



School of Medicine

Policy on Conflicts of Interest and Interactions between Representatives of Certain Industries and Faculty, Staff and Students of the WSU SOM

Approved by the Executive Committee of the Faculty Senate 5-22-14

A. Scope of Policy

This policy applies to all faculty, staff, and students of the WSU SOM, and to all healthcare professionals and staff employed and/or contracted by domestic locations of WSU SOM, and to all facilities owned or controlled by the WSU SOM. Faculty and residents/medical students must comply with this policy regardless of practice or rotation site. This includes WSU SOM part time, Full Time Affiliate and Voluntary faculty. While this policy addresses many aspects of Industry interaction, it supplements the existing conflict of interest policies of the WSU SOM, particularly as they apply to research conflicts of interest:

This policy also supplements existing WSU SOM policies, including but not limited to:

- WSU Conflict of Interest Policy
<http://fisopsprocs.wayne.edu/policy/08-01.htm>
- WSU Policy on Financial Conflict of Interest and Commitment for Researchers
http://irb.wayne.edu/policies/14-1_conflict_of_interest_pi-key_personnel.pdf
<http://research.wayne.edu/coi/docs/wsufinancialconflictinterestandcommitmentresearchpolicy.pdf>
- WSU Policy on Consulting by University Faculty and Research Personnel
<http://fisopsprocs.wayne.edu/policy/03-4.htm>

In all cases where this policy is more restrictive than a University or WSU SOM policy, this policy shall control.

This policy applies to interactions with all sales, marketing, or other product-oriented personnel of Industry, including those individuals whose purpose is to provide information to clinicians about company products, even though such personnel are not classified in their company as “sales or marketing.”

B. Statement of Policy

It is the policy of the WSU SOM that clinical decision-making, education, and research activities be free from influence created by improper financial relationships with, or gifts provided by, Industry. For purposes of this policy, “Industry” is defined as all pharmaceutical manufacturers, and biotechnology, medical device, and hospital equipment supply industry entities and their representatives. In addition, clinicians and their staff should not be the target of commercial blandishments or inducements – great or small – the costs of which are ultimately borne by our patients and the public at large. These general principles should guide all potential relationships or interactions between WSU SOM personnel and Industry representatives. The following specific limitations and guidelines are directed to certain specific types of interactions. For other circumstances, WSU SOM personnel should consult in advance with their

deans or department chairs or their senior departmental administrators to obtain further guidance and clarification. Charitable gifts provided by industry in connection with fundraising done by or on behalf of WSU SOM shall be subject to other policies.

C. Specific Activities

1. Gifts and Provision of Meals

WSU SOM personnel shall not accept or use personal gifts (including food) from representatives of Industry, *regardless of the nature or dollar value of the gift.*

Gifts from Industry that incorporate a product or company logo on the gift (e.g., pens, notepads or office items such as clocks) introduce a commercial, marketing presence that is not appropriate to a non-profit educational and healthcare system. Meals or other hospitality funded directly by Industry may not be offered in any facility owned and operated by the WSU SOM.

WSU SOM personnel may not accept meals or other hospitality funded by Industry, whether on-campus or off-campus, or accept complimentary tickets to sporting or other events or other hospitality from Industry. Modest meals provided incidental to attendance at an off-campus event may be accepted.

Industry wishing to make charitable contributions to the WSU SOM may contact the WSU SOM Development Office or other charitable foundations legally organized to support other WSU SOM entities. Such contributions shall be subject to any applicable policies maintained by the WSU SOM and the receiving organizations.

2. Consulting Relationships

Faculty and trainees are permitted to engage in consulting relationships with Industry about research and scientific matters. Faculty may provide valuable advice to Industry in the service of product innovation or refinement. Examples of such legitimate activities include:

- Assistance in designing and overseeing clinical trials.
- Technical assistance in creating or improving medical devices.
- Advice on potential avenues for future scientific research.

WSU SOM recognizes the obligation to make the special knowledge and intellectual competence of its faculty members available to government, business, labor, and civic organizations, as well as the potential value to the faculty member, the University, and WSU SOM.

However, consulting arrangements that simply pay WSU SOM personnel a guaranteed amount without any associated duties shall be considered gifts and are consequently prohibited.

In order to avoid gifts disguised as consulting contracts, when WSU SOM personnel have been engaged by Industry to provide consulting services, the consulting contract must provide specific tasks and deliverables, with payment of fair market value commensurate with the tasks assigned.

