

Conflict of Interest and Disclosure Policy

September 24, 2014

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 School of Medicine and Biomedical Sciences (SMBS or “School”) wishes to ensure that no activity of the SMBS and its members is unduly influenced by industry, 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 School therefore has developed a policy that embraces the following elements and values:

1. The School’s fundamental commitments are to advance scientific rigor, academic and clinical excellence, and the ethical underpinnings of ethical practice, namely autonomy, beneficence, nonmaleficence, and justice.
2. The pharmaceutical and device industries have provided much positive support for SMBS 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.
3. 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.
4. 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.
5. 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”) and SMBS.
6. In order to address potential conflicts of interest an ethical framework must be applied to pragmatically address issues affecting the SMBS, the faculty, and trainees and students.

7. 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 SMBS, its members, and industry.
8. Policies and procedures related to industry relationships will undoubtedly change over time, requiring ongoing review and modification.
9. 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 medical school faculty, should refrain from any activities that compromise the standing of the individual, the profession, the SMBS, 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.
10. This policy will address the following:
 - I. Definitions of Conflict of Interest
 - II. Faculty disclosure and management of conflicts of interest
 - III. Guidelines for support from and contact with the pharmaceutical, biotechnology and device industries (“industry”) and their representatives, including
 - A. Contact with industry representatives
 - B. Perquisites
 - C. Educational activities
 - D. Research
 - E. Patient care and other service
 - IV. Education of faculty and trainees about relations with industry and conflicts of interest
 - V. Monitoring and compliance with the guidelines
 - VI. Appeal process
11. The policy applies to all SMBS 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.
12. When a hospital or clinic has a less stringent conflict of interest policy, faculty members who work in those settings must follow the SMBS policy. When regulations of New York State, the University at Buffalo, and accrediting bodies are more stringent than the SMBS policy, those regulations must be followed in the settings in which the regulations apply (e.g., continuing medical education).

Policy Specifics

I. Definitions of Conflicts of Interest

- A. Conflicts of interest** involve any situation in which a significant financial interest (defined in **section I, B**) has the potential to influence or appear to influence clinical,

educational, service, or research decisions. In accordance with University policy, a significant conflict of interest in research can also exist when:

1. A significant financial interest of an investigator would reasonably be expected to be affected by the design, conduct or reporting by the Investigator of a University research, educational or public service activity.
2. An Investigator has a significant non-University obligation to an individual or entity that provides support for a University research, educational or public service activity.
3. An Investigator has a non-University obligation to an individual or an entity to which the University provides support through an agreement to perform a program, project, activity or service involving the Investigator.

B. Definitions of financial interest and significant financial interest. Any of the following within the past year is considered a financial interest:

1. Equity interests (e.g., stocks, stock options, warrants, or other ownership interests) by a faculty member, spouse or dependent child in the manufacturer. 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.
2. Serving on a paid advisory board or as a paid consultant for a device or pharmaceutical company.
3. Serving as a paid consultant or expert witness in cases involving clinical or investigational products.
4. Paid trustee, director, officer, board member, owner, director or other office in a device or pharmaceutical company.
5. Principal investigator on any industry sponsored study, including investigator initiated industry sponsored studies.
6. Intellectual property rights in a product of the company.
7. Participating in an industry speaker's bureau.
8. Other payments for services to a pharmaceutical or device company.
9. 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.
10. 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

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).

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 I,B, 2-9** above that equals or exceeds \$5,000 from a single entity constitutes a significant financial interest in that entity. When a significant financial interest has the potential to conflict with research obligations or service on committees such as pharmacy and therapeutics committees, the conflict must be managed or eliminated as described in **section II, C** below.

University policy (Investigator Disclosure Policy: <http://www.research.buffalo.edu/ovpr/policies/discl.cfm>), which applies equally to SMBS faculty who are not investigators, holds that significant financial interest does not include:

1. Salary, royalties or other remuneration paid to an Investigator by the University;
2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
3. Income from service on advisory committees or review panels for public or nonprofit agencies, foundations, professional societies or advocacy groups.

A disclosure of potential conflict of interest in research or formulary committee service 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. The chair's determination may be appealed as described in **section VI**, below.

