Wake Forest Baptist Medical Center	Policy on Conflict of Commitment and Conflict of Interest	Type:	Tier II
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Typed Name and Title: John D. McConnell, MC Chief Executive Officer	

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I. General Purpose

The purpose of this policy is to provide guidelines for establishing principled outside relationships with industry and other organizations and to establish rules for interactions with Industry, medical service representatives and other vendors throughout Wake Forest Baptist Medical Center (Institution), defined as Wake Forest University Health Sciences (WFUHS) and North Carolina Baptist Hospital (NCBH) and their controlled affiliates, while remaining in compliance with disclosure, management and approvals. The Institution supports principled relationships with industry and other organizations in which its faculty and staff collaborate. The Institution has adopted this policy to promote the public's trust in the Institution and the healthcare profession. The policy supports the highest level of patient care, objectivity of education, the reputations of faculty and staff, and their professional commitment to the Institution. The policy is also designed to protect the integrity of research and the safety of human subjects involved in research..

A. Scope of Policy

Faculty and exempt employees are required to disclose to the Institution any outside interests, including time commitments and financial relationships, with Industry or other outside organizations, including outside interests of immediate family members that are related to Institutional duties. The Conflict of Interest Office will assist faculty and exempt employees in managing any associated conflicts of interest or commitment which might arise in permissible personal outside financial relationships, and eliminating those that cannot be effectively managed.

This policy applies to all faculty members, NCBH or WFUHS employees, students, trainees or volunteers and employees of WFBMC's controlled affiliates. Provisions addressing disclosure are specified in sections III and IV.

B. Responsible Parties

Policy Owner: Medical Center Conflict of Interest Office

Procedure: Medical Center Conflict of Interest Office

Supervision: Office of Compliance

Implementation: Executive Management

II. Definitions

A. **Individual:** a faculty member, NCBH or WFUHS employee, student, trainee or volunteer who owes a primary duty of loyalty and support to the Institution, including part-time appointments. *Individual includes spouse and dependent children when considering financial or fiduciary interests*

B. **Institution**: Wake Forest Baptist Medical Center, defined as Wake Forest University Health Sciences and North Carolina Baptist Hospital and their controlled affiliates

C. **Industry*:*** biomedical, pharmaceutical and medical device companies and companies that make other products used in the treatment of patients or the provision of medical care and/or vendors of the Institution

D. **Income:** the amount of money received during a period of time in exchange for labor or services, from the sale of goods or property, or as a profit from financial investments.

E. **Entity:** a for-profit or not-for-profit organization for which an Individual spends considerable time and/or receives income

F. **Equity:** the ownership interest of shareholders in a for-profit corporation, partnership, or similar organization, as determined through reference to public prices or other resources of fair market

value.

G. **Conflict of Commitment**: a situation in which an Individual's Outside Interests may appear to interfere with the Individual's ability to fulfill his or her commitment to the Institution; or an Individual's responsibilities, financial interest or opportunity for personal benefit in connection with an Outside Interest may appear to interfere with the Individual's professional judgment in exercising any Institutional duty or responsibility. Any relationship with an outside entity that requires frequent and/or prolonged hours of effort spent outside the Medical Center may present a conflict of commitment, *regardless of amount of income received or the, number of days, time of day or day of the week devoted to these activities.*

1. Reportable conflicts of commitment include, but are not limited to ongoing or repetitive arrangements with outside entities include consulting, speaking, expert testimony, paid court appearances, research, laboratory testing, and teaching. Other reportable activities are fiduciary and management roles in organizations outside the Institution, including board of directors, officer, manager, or medical director of a for-profit company, non-profit organization or charitable foundation.
2. Non-reportable conflicts of commitment include writing, membership on peer review panels, visiting professorships or lectureships at academic medical centers, federal and non-federal study section membership, grant review panels, textbook editorships, membership on advisory groups/councils for not-for-profit organizations, and fiduciary and management roles in academic societies.