The Dean, Department Chair or Senior Departmental Administrator reserve the right to require faculty or staff to modify or terminate consulting arrangements that are not consistent with WSU SOM policies. Faculty and trainees are prohibited from engaging in consulting relationships that are solely or primarily for commercial marketing purposes.

3. Site Access

The University and WSU SOM always reserve the right to refuse access to their facilities or to limit activities by Industry representatives consistent with their non-profit mission. However, interaction with representatives of Industry is appropriate as it relates to exchange of scientifically valid information and other data, interactions designed to enhance continuity of care for specific patients or patient populations, as well as training intended to advance healthcare and scientific investigation. Such access is restricted to their roles in providing technical assistance and education on products or medical devices.

All industry representatives must have an appointment before visiting any WSU SOM office or clinic. Enforcement of this policy is the responsibility of the administrator for each site. Individual physicians or groups of physicians or other healthcare professionals may request a presentation by or other information from a particular company.

Representatives without an appointment as outlined above are not allowed to conduct business in patient care areas (inpatient or outpatient), in practitioners' office areas, or other areas of WSU SOM clinical facilities. While in WSU SOM facilities, all Industry representatives must be identified by name and current company affiliation in a manner determined by such department, as applicable.

All Industry representatives with access to University and WSU SOM clinical facilities and personnel must comply with institutional requirements for training in ethical standards and organizational policies and procedures.

On-campus vendor fairs intended to showcase Industry products may be permitted if approved by the appropriate (WSU SOM or University) departments or Deans. Such events must comply with the "no gifts" provisions of Sections 1 and 3 of this policy. In such situations, vendors would not be permitted to distribute free samples, free meals, raffle tickets, or any other gifts to attendees.

4. Support of Continuing Education in the Health Sciences

Industry support of continuing education ("CE") in the health sciences can provide benefit to patients by ensuring that the most current, evidence-based medical information is provided to healthcare practitioners. In order to ensure that potential for bias is minimized and that CE programs are not a guise for marketing, all CE events hosted or sponsored by the WSU SOM physicians must comply with the ACCME Standards for Commercial Support of Educational Programs (or other similarly rigorous, applicable standards required by other health professions), whether or not CE credit is awarded for attendance at the event. All such agreements for Industry support must be negotiated through and executed by the WSU SOM Division of CME, and must comply with all policies for such agreements. Any such educational program must be open on equal terms to all interested practitioners, and may not be limited to attendees selected by the company sponsor(s). Industry funding for such programming should be used to improve the quality of the education provided and should not

be used to support hospitality, such as meals, social activities, etc. except at a modest level. Industry funding may not be accepted for social events that do not have an educational component. Industry funding may not be accepted to support the costs of internal department meetings or retreats (either on- or off-campus).

WSU SOM facilities (clinical or non-clinical) may not be rented by or used for Industry funded and/or directed programs, unless there is a CE agreement for Industry support that complies with the policies of the WSU SOM Division of CME. Dedicated marketing and training programs designed solely for sales or marketing personnel supported by Industry are prohibited.

5. Industry Sponsored Meetings or Industry Support for Off-Campus Meetings

WSU SOM faculty, personnel, or students or WSU SOM providers or staff may participate in or attend Industry-sponsored meetings, or other off-campus meetings where Industry support is provided, so long as: (a) the activity is designed to promote evidence-based clinical care and/or advance scientific research; (b) the financial support of Industry is prominently disclosed; (c) attendees do not receive gifts or other compensation for attendance; (d) meals provided are modest (i.e., the value of which is comparable to the Standard Meal Allowance as specified by the United States Internal Revenue Service) and consistent with the educational or scientific purpose of the event. In addition, if a WSU SOM representative is participating as a speaker: (a) all lecture content reflects a balanced assessment of the current science and treatment options, and the speaker makes clear that the views expressed are the views of the speaker and not the WSU SOM (b) compensation is reasonable and limited to reimbursement of reasonable travel expenses and a modest honorarium.

Travel sponsored by a membership based professional organization, with no commercial activity, is permitted.

