

CONFLICT OF INTEREST AND
DISCLOSURE POLICY OF THE JACOBS
SCHOOL OF MEDICINE AND BIOMEDICAL
SCIENCES¹

¹ Faculty Council approved—11/29/2017

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1 PREAMBLE

Increasingly there is concern nationally and internationally about perceived and potential conflicts of interest between physicians and the pharmaceutical, medical device, and other biotech industries.

While all relationships involve differing priorities and interests, the concern is that the *duality* of interests can become or can create the perception of *conflicts* that compromise education, patient care, research, or the integrity of the field. While this duality has been recognized for many years, because of decreases in support for the educational and research missions of academic medicine from federal and other traditional funding agencies, medical school departments increasingly look to other sources to support such vital functions. Medical schools have not been immune to these trends and there has been increasing concern about the degree of influence that industry exerts over individual residents and physicians, researchers, academic health centers, and the field as a whole. Recognized industry interactions include support of biomedical research; widespread presence at national, regional, and local organizational and educational conferences and activities; pervasive industry representatives, and meal support at meetings estimated to translate into thousands of dollars per physician annually.

In recognition of these issues, the University at Buffalo Jacobs School of Medicine and Biomedical Sciences (JSMBS) wishes to ensure that no activity of the JSMBS and its members is unduly influenced by industry or other potential and perceived interests, and that we assiduously avoid even the perception of abridgment of the implicit trust (which is based both on reality *and* perception) the public places in us to practice in the best interests of our patients and with the greatest integrity. The JSMBS therefore has developed a policy that embraces the following elements and values:

The fundamental commitments of the JSMBS are to advance scientific rigor, academic and clinical excellence, and the ethical underpinnings of practice, namely autonomy, beneficence, non-maleficence, and justice.

The pharmaceutical and device industries have provided much positive support for JSMBS functions including (but not limited to) grand rounds, major continuing medical education (CME) programs; book and travel allowances for trainees; research support; and the sponsorship of professional organizations. Industry has also provided notifications of product availability and exposure to proprietary information, assistance with the operation of complex devices, and samples for populations unable to afford or access medications.

The primary missions of clinical and academic medicine are to benefit patients and society and to acquire and disseminate knowledge. Medicine's primary responsibility is to patients.

Industry asserts that its primary aim is to benefit patients and society “by developing and marketing new [products]” (PhRMA Code); however, profit is fundamental to the existence of pharmaceutical and device companies and there exists a primary fiduciary responsibility to shareholders to maximize revenues.

Because of these fundamental differences between academic medicine and industry in aims and priorities, there is a potential for conflict of interest that must be addressed for the protection of our patients and society, as well as the University at Buffalo (“University” or UB) and JSMBS.

In order to address potential conflicts of interest an ethical framework must be applied to pragmatically address issues affecting the JSMBS, the faculty, and trainees and students.

While no policy can address every possible conflict, our intent is to promote an ongoing dialogue about what constitutes appropriate and constructive relationships between the JSMBS, its members, and industry.

Policies and procedures related to industry and other relationships will undoubtedly change over time, requiring ongoing review and modification.

The American College of Physicians (ACP) has adopted the principle of “a useful criterion in determining acceptable activities and relations is: would you be willing to have these arrangements generally known?” More specifically ACP expands this to: “What would my patients think about this arrangement? What would the public think? How would I feel if the relationship was disclosed through the media? What would my colleagues think about this arrangement? What would I think if my own physician accepted this offer?” We, as individuals and as members of the JSMBS faculty, should refrain from any activities that compromise the standing of the individual, the profession, the JSMBS, or University with respect to patients and their families, peers, and at times, public officials and the media. The spirit of this policy is to take an *affirmative stand* about our optimal relationships with industry.

The policy applies to all JSMBS full-time and volunteer faculty, residents, fellows, medical students and administrators, at all locations at which they work in any capacity, even if a site does not have a similar policy.

When a hospital or clinic has a less stringent conflict of interest policy, faculty members who work in those settings must follow the JSMBS policy. When regulations of New York State, the University at Buffalo, and accrediting bodies are more stringent than the JSMBS policy, those regulations must be followed in the settings in which the regulations apply (e.g., research, continuing medical education).

It is the obligation of all JSMBS faculty to understand and identify all potential conflicts of interest in their teaching, practice, research, and other scholarly activity. All conflicts, regardless of whether or not they are directly described in this document or covered under the separate *University at Buffalo Investigator Conflict of Interest Policy* must be either eliminated or promptly reported to the appropriate department chair for remediation.