H. **Conflict of Interest**: in professional and scientific endeavors refers to a situation in which financial or other personal considerations may compromise, or have the appearance of compromising, an Individual's professional judgment in conducting or reporting research, patient care, or carrying out or directing other types of institutional programs. The bias that may result from such conflicts could impact not only the collection, analysis, interpretation and reporting of data, but also on the hiring of staff, procurement of materials, or other activities influencing the course of the institution's objectives.

I. **Industry-Sponsored Travel**: Individuals must disclose on the *Travel Authorization* the occurrence of any reimbursed or industry-sponsored travel (i.e., that which is paid on behalf of the Individual and not reimbursed to the Individual so that the exact monetary value may not be readily available), related to the Individual's institutional responsibilities. However, the disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

1. A federal, state, or local government agency
2. An Institution of higher education as defined at 20 U.S.C. 1001(a)
3. An academic teaching hospital
4. A medical center
5. A research institute that is affiliated with an Institution of higher education.

J. **Travel Authorization**: a form that serves as the disclosure for Industry-Sponsored Travel and must be completed in its entirety prior to any professional travel. Reimbursed or Industry-Sponsored travel information will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of travel. An Institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest (FCOI) with PHS-funded research.

K. **Conflict of Interest in Research Committee (CIRC):** a committee of faculty/administrators/directors responsible for ensuring that individual conflicts of interest in

research are identified, managed, or eliminated, in accordance with federal regulations and in the best interests of research subjects, trainees, researchers and the Institution

L. **Conflict of Interest with Industry in Clinical Care and Education Committee (Co-ICE):** a Committee of faculty/administrators/directors responsible for identifying, reviewing and managing individual and institutional conflicts of interest in clinical care and education to ensure the best interests of patients, trainees, clinicians and the Institution

M. **Outside Employment:** personal contractual services provided for entities outside the Institution for which one spends considerable time and/or receives a regular retainer or income. Faculty and exempt employees are required to obtain prior approval for all Outside Employment which includes, but is not limited to, consulting, scientific advisory board memberships, clinical trial review panels, developing educational materials, teaching, laboratory testing, expert legal testimony, paid court appearances, and legal expert witness consultation activities. Other activities considered Outside Employment that require prior approval are fiduciary and management roles in organizations outside the Institution, including board member appointments, and serving as an officer, manager, or medical director of a for-profit company, non-profit organization or charitable foundation.

N. **Outside Interest**: a personal professional relationship with any domestic or foreign, public or private, entity (excluding a Federal agency) with which an Individual (and spouse and dependent children) has a financial interest or regular time commitment

O. **Financial Interest**: anything of monetary value, whether or not the value is readily ascertainable; including, but not limited to, income for services, ownership, equity interest, and fiduciary or management relationships, whether paid or unpaid

P. **Significant Financial Interest (SFI):** a financial interest consisting of one or more of the following interests of an Individual (and those of the Individual's spouse and dependent children):

1. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any income received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000.
2. With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any income received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or
3. All royalties and intellectual property rights and interests (e.g., patents, copyrights)

Significant Financial Interest EXCLUSIONS:

1. Salary, or other income paid by the Institution to the Individual if the Individual is currently employed or otherwise appointed by the Institution
2. Any ownership interest in the Institution held by the Individual, if the Institution is a commercial or for-profit organization
3. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Individual does not directly control the investment decisions made in these vehicles
4. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an Institution of higher education as defined at 20 U.S.C.

1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education

5. Income from service on advisory committees or review panels for a federal, state or local government agency, Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Q. **Investigator:** the project director or principal Investigator and any other person, regardless of title or position, who the Institution deems is responsible for the design, conduct, or reporting of research, which may include, for example, collaborators or consultants

R. **Financial Conflict of Interest (FCOI):** a situation in which the Institution, through its designated official(s), reasonably determines that an Investigator's SFI is related to a PHS-funded research project and could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

S. **Subrecipient:** a party that receives a subaward from a recipient or another subrecipient under a Federal financial assistance award and is accountable to the recipient or subrecipient for the use of the Federal funds provided by the subaward

T. **Faculty and exempt employees:** for the purposes of this policy the term faculty and exempt employees refers to WFUHS faculty and WFUHS and NCBH exempt employees.