II. Faculty Disclosure and Management of Conflict of Interest

According to the University's Investigator Disclosure Policy, "the cognizant dean(s) or cognizant vice president(s) shall be the University's designated officials responsible for reviewing Investigator financial disclosure statements in the context of each proposal and/or award and for determining whether a conflict of interest or appearance of conflict of interest exists, and shall determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce or eliminate such conflicts. Cognizant deans and cognizant vice presidents have primary responsibility for assisting investigators to identify areas of potential concern and, whenever possible, for instituting remedies that permit affected research, creative activity or public service activity to proceed. Remedies instituted by cognizant deans and cognizant vice presidents to manage, reduce or eliminate conflicts of interest shall be in writing, signed by all affected parties, and a copy shall be forwarded to the Vice President for Research."

- A. Disclosure to the University of potential conflicts of interest.** University policy states that “The Annual Disclosure of Significant Financial Interests and Significant Obligations will serve as the mechanism for disclosing financial interests and obligations by all Investigators at the University.” New financial interests that occur after the annual disclosure should be disclosed to the SMBS within 30 days. A form will be developed by the Relations With Industry Committee to facilitate this process. Disclosures must be compliant with NIH conflict of interest policies and procedures.
- B. 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:
1. Name of the entity with which the conflict of interest exists
 2. Nature of the conflict of interest (e.g., honorarium, equity, etc)
 3. Value of the financial interest or statement that the value cannot be determined
 4. Description of how the financial interest relates to the research
 5. Basis for determination that a conflict of interest exists
 6. Institutional management plan
- C. Disclosure to patients of potential conflicts of interest.** A financial relationship 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.
- D. Public disclosure.** Financial relationships as defined in IB, above must be made available to any requestor within 5 business days of a request for information being submitted to the University, the SMBS, 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:
1. Investigator’s name, title and role with request to a research project if applicable
 2. Name of the entity in which the faculty member has a financial interest
 3. Nature of the interest (e.g., consultant, honoraria, etc)
 4. Value of the interest or a statement that the value cannot be determined
- E. Disclosure to trainees/audiences.** Faculty financial relationships should be disclosed to trainees and audiences not described elsewhere in this document.
- F. 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 SMBS, disclosure is sufficient for treatment recommendations to patients, educational and

promotional presentations and University reporting as required by University policy. In research, and service on formulary committees, additional measures are necessary to resolve or manage conflicts involving significant financial interests.

1. **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, after consultation with the cognizant dean(s) as stated in the Investigator Disclosure Policy, a faculty member can opt to retain the other relationship with the company and appoint a different PI while serving as a co-investigator on the study.
2. **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. **Management of conflicts of interest.** After consultation with the cognizant dean(s) as stated in the Investigator Disclosure Policy, in some instances, it is 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.
4. A plan to manage a conflict of interest must be independently reviewed by the Dean's Office (see **section II, C, 3.a-e**) to insure that the management plan will be effective in preventing the conflicts of interest from influencing the conduct of research.
 - a. It is the responsibility of the faculty member to identify all potential elements of the conflict of interest and submit a written management plan.
 - b. 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.
 - c. The management plan should be approved by the department chair and then by the Dean or designate. In accord with University's Investigator Disclosure Policy, a copy of the management plan signed by the investigator,

chair and dean must then be forwarded to the Vice President for Research. To facilitate the efficient conduct of research, all approvals should occur in a timely manner (generally less than one week).

5. Procedures that may be used alone or in combination to manage continued conflicts of interest include but are not limited to:
 - a. For research studies:
 - 1). The conflict is identified to all subjects and personnel participating in the study and to the IRB.
 - 2). A data/safety/study monitoring board is appointed by the Dean or designate and reviews the study at an interval specified by the Dean.
 - 3). The PI does not oversee subject participation.
 - 4). The PI does not participate in evaluation of staff or faculty working on the study.
 - 5). The PI does not participate in the decision making process.
 - 6.) The PI does not participate in data collection and data analysis.
 - 7). All conflicts of interest are reported in publications, posters, and other presentations of results.
 - b. For serving on advisory or consultant boards and speakers' bureaus
 - 1). The conflict is identified to other members of the board.
 - 2). The conflict is identified to the audience.
 - 3). 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).
 - c. Management of conflicts of interest on formulary committees is described in **section III, E** below.
6. **Document and Reporting Requirements.** The University's Investigator Disclosure Policy requires that "Remedies instituted by cognizant deans and cognizant vice presidents to manage, reduce or eliminate conflicts of interest shall be in writing, signed by all affected parties, and a copy shall be forwarded to the Vice President for Research" (UB Investigator Disclosure Policy, Section IV.4).
7. **Appeals.** Should a PI disagree with the cognizant 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 Associate Vice President for Research (AVPR) within then (10) working days of the dean's decision. The AVPR will render a judgment within ten (10) working days of receipt of the appeal (UB Investigator Disclosure Policy, Section VII).
8. **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. UB's Investigator Disclosure Policy states that "with the exception of activities sponsored by the United States Public Health Service (PHS), the cognizant dean or cognizant vice president may recommend in writing to the Vice President for Research 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. Research, training or educational activity in question may not commence until a final decision has been made in writing by the Vice President for Research” (Investigator Disclosure Policy, Section VI).