2 POLICY SPECIFICS

2.1 University at Buffalo Investigator Conflict of Interest Policy

JSMBS adheres to the University at Buffalo Investigator Conflict of Interest Policy, which can be found at the Administrative Services Gateway—UB Policy Library (<http://www.buffalo.edu/administrative-services/policy1/ub-policy-lib/>). All elements of the University policy that are not specified in this document apply to JSMBS faculty. Additional policies specific to JSMBS faculty are outlined in this document.

2.2 Definitions of conflicts of interest

Conflicts of interest involve any situation in which a significant financial or other interest has the potential to influence or appear to influence clinical educational, service, or research decisions. University policy indicates that conflicts of interest may be financial (involving the potential for financial gain), general (involving personal gain or privileges) or conflicts of commitment (involving obligations, responsibilities or commitments that could interfere with a faculty member's primary responsibilities). Potential conflicts of interest apply to faculty members, spouses, domestic partner or similar relationship, dependent children, and any other family member residing in the same household.

2.2.1 Definitions of financial interest and significant financial interest

Any of the following within the past year is considered a significant financial interest:

- a. Equity interests (e.g., stocks, stock options, warrants, or other ownership interests) greater than \$5,000.00 by a faculty member, spouse or dependent child in the manufacturer or sponsor. Income from investment vehicles such as mutual funds and retirement accounts is excluded if the investigator does not control investment decisions made in these vehicles and is unaware of the actual equity interests included in the vehicles.
- b. Serving on a paid advisory board or as a paid consultant for a device or pharmaceutical company.
- c. Serving as a paid consultant or expert witness in cases involving clinical or investigational products.

- d. Paid trustee, director, officer, board member, owner, director or other office in a device or pharmaceutical company.
- e. Principal investigator on any industry sponsored study, including investigator initiated industry sponsored studies.
- f. Intellectual property rights to any product or device.
- g. Any royalty, licensing or other income linked to a product, or the contractual right to future royalties or other proceeds directly or indirectly under a pending or issued patent, license or other property right.
- h. Participating in an industry speaker's bureau.
- i. Other payments for services to a pharmaceutical or device company.
- j. Potential for financial benefit from an invention or patent owned by or licensed to a pharmaceutical or device company except for patent income paid directly from the University at Buffalo as noted below.
- k. Travel reimbursement or sponsorship except for travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, or a research institute that is affiliated with an institution of higher education.

2.2.2 Significant general and obligation interests

These include:

- a. Ownership or investment in an outside business or enterprise
- b. Serving as director, officer, partner, consultant or other agent of any outside enterprise
- c. Outside professional or other activity
- d. Other Employment

A significant financial interest exists if equity interests (e.g., stocks, stock options, warrants or other ownership interests) by a faculty member, spouse, or dependent child equals or exceeds \$5,000 in value in the aggregate over the past year as determined through reference to public prices or other reasonable measures of fair market value or represent more than a 5% ownership interest in a single entity, including non-publicly traded entities. In addition, aggregate remuneration to the faculty member, spouse, domestic partners and/or dependent children from activities listed in section 2.2.1 that equals or exceeds \$5,000 from a single entity constitutes a significant financial interest in that entity. Any intellectual property rights and interests, as well as related royalties, are considered to be significant financial interests except when these are received by current UB faculty from SUNY or the Research Foundation. UB considers any income from

foreign entities and sponsored travel to be significant financial interests. A significant obligation includes positions held by a faculty member or immediate family members as an officer, trustee, director, employee or consultant to any outside entity, regardless of whether the position is paid or the entity is for profit or not for profit that could appear to influence responsibilities as a faculty member. When a significant financial interest or obligation has the potential to conflict with research obligations, patient care, or service on committees such as pharmacy and therapeutics committees, the conflict must be managed or eliminated as described below.

The *University at Buffalo Investigator Conflict of Interest Policy* holds that significant financial interest does not include:

- a. Salary, royalties, or other remuneration paid to an investigator by the university (State, Research Foundation, or University at Buffalo Foundation (UBF)), if the investigator is currently employed or otherwise appointed by the university.
- b. Intellectual property rights assigned to SUNY or the RF and agreements to share in royalties related to such rights.
- c. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles.
- d. Income received from U.S. based organizations for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

3 FACULTY DISCLOSURE AND MANAGEMENT OF CONFLICT OF INTEREST

Disclosure of conflicts of interest for funded investigators follows the University's Investigator Conflict of Interest Policy.

