved drugs or devices; and

3 www.accme.org

4 www.acpe-accredit.org

5 www.ada.org

6 Control means that a speaker directly determines and has ultimate responsibility for the substance and content of the presentation. The speaker must always cite the source of the slide if not developed by the speaker.

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued:	September 1, 2009
	University of Southern California Page 5 of 19

- Disclose to attendees orally and/or in writing, their financial relationship with Industry and also that their opinions are their own and not intended to represent USC; and
- Ensure that the requirements set forth in A.1 and A.2 are satisfied.

B. Gifts, Invitations and Free Meals

B.1 USC Healthcare Professionals may not accept gifts of any kind from Industry, including food, branded items such as pens and notepads, even if such gifts are of nominal value. Existing branded items may not be utilized in patient-care areas and must be removed.

B.2 USC Healthcare Professionals may not accept any item from an Industry representative that is for the Healthcare Professional’s or family member’s personal benefit, such as floral arrangements, artwork, golf balls, sporting bags, or tickets to sporting, musical or other types of entertainment events.

B.3 USC Healthcare Professionals and/or their family members may not accept Industry invitations for free or discounted admission to entertainment events such as plays, sporting events or golf outings, even where some business may be discussed.

B.4 With the exception of food provided in accordance with CE accredited programs, or meals provided in accordance with Section C of this policy, USC Healthcare Professionals may not accept any food or meals from Industry representatives. For example:

- USC Healthcare Professionals may not accept meals on or off campus that do not meet the criteria set forth in Section C below.
- Industry may not provide/deliver to educational/instructional settings, meals for students, residents or fellows.
- Industry may not provide/deliver any meals in patient care areas (e.g., clinics, hospitals).

B.5 USC Healthcare Professionals may not accept payment or any other remuneration from Industry in exchange for attending any lunch, dinner or reception.

B.6 USC Healthcare Professionals may not accept Industry donations/loans of equipment, devices or supplies, except as follows:

- Research: Industry may provide equipment for use in research related activities conducted on behalf of the manufacturer.
- Evaluation: Industry may provide demonstration or evaluation products without charge, to allow the USC Healthcare Professional to assess the appropriate use and

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued: September 1, 2009
University of Southern California
Page 6 of 19

functionality of the product and to determine whether and when to use, order, purchase or recommend the product in the future.

- Early Adopter Feedback: Industry may provide new technologies without charge to promote education and clinical care in an effort to solicit early adopter feedback on the new technology.
- Bona fide Discount: Industry may provide free or discounted equipment, devices or supplies in connection with the purchase of other items as part of a bona fide discount that complies with the Discount Safe Harbor to the federal Anti-Kickback laws.

These arrangements:

- Must comply with Sections A, F and H.3 of this policy, as appropriate; and
- Must be managed centrally by the appropriate School (ex. Keck, Dentistry, Pharmacy); and
- Unless otherwise approved by the Office of Compliance, provide for the title of the equipment to be retained by the manufacturer; and
- Be documented in writing and submitted to the Office of Compliance for prior review and approval; and
- Most importantly, will never be taken into account in awarding contracts or in making purchasing or prescribing decisions.

C. Attendance at Industry-Sponsored Conferences

C.1 USC Healthcare Professionals may attend Industry-sponsored educational meetings, lectures and conferences containing objective scientific and educational information that promotes evidence-based medicine and scientific research and where support of industry is prominently disclosed.⁷ USC Healthcare Professionals shall follow these standards when attending Industry-sponsored educational meetings:

- Educational programs sponsored by Industry must be structured so as not to improperly influence purchasing or prescribing decisions.

⁷ USC Healthcare Professionals are attending conferences as attendees, and not faculty/lecturers, if they only present a peer-reviewed poster or paper.