III. Guidelines for support and contact with pharmaceutical and device industry representatives

A. Contact with industry representatives

1. Contact with residents. 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, 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 product occurs.

2. Scheduled vs informal contact with faculty.

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 university 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.

3. 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 III, A, I** above.

4. 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.

5. 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 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.

6. Invitations. Invitations for trainees to industry sponsored activities outside the School 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.

B. Perquisites and paid activities

1. Gifts. No gifts from industry are permitted.

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.

3. Travel support (including 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. 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.

5. Industry sponsored meals conducted in association with regular activities of SMBS 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 must be ≤ \$10 per attendee.

C. Educational activities

1. 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.

cd 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.

2. Departmental, practice plan, or SMBS-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.

3. To ensure absence of commercial bias, CME activities must be reviewed by the relevant departmental CME committee and by the SMBS CME Committee. As provided in medical school rules, the latter committee will certify absence of any commercial interest in the activity.

4. 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.

5. 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.) 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 to whom the 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 SMBS or the department or practice plan in such activities must be avoided.

- 1). 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.
- 2). 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 SMBS do not endorse, support or benefit from the presentation in any way.
- 3). Slides produced or vetted by industry should be identified as such.
- 4). 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.

D. Research

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 Disclosure Policy and by additional requirements of the SMBS outlined in this document. The University disclosure policy assigns the authority for monitoring and addressing conflicts to the Dean of the School of Medicine and Biomedical Sciences, or his/her designee.
2. 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 ¹should not serve as PI on any study sponsored by that entity or corporation without a waiver as described in **section II, C**. 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.
3. 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 the industry sponsored studies are consistent with the missions of the department and the School 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. Analysis and Dissemination of the Results of Clinical Trials. Investigators are accountable for the integrity of any publication that bears their names.
5. Ghost writing and honorary authorship of research or any other publications are strictly prohibited.
6. Disclosure statements (Annual Disclosure of Significant Financial Interests and Significant Obligations) must be submitted to the cognizant dean(s) or cognizant vice president(s) not later than the time applications for external and selected types of

internal support are submitted by the University, or prior to acceptance of an award made without prior submission of a proposal. Disclosure statements may also be submitted at any other time, but must be updated whenever significant financial interests or obligations change during the period of the proposal and the performance period of the award.

7. 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.

78 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 written certification by the cognizant dean or cognizant vice president that the appropriate disclosure form has been submitted. Applications for support of a University program, project, activity or service will not be submitted to an outside party, unsolicited support will not be accepted by the University and selected University internal support will not be awarded unless accompanied by the cognizant dean or cognizant vice president's certification that the appropriate disclosures have been made.

a. In instances where a cognizant dean or cognizant vice president is an Investigator on an application for external or selected types of internal support, the Vice President for Research shall be responsible for reviewing financial disclosure statements, determining whether a conflict of interest exists, and shall determine what conditions or restrictions, if any, should be imposed by the University to manage, reduce or eliminate such conflicts.

b. On receipt of a grant award, the Office of Sponsored Projects Services shall request that the cognizant dean's or cognizant vice president's office (or their delegate) certify that no conflict of interest or conflict of obligation exists, or that any such conflict has been resolved. No funds for externally or selected types of internally funded projects may be expended until all conflicts of interest have been managed, reduced or eliminated as outlined in **section II, C** above.

c. The Vice President for Research shall report to the appropriate funding source any instance where an Investigator participating in funded research or creative activity has not complied with this Policy, and the specific corrective measures taken by the University.

d. 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.

e. When it is determined there is a conflict of interest involving staff responsible for the design, conduct or reporting of a sponsored project, the Vice President for Research will, consistent with university and sponsor policy, report the conflict to the sponsor and provide assurance that the conflict has been managed, reduced, or eliminated.

- f. The Vice President for Research shall inform all sponsoring entities of cases in which the University is unable to satisfactorily manage a conflict of interest.

The University will maintain all disclosures and records of actions taken to resolve conflicts of interest for at least three (3) years after the termination or completion of the award to which they relate, or until after the resolution of any state or federal government action involving those records whichever is later. Maintenance of these materials will be the responsibility of the cognizant deans and cognizant vice presidents.”