3.1 Disclosure to the University at Buffalo of potential conflicts of interest

University policy requires disclosure of significant financial interests and obligations annually, in association with requests for research funding, Institutional Review Board (IRB) submissions and within 30 days of a new significant financial interest. Disclosures must be compliant with UB and NIH conflict of interest policies and procedures, including disclosure of conflicts of interest in public presentations or publications of research results.

3.2 Disclosure to the PHS/NIH/NSF of potential conflicts of interest

In accordance with the PHS Final Rule, conflicts of interest related to a PHS-sponsored grant should be described to the PHS in an initial report that includes the grant number, name of the PI or PD, name of the investigator with a conflict of interest, and whether the conflict of interest was managed, reduced or eliminated. An annual report should include status of the conflict of interest and any changes in the management plan. The initial report should include:

Name of the entity with which the conflict of interest exists

Nature of the conflict of interest (e.g., honorarium, equity, etc)

Value of the financial interest or statement that the value cannot be determined

Description of how the financial interest relates to the research

Basis for determination that a conflict of interest exists

Institutional management plan

3.3 Disclosure to patients of potential conflicts of interest

A financial relationship, or any other interest listed in section 2.2, with a manufacturer must be disclosed to patients as part of the process of obtaining informed consent involving a recommendation for any product made by that manufacturer. Such disclosure is necessary for any product made by a manufacturer with whom the faculty member has a financial interest, not just the product with which the faculty member has worked.

3.4 Public disclosure

Financial relationships as defined above must be made available to any requestor within 5 business days of a request for information being submitted to the University, the JSMBS, a faculty member's department, or a faculty member. The Office of the Vice President for Research will provide a web-based form for faculty to complete and update on a regular basis. The information will only be released in response to a specific request. The information should include:

- a. Investigator's name, title and role with request to a research project if applicable
- b. Name of the entity in which the faculty member has a financial interest
- c. Nature of the interest (e.g., consultant, honoraria, etc.)
- d. Value of the interest or a statement that the value cannot be determined

3.5 Disclosure to trainees/audiences

Faculty financial, general, and commitment interests should be disclosed to trainees and audiences not described elsewhere in this document.

3.6 Resolution and management of potential conflicts of interest

University policy states that conflicts of interest in research should be managed, reduced, or eliminated by divestiture of financial interests, modification of the research, or public disclosure and monitoring. In the JSMBS, disclosure is sufficient for treatment recommendations to patients, and educational and promotional presentations. In research and service on formulary committees, additional measures are necessary to resolve or manage conflicts involving significant financial interests.

3.6.1 Administrative recusal

The individual receiving report of a conflict should themselves be a disinterested party. If they have a significant interest, then they should recuse themselves from further discussions about the management, reduction, or elimination of the reported conflict. Examples would be if the reportee is a co-author or co-principle investigator in the work that generated the conflict, or if the reporter and reportee both have an interest in the same commercial entity.

3.6.2 Elimination of conflicts of interest

It is usually preferable to eliminate potential conflicts of interest by divesting oneself of one or more of the conflicting activities. For example, a faculty member who is PI on an industry sponsored study might not also serve on an advisory board or speaker's bureau for the same company, although it is permissible to perform one of these functions for another company. Alternatively, a faculty member might opt to retain the other relationship with the company and appoint a different PI while serving as a co-investigator on the study.

3.6.3 Reduction of conflicts of interest

A financial conflict of interest may be reduced so that it falls below the threshold that constitutes a significant financial conflict (See 1.B, above). Remuneration of less than \$5,000 annual or equity interests of less than 5% are allowable and do not require elimination, further reduction or management.

3.6.4 Management of conflicts of interest

With approval of the Dean or Vice President, in some instances, it may be appropriate to manage rather than eliminate the conflicts of interest. Examples of such situations include:

- a. The faculty member is best qualified to serve as PI.
- b. A proof of concept study is being conducted of an innovative therapy developed by the PI in collaboration with industry or developed by a company in which the PI has a significant interest.
- c. A multicenter industry sponsored trial is being conducted and the faculty member is a local PI but not the lead investigator.
- d. The faculty member receives royalties on a patent from work performed at another university.
- e. A potential conflict of interest has been identified and resolved less than one year before becoming PI or participating in another industry sponsored activity.