U. **Abbreviations:**

CE	Continuing Education	PHS	Public Health Service
CEO	Chief Executive Officer	VP	Vice President
CFR	Code of Federal Regulations	WFBH	Wake Forest Baptist Health
CME	Continuing Medical Education	WFBMC	Wake Forest Baptist Medical Center
COO	Chief Operating Officer	WFSM	Wake Forest School of Medicine
IRB	Institutional Review Board	WFUHS	Wake Forest University Health Sciences
NCBH	North Carolina Baptist Hospital	WFUSM	Wake Forest University School of Medicine

III. Conflict of Commitment and Disclosure

Individuals, in recognizing that their primary professional responsibility is to the Institution will devote their energies to external activities in congruence with the Institution's mission and will conform to each section of this policy. Faculty members and exempt staff/employees are required to disclose any outside commitments annually through electronic procedures established by the Conflict of Interest Office (COI). Department Chairs/Section Heads/Directors/Vice Presidents are responsible for reviewing, evaluating and managing any conflicts of commitment identified.

A. Commitment of Time to Consulting and Outside Employment

The use of time for outside employment and consulting activities is a privilege and not a right. Faculty and exempt employees who participate in consulting or outside employment must obtain prior written approval in accordance with the provisions in Section *VB* of this policy and the *Expert Medical Witness Testimony Policy Section IV-57 of the WFUHS Organization and Policies Handbook.*

B. Authority in Assignment of Duties

Department Chairs, departmental Managers/Directors or Vice-Presidents will review and consider requests and contracts/agreements for external employment or external personal professional

relationships presented by their faculty and exempt employees. Approvals will be based on the appropriateness of the activity within the context of professionalism and ethics; compliance with Institutional policies; the benefit to the Institution and the community; and the amount of time proposed for the activity. The number of allowed days for outside employment will be determined based on departmental needs and responsibilities, and this number may vary from discipline to discipline. The determination will be made by the following as appropriate:

Faculty:	Department Chair
Department Chair:	Dean or designee
Clinical Department Chair:	Dean and President/COO of WFBH or designee
Departmental Directors:	Dean or designee, or appropriate VP
Vice Presidents:	President/COO of WFBH or CEO of WFBMC
Department Managers:	VP or designee
Staff:	Department Manager/Directors

C. **Clinical and Adjunct (Volunteer) Appointments of Faculty at Other Institutions**

Any faculty member's clinical or medical practice occurring outside the Institution, unless otherwise specifically directed, is not permitted (*e.g.*, moonlighting). Any exception must be reported and receive prior approval from the department chair and the President/COO of WFBH if clinical or in conjunction with the Dean for adjunct faculty appointment.

Verification of professional liability insurance to outside entities will be provided only if the activity is within the scope of employment and after a report is made to, and approved by Risk Management.

The existence of malpractice coverage with a carrier other than through the Institution does not preclude the requirement that the Individual disclose plans for outside clinical practice and obtain permission for such activities in the manner prescribed above.

D. **Use of the Institution's Resources**

The WFUHS Organization and Policies Handbook- *Office of Research Section* governs an Individual's participation in any agreement under which an outside entity will profit from the resources (including information) of the Institution as well as from the Individual's personal involvement. Examples include but are not limited to start-up companies, inventions and patent ownership, data ownership, authorship and copyright ownership.

Because consulting arrangements and publication of books involve an Individual's personal effort, contracts for publications and payment of related royalties are not subject to sharing of income with the Institution, although they still must be reported and approved by the Individual's immediate supervisor, prior to any activity.

Prior approval must be obtained and approved by the faculty member or exempt employee's immediate supervisor if the Institution will be investing its resources and sharing in the risks of a venture or in any other way subsidizing the activity, whether or not sharing in any revenues generated by the activity.