- E. Conflicts of interest with 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.

- IV. Education about relations with industry, conflicts of interest and interpretation of information provided by industry.** 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 as in **section IV, C** below. At the minimum, the following must be performed:

- A. This policy should be disseminated to and discussed with all SMBS full time and volunteer faculty, residents and students
1. Training in the conflict of interest policy must be completed by
 - a. New faculty members
 - b. Faculty members who are noncompliant with the policy
 2. Training should occur prior to engaging in funded research, every four years after joining the faculty, and whenever a significant change in the policy occurs
 - a. Faculty who begin funded research do not require additional training if they have completed training on the policy within the previous 4 years
 3. The Relations With Industry Committee (V, A, below) 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.

- B. Faculty, medical students, fellows and residents are expected to read and abide by the relevant AMA, ACCME, and ACGME guidelines
- C. 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 potential interactions with industry:
1. 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.
 2. Additional or alternative methods for education about conflicts of interest may be considered. Examples include:
 - a. During regularly scheduled classes, industry representatives (usually representing at least two competing products) may be invited to present peer reviewed articles relevant to their products. For example, representatives from industry making two different antibiotics might present information during a class on antibiotic treatment. These presentations will be followed by critiques by a faculty member and discussed by residents.
 - b. An industry symposium may be held 1-3 times per year during which representatives from two companies or experts to whom they delegate this task 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.
 - c. . Structured educational programs on conflict of interest will be presented to faculty, residents, and students and published on the SMBS website.

V. Monitoring and compliance

- A. Relations with Industry Committee (RIC).** This is an action committee of the SMBS Faculty Council composed of faculty and residents, reporting to the Dean and the Faculty Council. Industry representatives as well as representatives from other funding agencies and

University officials are invited to portions of the committee's meetings to discuss industry relations with the SMBS and evolving guidelines and policies. This structure is designed to create an atmosphere of collaboration in the best interests of patients, the SMBS, 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 SMBS for reporting purposes. The RIC will review the policy outlined in this document at least biannually. The RIC will also be responsible for educating the faculty about the overall conflict of interest policy as described in IV, E, above.

Members of the RIC 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 Medical School. 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.

B. Reporting responsibilities. As required by University policy (Investigator Disclosure Policy: <http://www.research.buffalo.edu/ovpr/policies/disl.cfm>), faculty must report potential conflicts of interest with industry on a yearly basis, or more frequently should there be a material change in a particular faculty member's financial relationship with industry. An annual report must be generated by each department summarizing actual and potential conflicts of interest among full time faculty.

C. Nonadherence. 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 SMBS 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 SMBS 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 RIC and the Dean. For nonadherence to conflict of interest policies in research, retraining in the policy is required. In addition, University policy holds that:

"The Vice President for Research shall report promptly in writing to the Provost all cases in which an Investigator has failed to comply with the University's Investigator Disclosure Policy or the means determined to resolve a conflict of interest. In such cases, the Provost shall, at the direction of the President, institute disciplinary proceedings against an Investigator who has failed to comply with the disclosure policy."

1. Disciplinary sanctions may include termination or alteration of the employment or academic status of persons against whom charges have been substantiated,

and 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.

2. Upon completion of disciplinary proceedings, the Provost or appropriate vice president shall report to the appropriate University officers or bodies, to cognizant federal agencies when federal funds are involved, and to other parties as necessary.
3. The University shall 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.”

The waiver process for research and other activities is summarized in **section II,C**.

- VI. Appeal.** With regard to research, University policy states that should an investigator disagree that a significant conflict exists, “or [should the investigator] disagree with the proposed remedy, the investigator may appeal to the Associate Vice President for Research within ten (10) working days of the dean's or vice president's decision. The Associate Vice President for Research will review the case, seek the advice of the Advisory Panel on Responsible Conduct, and render a judgment within ten (10) working days of receipt of the appeal. No expenditures for external and selected types of internal support of a program, project, activity or service may be made by the University until a final decision has been made.

When a cognizant vice president serves as the reviewer of a disclosure statement, the appeal shall be to the Vice President for Research. When the Vice President for Research serves as the reviewer of a disclosure statement ... the appeal shall be to the Provost.”

In the SMBS, appeals of conflict of interest determinations and remedies may be made to the department chair, and then to the Dean. If the conflict of interest applies to the department chair, appeal is to the Dean. If the Dean is the faculty member with a conflict of interest, appeal is to the Vice President for Research for research activities. Decisions of the Dean on appeals are then forwarded to the Associate Vice President for Research for final action in accordance with University policy.