3.6.5 Management plans

A plan to manage a conflict of interest must be independently reviewed by the Dean (or designee) to insure that the management plan will be effective in preventing the conflicts of interest from influencing the conduct of research.

It is the responsibility of the faculty member to identify all potential elements of the conflict of interest and submit a written management plan.

A management plan should include a brief description of the proposed research or activity, conflicting significant financial interests, reasons why complete elimination of the conflict is not necessary or possible, and a mechanism by which the conflict will be managed using elements listed in the next section.

The management plan should be approved by the department chair and then by the Dean. A copy of the management plan signed by the investigator, chair and Dean must then be forwarded to the University Conflict of Interest Officer. To facilitate the efficient conduct of research, all approvals should occur in a timely manner (generally less than one week).

3.6.6 Management procedures

Procedures that may be used alone or in combination to manage continued conflicts of interest include, but are not limited to:

3.6.6.1 For research studies

- a. The conflict is identified to all subjects and personnel participating in the study and to the IRB.
- b. A data/safety/study monitoring board is appointed by the Dean or designate and reviews the study at an interval specified by the Dean.
- c. The PI does not oversee subject participation.
- d. The PI does not participate in evaluation of staff or faculty working on the study.
- e. The PI does not participate in the decision making process.
- f. The PI does not participate in data collection and data analysis.
- g. All conflicts of interest are reported in publications, posters, and other presentations of results.

3.6.6.2 For serving on advisory or consultant boards and speakers' bureaus

- a. The conflict is identified to other members of the board.
- b. The conflict is identified to the audience.
- c. Activities that create the conflict of interest are independently reviewed to ensure that one activity is not being influenced by the other (including peer review of industry supported lectures and other presentations).

3.6.6.3 For serving on formulary committees

Management of conflicts of interest on formulary committees is described in section 4.10.

3.6.7 Documentation and reporting requirements

The University's Investigator Conflict of Interest Policy outlines reporting requirements for funded research. All other conflicts of interest outlined in this policy should be managed by the Dean in consultation with the COI Committee.

A potential conflict of interest should be identified by the faculty member. If it is not, and the conflict is identified by another individual and the faculty member in question does not agree, or if a faculty member does not believe that an industry relationship results in a conflict of interest, the department chair will determine whether a conflict exists. Unresolved disputes will be addressed by the COI Committee

Any financial interest in a pharmaceutical or device manufacturer must be disclosed to attendees at educational events presented by the faculty member, research subjects, IRBs, patients and other groups described below. No further action is required for financial interests with the exception that the award of CME credit is dependent on managing conflict involving financial interest as described in the document discussed below and that

any faculty member participating in any manner on a PHS sponsored grant must adhere to the PHS Final Rule on Financial Conflict of Interest (August 25, 2011).

3.6.8 Appeals

Should a PI disagree with the Dean's finding in determining that an actual or potential conflict of interest exists, or disagree with the proposed remedy, the investigator may appeal to the JSMBS Conflict of Interest Committee who will then make a recommendation to the Dean. Unresolved appeals of a COI finding regarding research are mediated by the JSMBS COI Committee.

3.6.9 Waiver of the requirement to eliminate, reduce or manage significant conflicts of interest

In rare instances, there may be justification to permit research to be undertaken without the elimination, reduction or management of significant financial conflicts of interest. In the case of funded research other than that sponsored by the United States Public Health Service (PHS), the Dean or Vice President may recommend in writing to the University COI Officer that an activity go forward without imposing conditions or restrictions if the Dean or Vice President determines that imposing such conditions or restrictions would be ineffective and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare.

4 GUIDELINES FOR SUPPORT AND CONTACT WITH PHARMACEUTICAL AND DEVICE INDUSTRY REPRESENTATIVES

4.1 Contact with residents and students

In view of compelling evidence that resident prescribing behavior is influenced by interactions with industry representatives, as well as experience demonstrating that early interactions with representatives forms the basis of later interactions, residents and medical students should not have unsupervised contact with representatives. In most circumstances, residents and students should only interact with representatives in an educational context in which a faculty member demonstrates how to interpret the information that is presented. However, in selected settings it may be permissible for a faculty member to delegate to a device manufacturer representative the task of explaining to residents and students the actions and operation of the representative's product when the representative's knowledge of its operation is more extensive than the faculty member's, while the faculty member is otherwise engaged. The faculty member is responsible for ensuring that the interaction is restricted to an explanation of technical details of the product and that no marketing of the product occurs.