E. **Use of the Institution's Names, Symbols or Logos**

Since collaborative relationships can be of great value to an outside entity, opportunities for outside activities may be offered to an Individual in part because of their association with the Institution. Individuals cannot participate in such activities completely independently of their affiliation with the Institution.

Approval prior to undertaking a secondary commitment serves to protect the Individual, the Institution, or both from possible discredit or embarrassment. Individuals must be discriminating in the selection of secondary commitments, regardless of whether they are professional or non-professional in character, and regardless of whether the obligation is to be discharged in "off hours" or during vacation.

If an outside entity wishes to use any of the Institution's names, symbols or logos, written approval from Communications, Marketing and Media must be obtained prior to such use. To request approval for use of the Institution's names, symbols or logos, complete a request at the following link: *Brand Champion*.

F. **Sharing of Intellectual or Tangible Property**

Individuals must disclose any relationship they are considering or are engaged in with an outside entity if the entity anticipates providing financial or other support for the Individual's work, or if the entity anticipates utilization of intellectual property (e.g., inventions, know-how) or tangible property (e.g., research materials) or original works of authorship (e.g., computer software but not textbooks) of that Individual's academic work or the work of a subordinate Individual in compliance with the WFUHS Organization and Policies Handbook- *Office of Research Section*.

G. **Submission of Research Proposals**

Individuals acting as Investigators must comply with all institutional and federal requirements regarding management of conflicts of commitment and conflicts of interest as specified in institutional policies and/or PHS Regulation *42 CFR, Part 50, Subpart F* and *45 CFR, Part 94*. Institutional policies on research proposals may be found in the WFUHS Organization and Policies Handbook- *Office of Research Section*.

H. **Employment of Relatives (Nepotism)**

Individuals acting as Investigators or otherwise conducting Industry-sponsored research will report their intention to employ an immediate family member as required in the *Human Resources Nepotism Policy*. Such Individuals will cooperate with the Conflict of Interest Office to minimize or eliminate the appearance of bias that may be created by collaborating or working directly with an immediate family member.

IV. Conflict of Interest and Disclosure

The Institution requires that faculty and exempt employees disclose annually all outside interests, both research and non-research related, each April through the online disclosure process. Annual disclosure must be completed within 30 days of receipt of the reminder notification from the Conflict of Interest Office. All annual disclosures will be reviewed by the faculty member or exempt employee' s department chair/section head/director/manager as defined by Human Resources. In the case of department chairs, the Dean of the Medical School will perform the review. Upon disclosing outside interests, the faculty member or exempt employee will cooperate with the COI Office to identify financial interests and the designated conflict of interest committee (CIRC or Co-ICE) to manage identified conflicts of interest. Sponsor specific disclosure is required for non-grant-funded, industry-sponsored travel. One must update his/her disclosure within 30 days of a substantial change in external activities.

- Disclosure of sponsor specific interests is required with submission of grants, contracts, and regulatory protocols and through requisitions to Institutional purchasing committees.
- Conflicts of interest in clinical research require disclosure of financial relationships with Industry to the human subjects enrolled in the project.
- Public disclosure of outside interests is required for all publications (including news releases), presentations (including posters) and approved media contact related to a faculty member or

exempt employee's relationship with the sponsor of his/her research or in the ownership of a related entity or intellectual property, such as new or experimental drugs, devices or therapies.

- Prior to professional travel, the Individual will disclose the Sponsor's name, the destination, purpose and duration of travel by fully completing the *Travel Authorization.*
- Clinicians with past and/or present financial relationships with Industry (e.g., consulting and speaking agreements, research contracts) must disclose relationships to patients when such a relationship might appear to be a conflict of interest.
- Disclosure of financial interests will be made by all IRB members, and by all institutional purchasing and formulary committee members. Committee members with a financial interest in a sponsor or vendor will recuse themselves from voting on decisions involving the entity in which they have an interest.