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued:	September 1, 2009
	University of Southern California Page 7 of 19

- USC Healthcare Professionals’ main incentive in attending the Industry-sponsored educational meetings should be to further their knowledge on the subject(s) presented. USC Healthcare Professionals should ensure that such meetings are inclusive of and led by those within Industry who are qualified to present a program that is aimed at promoting evidenced-based medicine and scientific research. Meetings led by marketing representatives in lieu of Industry’s scientific team would not qualify as a legitimate educational meeting.
- USC Healthcare Professionals may not accept any reimbursement from Industry for meeting registration fees, transportation, lodging, or incidentals to defray the costs of attending the conference.

C.2 USC Healthcare Professionals may attend modest receptions and meals provided by Industry in connection with educational meetings/conferences. The meals and receptions should be incidental and subordinate to the educational content of the meetings. The meal or reception should be modest in value and conducive to discussion among those participating in the event.

C.3 USC Healthcare Professionals may not “dine and dash” (i.e., take food provided by Industry without actually participating in the educational lecture or accept an Industry representative’s offer to provide a meal without providing educational content).

C.4 A USC Healthcare Professional shall not under any circumstances accept reimbursement for transportation, lodging, meals or incidentals for the cost of his or her spouse or other guest(s).

D. Education Grants and Trainee Scholarships

D.1 Education Grants: Education grants may provide funding for valuable activities that are important to the University’s mission. These activities include but are not limited to sponsorship of grand rounds, journal club or morbidity and mortality conferences, all of which are conducted to further education. USC Healthcare Professionals shall comply with the following guidelines when accepting education grants from Industry:

- All education grants received from Industry must be clearly documented in a written agreement signed by the authorized signers for USC⁸ and Industry.

⁸ USC-affiliated faculty practice plan corporations as noted in Exhibit B are not authorized to execute agreements for education grants.

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued: September 1, 2009
University of Southern California
Page 8 of 19

- USC Healthcare Professionals may only consider education grants from Industry for projects that directly benefit USC patients or that advance health policy or education. Research grants are separately addressed in Section F “Industry-Sponsored Research Projects.”
- Education events conducted by USC or a USC Healthcare Professional using grant funds from Industry must comply with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support, Accreditation Council for Pharmacy Education (ACPE), or the American Dental Association (ADA), as appropriate, regardless of whether continuing-education credit is awarded or available for the event.
- Educational grants for “bona fide fellowship”⁹ training may not exceed the actual direct costs of the fellowship program. Where the services of the fellow will generate clinical income to the department, the costs of the program must be offset by such income in determining the allowable funding.
- In general, USC Healthcare Professionals should not accept funding for education that originates from Industry’s sales and marketing departments or that is offered in connection with the purchase or sale of goods or services. The USC Office of Compliance should be contacted before a USC Healthcare Professional accepts funding for educational or other purposes that originates from Industry’s marketing and/or sales departments.
- No funds will be accepted or used for the personal benefit of individual Healthcare Professionals. All donated funds provided by Industry for education will be applied toward the applicable educational or other earmarked project. Donated funds must be deposited into a USC restricted account in accordance with USC policies and Industry requirements for the receipt, management and dispensing of grant monies. It is not acceptable to deposit these funds into Practice Plan or HRA accounts. Funds from other sources for other purposes will not be commingled with these grant monies.
- USC Healthcare Professionals will not accept funds from Industry for any project if Industry requires as a condition of the donation that it approve or influence the materials developed with such funds. This is to avoid any opportunity for Industry to transform a project into a marketing program for Industry’s benefit.

⁹ A bona fide fellowship is one that is ABMS accredited, if accreditation is available for the subspecialty training in question. Where such accreditation is not available (i.e. the subspecialty is not recognized by ABMS for certification purposes), the fellowship must be a formal subspecialty program with clearly identified didactic and clinical requirements where the training elements predominate over patient care as the focus of the program.