4.2 Scheduled vs informal contact with faculty

4.2.1 UBMD Practice sites.

At all sites at which full-time faculty provide clinical services (i.e., UBMD practice sites), including hospitals and clinics, there should be no unannounced or unscheduled contact between industry representatives and individual faculty members. Representatives can schedule appointments with faculty as faculty time and interest permits. Each UBMD practice site will designate an administrative support staff contact person and waiting area separate from patient waiting rooms (where possible) for industry representatives. On a schedule determined by each department, representatives from industry may have an opportunity to present information about their products to interested faculty and residents in a poster session in association with an industry symposium or other bona fide educational activity (see below). All interested representatives are eligible to present a poster for a fee negotiated with the department and paid to the practice plan.

4.2.2 Volunteer faculty practice sites.

Volunteer faculty members may schedule appointments with industry representatives. However, in all clinical settings, residents and students may not have any informal contact with industry representatives, they may not make independent appointments with industry representatives, and they may not interact with representatives without a faculty member present except as noted in section 4.1 (above).

4.3 Industry representatives in clinical areas

Industry representatives are generally not permitted in patient care areas. However, it is permissible for faculty members to meet with industry representatives in their clinical offices if patients are not present. At the specific invitation of a faculty member, representatives of device manufacturers may be present in patient care areas for technical procedures such as surgery and device insertion and programming if the representative is needed to explain the use of the product or might be needed to supply replacement parts. Such representatives must be registered at the institution. Identifying information about the patient may be made available to device industry representatives if necessary for device registration and follow-up and if HIPAA and institutional rules are followed. When they are involved in device insertion or maintenance, device manufacturer representatives must not promote the use of their product over other products.

4.4 Faculty industry liaison

A faculty or staff Industry Liaison (IL) will be appointed at each site at which UBMD provides clinical services to oversee, coordinate, and administer group educational and promotional activities. Each department may have an IL, or departments may share the same IL. This person will be the designated contact person for industry representatives

to arrange for group educational activities; distribution of literature, durable goods (e.g., CD ROMs, DVDs), and promotional items; and for accepting samples for resident and hospital clinics. The IL or a designated administrative support staff person will receive all gifts, literature, and other promotional items. These items will then be provided in a centralized manner (see below). All samples for resident services will be received by the IL and managed in accordance with the institutional policies for samples. No samples may be obtained or kept by residents or clinic directors for clinic use, unless designated by the IL or the Chair of the relevant department. Faculty practitioners may keep samples in their offices and are not required to use the IL. Volunteer faculty practicing in their own offices may follow whatever policy they prefer for receiving samples. However, residents or medical students assigned to those offices cannot accept any items from industry representatives. Any items for residents and students should go through the training director or director of medical student education.

4.5 Invitations to trainees to industry sponsored events

Invitations for trainees to industry sponsored activities outside of medical school functions should not be sent directly to residents or students. Instead, such invitations should be presented to the department's residency training director or director of medical student education (or their designees), who will decide whether to distribute them to selected residents or students.

4.6 Perquisites and paid activities

4.6.1 Gifts

No gifts from industry are permitted.

4.6.2 Educational Materials

Educational materials for patients, students, and others that are developed by industry may be accepted if they are the best source of such materials available and are for the purpose of education and not for the purpose of selling a product. Written materials and illustrations for patients are permitted for products for which the manufacturer's information and instructions are essential.

4.6.3 Travel support and conference fees

Direct industry support of travel for residents, fellows and students is prohibited. For faculty, funds from industry may only be accepted if the faculty member is a genuine consultant or participant (e.g. planning, presenting, receiving training, administering) for the activity, which must be primarily educational or professional in nature. Additional ACCME guidelines apply to activities for which CME credit is awarded.

4.6.4 Paid consultation to industry

Paid consultation is allowed for research and scientific activities. Consultation purely for marketing is prohibited. Reimbursement should be at fair market value. To avoid concerns about being paid twice for the same time, full-time faculty should engage in consultation to industry, speaking engagements and similar activities on their own time unless explicit provisos exist for being reimbursed by industry for activities during regular working hours.