A. **Conflict of Interest in Research**

On behalf of the Conflict of Interest in Research Committee (CIRC), the COI Office evaluates all disclosures of outside interests, including a review of related research projects to determine if a significant financial interest (SFI) may be a conflict of interest on sponsored research and if and FCOI exists for PHS-funded research. If the COI Office determines that a FCOI exists on PHS-funded research, the CIRC reviews the design, conduct, and reporting of the research to determine and implement the appropriate management process and Federal reporting in accordance with PHS Regulations *42 CFR, Part 50, Subpart F* and *45 CFR, Part 94*, to protect the credibility and integrity of the Institution and its faculty and staff. If the COI Office determines that a SFI exists for non-PHS sponsored research, it reviews the design, conduct and reporting to determine and implement the appropriate management process.

B. **Human Subject Research**

If a conflict of interest is identified in research involving human subjects, the IRB and CIRC will conduct their respective reviews in parallel, and the IRB will withhold final approval pending the completion of the CIRC review, resolution of the issues and recommendations for management.

C. **Compliance with PHS Regulation 42 CFR, Part 50, Subpart F and 45 CFR, Part 94**

Prior to the expenditure of funds and within 60 days of any subsequently identified FCOI on PHS-funded research:

1. The Institution shall adhere to its publicly available policy and provide reports regarding identified FCOI to the PHS Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed by this regulation.
2. The Institution will ensure that each Investigator is informed of its policy on FCOI, the Investigator's responsibilities regarding disclosure of SFI's, and of these regulations. Each Investigator is to complete training regarding FCOI requirements prior to engaging in research related to any PHS-funded contract and at least every four years, and immediately when any of the following circumstances apply:
    a. The Institution revises its FCOI policies or procedures in any manner that affects the requirements of Investigators
    b. An Investigator is new to the Institution
    c. The Institution finds that an Investigator is not in compliance with the Institution's FCOI policy or management plan.
3. If an Investigator carries out PHS-funded research through a subrecipient (e.g., subcontractors, or consortium members), the Institution will take reasonable steps to ensure subrecipient Investigator compliance through:

a. A written agreement with the subrecipient that establishes whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

b. The CIRC will provide FCOI reports to the PHS Awarding Component regarding all FCOI of all subrecipient Investigators consistent with this regulation.

4. If an Investigator's SFI is related to PHS-funded research:
   a. The CIRC determines if the SFI could be affected by the PHS- funded research, or is in an entity whose financial interest could be affected by the research.
   b. The CIRC determines if a FCOI exists when the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
5. Identification of an FCOI initiates development and implementation of a management plan by the CIRC and, if necessary, a retrospective review and mitigation report pursuant to § 94.5(a).
6. The Institution provides initial and ongoing FCOI reports to the PHS awarding component as required pursuant to § 94.5(b).
7. The Institution maintains records relating to all Investigator disclosures of financial interests, the CIRC's review of, and response to, such disclosures, and all actions under Institutional policies or retrospective review, if applicable, for at least three years from the date of the final expenditure of funds.
8. The Institution maintains enforcement mechanisms and provides sanctions and other administrative actions to ensure Investigator compliance as appropriate.
9. The Institution ensures public accessibility, via written response to any requestor within five business days of a request, for information concerning any SFI disclosed to the Institution that meets the following three criteria:
   a. The SFI was disclosed and is still held by Investigator
   b. The Institution determines that the SFI is related to the PHS-funded research
   c. The Institution determines that the SFI is a FCOI
10. The information available via written response to any requestor within five business days of a request shall include, at a minimum, the following:
    a. Investigator's name,
    b. Investigator's title and role with respect to the research project,
    c. Name of the entity in which the SFI is held,
    d. Nature of the SFI, and
    e. Approximate dollar value of the SFI, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

V. Permitted Outside Employment and Other External Professional Relationships Requiring Prior Approval

On behalf of the Conflict of Interest with Industry in Clinical Care and Education Committee (Co-ICE), the COI Office evaluates all disclosures of outside interest, including a review of requests for non- certified CE speaking and education funded by Industry. The COI Office may determine that a request needs additional review during the next Co-ICE meeting.