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued: September 1, 2009
University of Southern California
Page 9 of 19

- Education grant programs associated with a specific USC Healthcare Professional will be deposited into an appropriate University account as described above. To the extent possible, the funds will be administered in such a manner that the USC Healthcare Professional will not know the identity of donors or the amounts donated by Industry.
- Sponsorships and donations by Industry will never be taken into account in awarding contracts or in making purchasing or prescribing decisions.

D.2 Trainee Scholarships to Conferences: USC recognizes that attendance at educational conferences may further the knowledge of the attendees and benefit USC patients. However, receipt of such funding directly by Trainees from Industry could inappropriately influence medical or other clinical students, residents, fellows and other healthcare professionals in training (“Trainees”), or create the appearance of impropriety. To ensure that Trainees are not inappropriately influenced by Industry, the following guidelines shall apply to Industry funding of Trainee scholarships to educational conferences:

- Donated funds supporting Trainee scholarships must be managed as described in section D.1.
- The USC Healthcare Professional(s) must select the particular Trainees who will receive the Industry-donated funds with no input from the Industry.
- Trainees may not receive funds or be reimbursed for expenses directly by Industry for attendance at an educational conference.
- Offers and requests for funding for such scholarships should not come from or be directed to an Industry company’s marketing or sales departments.

E. Unrestricted Grants

Unrestricted grants, (e.g., grants not provided for educational or other purposes described in this policy), could have the appearance of inappropriately attempting to influence USC Healthcare Professionals. USC Healthcare Professionals may not accept unrestricted grants. Questions regarding unrestricted grants should be directed to the Office of Compliance.

F. Industry-Sponsored Research Projects

F.1 All Industry-sponsored research projects must be reviewed and approved by USC’s Health Research Association or the USC Department of Contracts and Grants, and are subject to USC’s research policies generally; see http://policies.usc.edu/faculty_teaching_research.html, and in particular USC’s Conflict of Interest in Research policy, a copy of which may be obtained at <http://ooc.usc.edu/ResearchCompliance/ConflictsOfInterest/Policy.cfm>.

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued:	September 1, 2009
	University of Southern California Page 10 of 19

F.2 Disclosures of potential or actual conflicts of interest in research must be made to the relevant Institutional Review Board (IRB) and/or Conflicts of Interest Committee (CIRC) per the Conflict of Interest in Research policy and IRB procedures.

F.3 The CIRC and IRB will consult with the Office of Compliance and Department Chair as appropriate, in cases where this policy and the Conflict of Interest in Research policy both may apply to a particular disclosure.¹⁰

G. Training and Education Regarding Use of Medical Devices

G.1 To ensure that USC Healthcare Professionals receive appropriate training free from inappropriate influences over their clinical decision-making, prescribing and purchasing decisions, the following policies shall be followed regarding attendance at medical device manufacturer-sponsored training sessions:

- USC Healthcare Professionals may attend educational training programs sponsored by manufacturers of clinical devices, so long as they are conducted in settings that are conducive to the effective transmission of knowledge. Conducive settings are limited to facilities specifically designed to approximate the conditions of a surgical suite, or a working clinical laboratory or those designed to provide medical training on large and/or technical medical devices, such as surgical equipment, implants, imaging and clinical laboratory equipment. Resort settings are not appropriate settings. USC Healthcare Professionals are discouraged from attending training sessions at international locations when a US location is reasonably available.
- USC Healthcare Professionals may accept reimbursement for reasonable travel, lodging and meals of modest value in connection with a training program meeting the criteria of Section G. See **Exhibit C** for guidelines on what constitutes “modest value.” Any meals and receptions provided in connection with the training program should be subordinate in time and focus to the educational/training purpose(s) of the program.
- Under no circumstances should USC Healthcare Professionals allow a medical device company to pay for meals, hospitality, travel or other expenses for their

¹⁰ There are circumstances where this policy and the Conflict of Interest in Research policy may overlap but have different objectives. For example, a USC Healthcare Professional may be a Principal Investigator on an Industry-funded research project, but have a Consulting Arrangement that creates an actual or potential conflict of interest as described under the Conflict of Interest in Research policy. The CIRC may review the Consulting Arrangement to confirm that it does not appear to bias the research design, protocol or outcomes. But the Consulting Arrangement also may require review under Section A of this policy to ensure that it does not appear to influence particular prescribing or dispensing habits.