4.6.5 Meals

Industry sponsored meals conducted in association with regular activities of JSMBS faculty, residents, fellows, students and staff at any location for meetings, grand rounds, conferences and similar activities must have a primary educational goal and focus and cannot involve any promotional activity including any presentation by industry representatives. Funding for meals associated with educational events must be paid to the department or practice plan; meals cannot be supplied directly by industry. However, the source of support for the meal may be acknowledged at the beginning of the meeting. Meals will be coordinated and scheduled through the IL, the Training Director or a designee of the department chair. The value of any food provided should be \leq \$10 per attendee.

4.7 Educational activities

4.7.1 Departmentally supported

Educational conferences sponsored by a department (including Grand Rounds and conferences) must follow Accreditation Council for Continuing Medical Education (ACCME) and other relevant guidelines if continuing medical education credits are to be awarded. Such guidelines are published in the document entitled “Guidelines for UB faculty involved in commercially supported CME programs”. In addition to ACCME rules,

- a. Industry support for an educational program must be through unrestricted educational grants and not by paying for speaker or other costs directly. Unrestricted educational grants will be accepted by departments or practice plans (not individuals) to subsidize educational activities. Speakers will be paid by the department or practice plan; speakers may not accept additional payments from industry for a departmental or practice plan event supported by an unrestricted educational grant.
- b. Industry sponsorship must be requested because it would be prohibitively expensive for the audience to attend without such support.
- c. Payment from industry to anyone with a full-time or volunteer faculty appointment is prohibited for presentations, lectures, case conferences or any other activity that

is part of the curriculum of any educational program for residents, medical students, or other trainees sponsored by JSMBS.

- d. Industry representatives may be present during grand rounds and during other CME activities but they may not be present in patient care areas before or after such presentations. No promotional activities (including individual contact with students or residents) or gifts are permissible in this setting. At CME events at which representatives have exhibits for a fee, the exhibits must be located separately from the educational event.

4.7.2 Support for JSMBS-sponsored activities

Departmental, practice plan, or JSMBS-sponsored retreats, meetings, symposia or other development activities may only be supported by unrestricted educational grants. Promotional materials (including branded items) may not be distributed at these activities.

4.7.3 CME activity review

To ensure absence of commercial bias, CME activities must be reviewed by the JSMBS Office of Continuing Medical Education.

4.7.4 Activity scheduling

Educational and promotional activities (e.g. teleconferences, lectures, etc) directly sponsored by industry or by a subcontractor to industry must occur outside of regular working hours and outside of assigned activities of full-time faculty, residents and medical students.

4.7.5 Faculty participation in promotional events

Faculty involvement in industry sponsored promotional events, including lectures and clinical discussions. Promotional activities are defined by any of the following:

- a. Identification as having the purpose of marketing industry products.
- b. All industry sponsored mealtime activities and presentations in offices and clinics.
- c. Industry generated slides and/or durable materials (i.e. written, CD, DVD, etc.) that are chosen by a company or its subcontractor and not by the speaker.
- d. All of the material presented is prepared or vetted by the company or its subcontractor.
- e. The agenda, topics of discussion, or cases presented are prepared by the sponsor. Sponsors include manufacturers and for profit third parties who subcontract the development of an event.

- f. Because promotional events are by their very nature biased, faculty members, students, fellows and residents are discouraged from attending such events. Should they choose to attend promotional events, residents, fellows and students must report each event they attend to the Training Director or Director of Medical Student Education so that their involvement in promotional activities can be monitored.
- g. Full time faculty members may not participate in promotional activities, including promotional talks and speaker's bureaus. If volunteer faculty members choose to participate in promotional events as speakers, any implication of endorsement, implicit support or other involvement by the University at Buffalo, the JSMBS, the department, or the practice plan in such activities must be avoided.
- h. Oral or written advertisements or any other communication of the promotional program, as well as slides presented during the presentation, may not include the faculty rank or university affiliation of the speaker.
- i. If the faculty title is mentioned when the speaker is introduced, the speaker should note that the presentation is separate from any departmental duties and the department, the practice plan, and the JSMBS do not endorse, support or benefit from the presentation in any way.
- j. Slides produced or vetted by industry should be identified as such.
- k. Faculty are responsible for ensuring that the industry representative as well as any third parties involved in the promotional event are aware of and will abide by the implementation of this policy.

4.8 Research

4.8.1 Conflicts of interest arising from significant financial interests of investigators

Conflicts of interest arising from significant financial interests of investigators with industry or its agents are governed by the University at Buffalo Investigator Conflict of Interest Policy and by additional requirements of the JSMBS outlined in this document. Monitoring and management of COIs in research is performed by the Dean, the COI committee, and the University COI officer.