A. Certified Continuing Education (CE) Activities and Non-Certified Continuing Education (non-certified CE) Activities

Industry support of continuing education ("CE") can provide benefit to patients by ensuring the

most current, evidence-based medical information is provided to healthcare practitioners. In order to ensure that potential for bias is minimized and that CE programs are not a guise for marketing or off-label promotions, all CE events receiving Industry support or Industry sponsorship that are hosted, sponsored, or jointly sponsored by the Medical Center must comply with the 2004 Updated Accreditation Council for Continuing Medical Education (ACCME) *Standards for Commercial Support of CME: Standards to Ensure the Independence of CME Activities* (or other similarly rigorous, applicable standards required by other health professions), whether or not CE credit is awarded for attendance at the event. All such agreements for Industry support must comply with the Wake Forest University School of Medicine ("WFUSM") Office of Continuing Medical Education ("CME") policies. Any such educational activity must be open on equal terms to all interested practitioners, and may not be limited to attendees selected by the company supporter(s). Co-ICE will review applications for Industry-supported non-certified CE activities, and will also advise on management of these activities. (See sections *VC* or *VD* of this policy)

B. Outside Employment

Any faculty member or exempt employee who wishes to undertake *Outside Employment*, including consulting and expert witness activities, must complete an Annual Request for Outside Employment* for each separate entity and obtain prior approval from his or her supervisor as follows:

- Faculty members outside clinical departments must obtain approval from the Department Chair and the Dean or designee
- Faculty members in clinical departments, must obtain approval from the Chair and the President/COO of WFBH, or designee
- All other exempt employees must obtain prior approval from the departmental Director or VP to whom they report
- Vice Presidents must obtain approval from the CEO of WFBMC, or designee

*If Outside Employment involves expert medical witness testimony, Individuals must also comply with the *Expert Medical Witness Testimony Policy Section IV-57 of the WFUHS Organization and Policies Handbook*.

1. Consulting agreements are personal contracts between a faculty member or employee and a separate Industry Entity, and does not include the Institution as a party to the consulting agreement. Nor does the Institution provide review or insurance coverage for such contracts. Any faculty member or employee considering entering into a consulting arrangement may wish to seek the advice of an attorney retained at the faculty member's or employee's expense.
2. The first commitment of the faculty or employee is to the Institution, and that no conflict between a faculty member's or employee's employment exists when that faculty member or employee enters into a personal consulting relationship with an outside entity. Reporting of outside time commitments is required in accordance with *section III* of this policy.
3. Income earned from outside employment must be reported in accordance with *section IV* of this policy.
4. Faculty members and employee may consult with Industry to provide scientific advice, provided any compensation for consulting services is reasonably related to specified services and is at fair market value; the arrangement is governed by written agreement specifying the service(s) to be provided; the consultant's duties are based on relevant

expertise; the consultant is free to provide advice and services that reflect his or her expertise and judgment; and the arrangement complies with applicable institutional policies on conflicts of interest and commitment.

5. The following paragraph (adapted to the particular agreement) should be included in any and all personal consulting agreements:
   a. "The Entity acknowledges that Consultant's primary obligation is to WFUHS or NCBH. It is the intent of the parties that efforts and specific responsibilities under this Agreement be separate and distinct from those duties performed for WFUHS or NCBH. In the event of any conflict between this Agreement and any terms of employment between the Consultant and WFUHS or NCBH, including work responsibilities and ownership of any resulting intellectual property, the terms and conditions of the Consultant's employment with WFUHS or NCBH will take precedence unless specific written arrangements have been made in advance between the Entity and WFUHS or NCBH."