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued:	September 1, 2009
	University of Southern California Page 11 of 19

spouses or other guests who do not have a *bona fide* professional interest in the information being provided at the training.

H. Pharmaceutical Samples, Discounts and Other Reductions in Price

H.1 Use of Samples:

- It is permissible for USC Healthcare Professionals to utilize drug samples in the treatment of their patients, so long as the samples are not resold, billed for or used for an individual healthcare professional’s personal benefit, and are distributed in accordance with this policy. However, USC Healthcare Professionals should never allow the provision of free drug samples to influence their clinical decision-making or purchasing decisions.

H.2 Pharmaceutical Sample Distribution:

- Pharmaceutical samples may not be delivered to or dispensed from a practitioner’s office location. For clinics located outside of the USC Health Science Campus, special procedures for distribution must be developed with and approved by the Office of Compliance.
- Pharmaceutical samples must be delivered to a campus pharmacy for storage and dispensing. The dispensing of samples must comply with the provisions of USC Care Policy 135 entitled: Centralized Sample Management Program.

H.3 Discounts:

It is permissible for USC Healthcare Professionals to accept discounts and other price reductions on goods or services only to the extent the discounts and price reductions comply with the federal Anti-Kickback laws and the following:

- USC Healthcare Professionals may only accept a discount that is made at the time they purchase the goods or services or where the terms of any rebate are fixed and set forth in writing at the time of the initial sale of a good or service.
- USC Healthcare Professionals who have received a discount must ensure that any invoice, coupon or statement provided by Industry accurately reflects the discounted price.
- USC Healthcare Professionals must retain documentation of any discount received from Industry for items or services billed to federal or state health care programs so that such documentation is readily accessible should it be requested by a federal or state health agency.

H.4 Under no circumstances may USC Healthcare Professionals charge a patient for a drug sample, or provide a drug sample to a patient, who is covered by a federal or state

Issued by: Chrysostomos L. Nikias
Executive Vice President and Provost

Todd R. Dickey
Senior Vice President, Administration

Date issued: September 1, 2009
University of Southern California
Page 12 of 19

health care program where the cost of the drug is otherwise included within the payment received from the federal or state health care program.

I. **Site Access by Industry Representatives**

I.1 Registration:

Industry representatives must be registered in USC's centralized Industry representative tracking system and comply with USC Care Medical Group Policy CL 135 entitled "Site Access by Pharmaceutical and Device Manufacturer Representatives." As a part of this registration process, representatives are required to:

- Provide their name, contact information, immediate supervisor and the contact information for the Industry company's Chief Compliance Officer;
- Attest that they will abide by this policy;
- Satisfy USC's credentialing requirements as applicable.

I.2 Site Access/Pharmaceutical Representatives: Site access by a registered Industry representative may occur only:

- By appointment with a USC Healthcare Professional;
- In non-patient care areas;
- After obtaining security identification pass. Industry representatives may obtain a pass by checking in at one of the Industry representative kiosks which are located at both the Health Science Campus and University Park Campus.

Representatives failing to obtain a security pass will be asked to leave the campus.

I.3 Site Access/Device Representatives: It is understood that site access by device manufacturers may be required for training or ongoing device refinement. Site access by a registered Industry representative in this case may occur only:

- By appointment with a USC Healthcare Professional;
- After obtaining a security identification pass; and
- After the patient has signed USC's applicable HIPAA authorization.

It is unacceptable for a device representative to be in a patient-care area solely for marketing purposes and with the intent of influencing a USC Healthcare Professional's treatment decisions.