4.9 Avoiding PI conflicts of interest

In order to minimize even the appearance of influence by industry on the outcome of research, faculty members with a significant financial interest in an entity or corporation should not serve as PI on any study sponsored by that entity or corporation without a waiver as described above. However, faculty members may serve as PI on more than one study supported by the same sponsor. Consistent with federal guidelines,

investigators serving as consultants or members of study sections for federal agencies must recuse themselves from discussions of their own studies and competing studies in the study section.

4.9.1 Review of industry sponsored clinical research

Relevant IRBs are charged with reviewing all research involving human subjects, including industry sponsored research. In addition, each department should ensure that industry sponsored studies are consistent with the missions of the department and the JSMBS, and that any increased burden on faculty members or staff as well as other departmental costs associated with the research are appropriately compensated by the grant so that the department, University and/or practice plan do not pay for industry sponsored product development.

4.9.2 Analysis and dissemination of clinical trial results

Investigators are accountable for the integrity of any publication that bears their names.

4.9.3 Authorship

Ghost writing and honorary authorship of research or any other publications are strictly prohibited.

4.9.4 Disclosure

Disclosure of conflicts of interest by PIs is governed by the University Conflict of Interest Policy (University policy) and the additional provisos for the JSMBS noted in this document.

4.9.5 List of authors

To ensure compliance with this policy, each proposal for external or selected types of internal support must be accompanied by a list of all Investigators.

4.9.6 UB policy on disclosures

As required by UB policy, all applications for external support submitted by the University and for selected types of internal support must be accompanied by appropriate disclosures. The Dean and the University COI officer will review all actual or potential financial conflicts of interest and plans for managing them. Conflicts of interest and management plans are reported to funding agencies in accordance with those agencies' requirements.

4.9.7 Confidentiality of disclosures

The review of financial disclosure forms requires all participants to exercise the utmost discretion. To the maximum extent permitted by federal and state law and by University policy, all elements of this process are to be treated as strictly confidential. The purpose of confidentiality is to assure that the integrity of the research and the privacy of the Investigator as well as the interests of the University are protected at all times.

4.10 Institutional and/or insurance formularies

Formularies must be developed with the most objective and unbiased data available and should not be subject to the perception of influence by faculty who could have an interest in the inclusion or exclusion of specific products. Ideally, faculty with significant financial relationships with industry should not be members of or make recommendations to formulary (e.g. “pharmacy and therapeutics”) committees at hospitals, insurers, or other institutions or organizations that make final decisions about health care products for large groups of individuals. When this goal is not possible, faculty members with significant relationships with a company should recuse themselves from all discussions in the formulary committee about any product of that company or a competing product for a similar indication.

5 EDUCATIONAL RESPONSIBILITY

It is the responsibility of the faculty to educate the university community about the influence of marketing and industry interactions on physician practice. A single activity may be used for education of more than one group. At the minimum, the following must be performed:

5.1 Dissemination

This policy should be disseminated to and discussed with all JSMBS full time and volunteer faculty, residents and students.

5.1.1 UB Investigator Conflict of Interest Policy

The University at Buffalo requires that training in the UB conflict of interest policy must be completed by new faculty members, faculty engaged in funded research, after failure to disclose or manage a significant COI, and after a significant change in the policy. Training must be repeated every four years. Faculty who begin funded research do not require additional training if they have completed training on the policy within the previous 4 years.

5.1.2 JSMBS Conflict of Interest Policy

The Conflict of Interest Committee will disseminate the policy and determine the method of training of faculty in the policy as described above. At a minimum, training should include review of the policy and affirmation of compliance with it. Faculty, medical students, fellows and residents are expected to read and abide by the relevant UB, AMA, ACCME, and ACGME guidelines

5.1.3 Training and education

Medical students and residents should receive at least one educational program on this topic during each year of training. In addition to the above activities, supplemental activities as described below are suggested for those with more frequent interactions with industry:

- a. One Grand Rounds per year should be dedicated to a discussion of industry conflicts of interest. Departments may collaborate in presenting joint grand rounds on this topic.
- b. Additional or alternative methods for education about conflicts of interest may be considered. Examples include:

During regularly scheduled classes, industry representatives may be invited to present peer reviewed articles relevant to their products. For example, representatives from industry might present information during a class on antibiotic treatment. These presentations will be followed by critiques by a faculty member and discussion by residents.