C. **Attending Industry-Sponsored Non-Certified CE Activities**

Individuals should evaluate carefully their attendance at non- certified CE meetings, conferences and other activities that are fully or partially sponsored by Industry due to the potential for perceived or real conflict of interest and should follow these guidelines:

1. The lecturer is expected to provide a fair and balanced assessment of the subject and to promote objective scientific and educational activities and discourse.
2. The main reason for attending the Industry-sponsored or supported educational activity should be to further the Individual's knowledge on the subject(s) presented.
3. The activity is not a dedicated marketing and training program designed by Industry solely to influence purchasing or prescribing decisions.
4. Receptions and meals of modest value provided in connection with an educational activity may be accepted by WFBMC attendees when incidental to the educational activity and available for all attendees, except as described in section VC.5 below. The receptions and meals should promote discussions among those attending. Individuals may not attend the reception and accept the meal if they will not be attending the educational component of the activity.
5. WFBMC attendees must pay for their own meals if attending a meeting organized by an Industry sponsor as an invitation-only event held at a restaurant and not incidental to a conference or certified CE activity.
6. Attendees may not receive material gifts, travel reimbursement or other compensation for attending the educational activity.
7. Faculty members and exempt employees must submit a request (Offsite Industry-Funded Non-Certified CE Training Request) and obtain approval from their Chair/Section Head/VP/Director and the COI Office prior to attending an offsite non-certified CE educational activity. In the case of group attendance, each department should submit a separate request form for each activity with its attendees listed. When attending an approved certified CE activity and an unanticipated non-certified CE educational activity is offered in conjunction with it, attendees do not need to seek additional prior approval to attend, but must be mindful of policy guidelines.
8. Faculty members and exempt employees must submit a request (Onsite Industry-Funded Non-Certified CE Training Request) and obtain approval from their Chair/Section Head/VP/Director and the COI Office prior to organizing an onsite non-certified CE educational activity.

D. **Speaking and Leadership at Industry-Sponsored Non-Certified CE Activities**

Individuals should evaluate carefully the potential for perceived or real conflict of interest especially when considering whether to play a leadership role in non-certified CE meetings, conferences and other activities by giving a lecture, organizing the meeting and the like. Individuals may participate in non-certified CE Industry sponsored or supported educational activities when such activities follow these guidelines:

1. The lecturer prepares the meeting or lecture content, and does not use a slide set or presentation provided by the Industry sponsor which promotes or markets their product(s).
2. The activity is designed to promote evidence-based clinical care, advance scientific research and/or teach desirable clinical skills.
3. The lecturer is expected to provide a fair and balanced assessment of the subject and to promote objective scientific and educational activities and discourse.
4. Financial support by Industry is fully disclosed to the attendees by the Sponsor of the activity.
5. When the lecturer is speaking as part of consulting activities, he or she makes clear that content reflects individual views and not the views of the Institution.
6. The use of the WFBMC and its component institutions names in a non-WFBMC event is limited to the identification of the individual by his or her title and affiliation.
7. The activity is not a dedicated marketing program designed by Industry solely to influence purchasing or prescribing decisions.
8. Compensation or honoraria may be accepted by the lecturer only for the services provided and the compensation must be reasonable and reflect fair market rates. Reasonable reimbursement for related travel and meals may be accepted by the lecturer.
9. Attendees do not receive gifts or other compensation for attending the activity.
10. Receptions and meals of modest value should promote discussions among those attending the educational activity, be incidental to the educational activity and be available to all attendees.
11. Faculty members and exempt employees must submit Offsite Industry-Funded Speaking Request and Travel Authorization forms for approval from his/her Chair/Section Head/VP/Director and the COI Office prior to speaking at or organizing an offsite non-certified CE educational activity.

E. **Receiving Travel Funds from an Industry Sponsor**

Prior to receiving travel funds from an Industry sponsor, faculty members and exempt employees must complete a Travel Authorization form in conjunction with other activity specific forms.