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued:	September 1, 2009
	University of Southern California Page 13 of 19

J. Ghostwriting

The AAMC defines ghostwriting as “the provision of written material that is officially credited to someone other than the writer(s) of the material.” Transparent writing collaboration with attribution between academic and industry investigators, medical writers and/or technical experts is **not** ghostwriting. It is not permissible for USC Healthcare Professionals, students or trainees to allow their professional presentations to be ghostwritten by any party.

K. Recusal from Purchasing Decisions

Every employee of the university must avoid both actual conflicts of interest and the appearance of conflicts of interest and be in compliance with the university’s Conflict of Interest and Ethics Policy and Procedures.

USC Healthcare Professionals are obligated to disclose to the appropriate parties (e.g., Pharmacy and Therapeutics Committees, Chair/Supervisor), any past or current financial interests, management roles or consulting relationships with Industry which are relevant to the product/service under consideration.

USC Healthcare Professionals must recuse themselves from any purchasing deliberations or decisions relevant to the conflicting interests that pertain to the Industry’s products or services when there is an ongoing or current consulting relationship.

5.0 Enforcement

The Office of Compliance in conjunction with various impacted units is available as a resource for the implementation and interpretation of this policy. All USC Healthcare Professionals are encouraged to call the office should they need assistance or have questions about the policy.

5.1 Faculty and Staff: Sanctions for violations of this policy for faculty will be in accordance with the Faculty Handbook. Sanctions for violations of this policy for staff will be in accordance with the Staff Employment Policies and Procedures. Any disciplinary action against a faculty member or a staff employee under this policy should take into account the scale of the offense, the individual’s intent, and the degree of wrongdoing.

5.2 Students: Sanctions for violations of this policy for students will be in accordance with SCampus.

5.3 Industry: Violation of this policy by Industry representatives will result in disciplinary action, including but not limited to the following:

- Verbal and written warning to the representative and written notification to the representative’s supervisor. First violations will be documented in USC’s Site Access tracking system.

Issued by: Chrysostomos L. Nikias
Executive Vice President and Provost

Todd R. Dickey
Senior Vice President, Administration

Date issued: September 1, 2009

- Suspension of the representative from campus. The representative's supervisor must attest in writing that said representative has been counseled.
- Suspension of the representative and all other company sales/marketing representatives from campus and any other interactions with faculty/staff on or off campus for a period of six months.

Issued by: Chrysostomos L. Nikias Todd R. Dickey
 Executive Vice President and Provost Senior Vice President, Administration

Date issued: September 1, 2009

EXHIBIT A
Summary of Applicable Law and Standards

It is USC policy to ensure that all interactions with Industry are conducted in conformity with the federal Anti-Kickback laws, in addition to other applicable federal, state and local laws. Generally, the Anti-Kickback laws prohibit paying or receiving anything of value, for which one purpose is to induce the receiver to use, recommend or purchase any products or services that may be paid for by Medicare, Medi-Cal or any other state or federal health care program. Violations of the law are punishable by up to five years in prison, criminal fines up to \$25,000, administrative civil money penalties up to \$50,000, and exclusion from participation in federal health care programs.

USC policy is informed by the voluntary guidelines developed by the American Medical Association (Ethical Opinion E-8.061), the Pharmaceutical Research and Manufacturers of America “Code of Interactions with Health Care Professionals” (“PhRMA Code”), the Advanced Medical Technology Association’s “Code of Ethics on Interactions with Health Care Professionals” (“AdvaMed Code”), the Office of the Inspector General’s (“OIG”) “Compliance Program Guidance for Pharmaceutical Manufacturers” (“OIG Compliance Guidance”) and the ACCME Standards for Commercial Support (“ACCME Standards”).

In particular, USC seeks to comply with the general principles set forth in the OIG Compliance Guidance and to ensure that no interactions with Industry have the potential to improperly influence clinical decision-making, inappropriately increase Medicare/Medicaid or other insurance costs, increase the risk of overutilization of health care services, or create patient safety or quality of care concerns.