An industry symposium may be held 1-3 times per year during which representatives or others (e.g., MSLs) from industry present peer reviewed research they feel is relevant to their products. Each presentation will be followed by a discussion of methodology and interpretation of results by a faculty member. Faculty discussants will then formally summarize clinical and research implications of the presentations, followed by general discussion. An “Industry Fair” may be held before each symposium with lunch provided by the department, not by industry (although unrestricted grants to the department or practice plan to support lunch are permissible). Representatives who pay an appropriate fee may display promotional material prior to the symposium in a room separate from the symposium and separate from where lunch is available. Consistent with FDA regulations, industry displays may not be located directly in the path attendees must take to attend the symposium.

Structured educational programs on conflict of interest will be presented to faculty, residents, and students and published on the JSMBS website.

6 MONITORING AND COMPLIANCE

6.1 JSMBS Standing Committee on Conflict of Interest (COIC)

The COIC is a standing committee of the JSMBS Faculty Council reporting to the Dean and the Faculty Council. Their charge is to review and propose updates to this policy, maintain the “Conflict of Interest FAQ” on the Faculty Council web site, and to provide COI mediation and advice. Industry representatives as well as representatives from other funding agencies and University at Buffalo officials may be invited to portions of the committee’s meetings to discuss industry relations with the JSMBS and evolving guidelines and policies. This structure is designed to create an atmosphere of collaboration in the best interests of the patients, medical students, the JSMBS, funding agencies, and industry. The committee is charged with monitoring and proposing amendments and changes to policy, as well as providing input to the administration of the JSMBS for reporting purposes. The COIC will review the policy outlined in this document at least biannually. The COIC will also be responsible for educating the faculty about the overall conflict of interest policy, and for mediating disputes about COI management within the JSMBS that are not covered by the UB Investigator Conflict of Interest Policy.

Members of the COIC and its chairman will be nominated by the Steering Committee of the Faculty Council and appointed by the Dean. The Committee will be comprised of five members and two alternates, all selected for three year terms from the faculty of the JSMBS.

Two members will rotate off the Committee each year. The chairman will serve for two years and will be replaced by a member who has served for at least one year. If a committee member is directly involved in a particular case of conflict of interest, he/she will be recused from the deliberations of that case.

6.2 Reporting responsibilities

In accordance with University policy, investigators must complete an “Investigator Disclosure Statement” when applying for funded research or prior to activation of an award, whichever occurs first, before submission of a protocol to the IRB, within 30 days of discovering a new COI, and annually thereafter. Other conflicts of interest must be disclosed as previously described (Section 3). Departments must keep a file summarizing actual and potential conflicts of interest among full time faculty.

6.3 Noncompliance

It is expected that this policy will be followed by residents, fellows, students, faculty, staff and industry representatives. A single violation of policy by an industry representative will result in a warning letter to that individual with a copy to the district manager. Violations of policy that occur at an affiliated hospital will also be forwarded to the Corporate

Compliance Officer of that site who oversees industry representatives' professional conduct. Following a second violation, the representative will be denied access to all JSMBS clinical sites (ECMC, BGH, WCHOB, Great Lakes Health, VA Medical Center, outpatient sites, etc.) for one year. A warning letter will be sent to volunteer faculty members who violate the JSMBS policy for the first time. Subsequent violations may result in revocation of the volunteer faculty appointment. Violations by full time faculty members will be addressed on an individual basis by the department chair, in collaboration with the COIC and the Dean. If the Chair, Dean, or members of the COIC have a significant interest, then they should recuse themselves from further discussions regarding the violation. For nonadherence to conflict of interest policies in research, retraining in the policy is required, and referral to the Provost may be necessary for repeated failure by an investigator to comply with policies regarding management of conflicts of interest.

Any disciplinary actions must be consistent with established UB and State University of New York Board of Trustees policies, and applicable collective bargaining agreements. Article 19 of the UUP Agreement shall be the sole source of University discipline for members of the UUP-represented unit. Upon completion of disciplinary proceedings, the Provost or appropriate vice president may report to the appropriate University officers or bodies, to cognizant federal agencies when federal funds are involved, and to other parties as necessary. The University may require the Investigator to include a notice, with each public presentation of research and creative activity, of conflicts of interest that were not disclosed or resolved prior to the expenditure of funds or which arose during the course of the activity.