6. Industry Support for Scholarships or Fellowships or Other Support of Students, Residents, or Trainees

The WSU SOM may accept Industry support for scholarships or discretionary funds to support trainee or resident travel or non-research funding support, provided that all of the following conditions are met:

- a. Industry support for scholarships and fellowships must comply with all University or WSU SOM requirements for such funds, including the execution of an approved budget and written gift agreement through WSU SOM Development Office, and be maintained in an appropriate restricted account. Selection of recipients of scholarships or fellowships will be completely within the sole discretion of the school in which the student or trainee is enrolled or, in the case of graduate medical education, the Program Director for the residency or fellowship. Written documentation of the selection process will be maintained.
- b. Industry support for other trainee activities, including travel expenses or attendance fees at conferences, must be accompanied by an appropriate written agreement and may be accepted only into a common pool of discretionary funds, which shall be

maintained under the direction of the dean or department (as specified in the funding agreement) for the relevant school. Industry may not earmark contributions to fund specific recipients or to support specific expenses. Departments or divisions may apply to use monies from this pool to pay for reasonable travel and tuition expenses for residents, students, or other trainees to attend conferences or training that have legitimate educational merit. Attendees must be selected by the department based upon merit and/or financial need, with documentation of the selection process provided with the request. Approval of particular requests shall be at the discretion of the dean.

7. Authorship and Speaking

Authorship on papers by WSU SOM personnel should be consistent with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship developed by the International Committee of Medical Journal Editors (www.icmje.org). Ghostwriting (honorary authorship) is explicitly forbidden.

The content of all presentations given or co-authored by WSU SOM personnel must be evidence based. All clinical recommendations must be in the best interest of patients based on evidence available at the time of the presentation.

Participation on pharmaceutical industry funded speaker's bureaus, i.e. promotional speaking concerning specific pharmaceutical products, is forbidden.

8. Other Industry Support for Research

WSU has established policies and contract forms to permit Industry support of basic and clinical research in a manner consistent with the non-profit mission of the University and WSU SOM. Researchers may accept, for testing purposes, samples of unique research items or drugs, produced by only one manufacturer, where no other alternatives exist. Should multiple options exist, acceptance of samples is acceptable only if received from all companies manufacturing similar products, so that a decision to purchase may be made based exclusively on the performance of the product, without preference for any given manufacturer.

All products received as gifts for research must be disclosed and explicitly acknowledged in all pertinent documents, including publications.

True philanthropic gifts from Industry may be accepted through the WSU SOM Development Office.

D. Reporting, Disclosure and Enforcement

WSU SOM personnel shall report their outside relationships with Industry using the Wayne State "Conflict of Interest Form" at least annually and more often as needed to disclose new relationships. All relevant outside relationships with industry will be made available to the public on the WSU SOM website.

Suspected violations of this policy shall be referred to the individual's department chair (in the case of the WSU SOM faculty), or to the individual's immediate supervisor (in the case of WSU SOM personnel), or both (in the case of persons with dual status), who shall determine what actions, if any, shall be taken. The Vice Dean for Clinical Affairs (clinical faculty) or Vice Dean for Faculty Affairs (basic science faculty) shall also be notified of suspected violations by WSU SOM faculty. Violations of this policy by a WSU SOM employee may result in the following actions (singly or in any combination), depending upon the seriousness of the violation, whether the violation is a first or repeat offense, and whether the violator knowingly violated the policy or attempted to hide the violation:

1. Counseling of the individual involved
2. Written reprimand, entered into the violator's employment or faculty record;
3. Banning the violator from any further outside engagements for a period of time;
4. Requiring that the violator return any monies received from the improper outside relationship;
5. Requiring the violator to complete additional training on conflict of interest;
6. Removing the violator from supervision of trainees or students;
7. Revoking the violator's WSU SOM clinical privileges;
8. Fines;
9. Termination for cause.

Any disciplinary action taken hereunder shall follow the established procedures of the University and/or WSU SOM.

Industry representatives who violate the above policies may be subject to penalties outlined in WSU SOM Guidelines for Purchasing Policy, or other applicable University or WSU SOM policies, as well as other actions or sanctions imposed at the discretion of the Dean of the Medical School. Such penalties include the following:

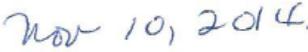
Violation of any of the above procedures by representatives shall result in disciplinary action, which may include but shall not be limited to the following:

1. First violation: Verbal and written warning to representative; written notification to district manager or representative's supervisor.
2. Second violation: Suspension of representative and all other company sales/marketing representatives from the WSU SOM for six months.
3. Third violation: Suspension of representative and all other sales and marketing representatives of the company from the WSU SOM for one year or more. A review of multi-source products obtained from the company will be conducted.

Representatives found trespassing as defined in this policy will be escorted from the premises and their companies notified as appropriate.

For Wayne State University School of Medicine

Signed: 
Valerie M. Parisi, M.D., M.P.H., M.B.A.
Dean, WSU SOM


Date