Shown below are links to the voluntary guidelines and government guidance noted above:

American Medical Association Ethical Opinion E-8.061

See <http://www.ama-assn.org>

PhRMA Code

See <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>

AdvaMed Code

See <http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf>

OIG Compliance Program Guidance for Pharmaceutical Manufacturers

See <http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>

ACCME Standards for Commercial Support

See http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf

Medicare Anti-Kickback laws

See http://www.law.cornell.edu/uscode/html/uscode42/usc_sec_42_00001320---a007b.html

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued:	September 1, 2009
	University of Southern California Page 16 of 19

EXHIBIT B

The following are the USC affiliated faculty practice plan corporations that are “Healthcare Professionals” under this policy*:

USC Occupational Therapy Associates, Inc.
USC Physical Therapy Associates, Inc.
USC Care Medical Group, Inc.

* Schools and departments that are not faculty practice plan corporations but who interact with Industry, including but not limited to, Dentistry, Pharmacy and the Student Health Center, are subject to the same obligations as the faculty practice plan corporations under this Policy.

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued:	September 1, 2009
	University of Southern California Page 17 of 19

EXHIBIT C

Specific Guidelines for establishing “Modest Value” in Meals, Travel and Lodging

For USC-related activities, “Modest Value” is defined by the USC Expenditure Manual (see www.usc.edu/policies). Modest value means modest by local standards, but in no event may exceed the following: (1) for out-of-town travel, the maximum value of meals, hospitality, travel (exclusive of plane fare) and lodging should not exceed the maximum rate of USC travel reimbursement for actual expenses, which is set each at a maximum dollar value; and (2) if only certain individual items are provided, those items should not exceed the maximum allowed per item.

For non-USC related activities, we recommend utilizing the USC definition of “modest value” along with the additional guidance provided below:

- *Lodging in Expensive Cities.* For travel to more expensive cities (e.g., New York, Boston and certain foreign cities), the maximum lodging per night may exceed the USC maximum allowable. To select lodgings in such cities that fall within the definition of modest value, utilize pricing guidance found in travel guides such as Fodors. For example, go to <http://www.fodors.com>. Click on the “hotels” tab and search for the city in question by price range. Do not select a hotel found in the most expensive category but rather one that is listed at no more than \$\$\$ by the Fodor scale.
- *Meals, Travel, Lodging and Other Incidentals beyond the Above Norms.* Meals, hospitality, travel and lodging outside these norms would not be incidental to the work involved under the consulting or other service contract. Such benefits are permitted only if treated as extra compensation that, combined with monetary compensation, is still fair market value for services provided by the USC Healthcare Professional.
- *Plane Fare.* First-class or business-class tickets are generally prohibited except as otherwise permitted by USC policy.
- *Locations of Meetings.* Meetings should take place at appropriate venues, such as conference hotels or other commercial meeting spaces, rather than at resorts.
- *Meals, Travel, Lodging must be Incidental.* Meals, receptions and other hospitality are permitted so long as they constitute only an incidental part of any meetings for consulting services. For example, in connection with an all-day meeting, a one-hour reception or meal would be acceptable. However, it would not be appropriate for an “all-day meeting” to consist of only three hours of lectures or meetings followed by an afternoon of golf or other entertainment at a resort paid for by Industry. In this case, the hospitality provided to the USC Healthcare Professional would not be incidental to the work involved under the consulting or other service contract. Such benefits are permitted only if treated as extra compensation that,

Issued by:	Chrysostomos L. Nikias Executive Vice President and Provost	Todd R. Dickey Senior Vice President, Administration
------------	--	---

Date issued:	September 1, 2009
	University of Southern California Page 18 of 19

combined with monetary compensation, is still fair market value for services provided by the USC Healthcare Professional.

Issued by: Chrysostomos L. Nikias Todd R. Dickey
 Executive Vice President and Provost Senior Vice President, Administration

Date issued: September 1, 2009
 University of Southern California
 Page 19 of 19