Individuals may accept travel funds or reimbursement from industry in the following circumstances:

1. For reimbursement for travel to provide contractual services, such as approved consulting, and as described in section *VB above*.
2. To participate in meetings directly related to ongoing sponsored research.
3. To view capital equipment in situ if the equipment is being considered for purchase by WFBMC; must submit request for prior approval by his/her Chair/Section Head/VP/Director (Industry-Funded Travel to View Capital Equipment or for Specialized Training).

4. To participate in initial and ongoing education necessary to operate or use products and devices which require specialized expertise and are currently being used at the Institution; must submit request for prior approval by his/her Chair/Section Head/VP/Director (Industry-Funded Travel to View Capital Equipment or for Specialized Training).
5. May accept travel funds from scientific societies whether or not Industry is the source of the funds, provided that the society controls the selection of the recipient of travel support.

F. **Licenses, Royalties and Equity**

Faculty members and exempt employees must report their proposed outside relationships with Industry and other entities in which they expect to receive royalties or equity under which they or WFBMC is expected to license WFBMC-owned technology or copyrights, as defined in the *Inventions and Patent Policy* and the *Copyright Ownership Policy*. These relationships must be reported in advance to the appropriate Department Chair/Section Head/VP/Director for review and approval prior to agreeing to, engaging in, or accepting income for the activities.

G. **Engaging in a Faculty Start-up Company**

Faculty members and exempt employees must disclose their proposed outside professional relationships with all start-up companies in which they have or expect to have a financial interest or under which they or WFBMC is expected to license WFBMC-owned technology or copyrights, as defined in the *Inventions and Patent Policy* and the *Copyright Ownership Policy*. These relationships must be reported in advance to the appropriate Vice President/Department Chair/Director for review and approval prior to agreeing to, engaging in, or accepting income for the activities.

VI. Prohibited Personal Professional External Activities with Industry and Other Entities

Individuals may not participate in promotional speakers' bureaus or other promotional events for Industry designed to influence purchasing or prescribing decisions. This includes advising or creating materials for Industry on marketing and promoting their products or services, and participating in focus groups where the focus is on marketing products for Industry. This section is not intended to prohibit legitimate, principled activities that meet the guidelines in *section V*.

VII. Gifts from Industry

A. **Gifts to Individuals**

Personal gifts from Industry may not be accepted by Individuals. Examples of personal gifts include off-campus meals which are not incident to research or educational activities, pens, notepads, food baskets, flowers, gift cards, and entertainment, regardless of the value.

Gifts of educational materials to faculty and staff are permissible only if they are received by the departmental library for general use as determined by Department Chair/VP/ Director or designee. Personal gifts of educational materials and textbooks are not permissible.

B. **Gifts of Food (Onsite)**

Industry supplied or supported food and drinks are prohibited onsite at WFBMC. WFBMC personnel may only accept modest meals funded by Industry when they are provided incidental to sponsored research or when the activity complies with the provisions of sections *VA* and *VC-VD*.

C. **Gifts of Funds to Departments to Support Education and Other Professional Activities**

Departments may establish a departmental education account in which all unrestricted gifts and donations from Industry intended for education or professional support may be deposited. There

may be no expressed or implied quid pro quo for the funds. The department may use monies from this fund to pay for reasonable travel expenses and registration fees as determined by the Department Chair/ VP/Director.

Gifts which have an educational value and are for the benefit of patient care or medical education, including books, anatomical models, illustrations, clinical diagrams, etc. are permitted provided they are of nominal value. These items may not promote Industry products or services. Industry-branded charts or anatomic models that are deemed critical for patient education are permitted, but the Industry branding (e.g. logo, company name, and representative contact information) should be removed or covered.

D. **Gifts of Medications and Pharmaceutical Samples**

1. Individuals may not personally accept medications or pharmaceutical samples. The NCBH Pharmacy may accept medications or pharmaceutical samples from Industry representatives if approved by the Ambulatory Medication Management Subcommittee (AMMSC) of the Pharmacy and Therapeutics Committee. The committee will approve requests for use of samples in the Institution's outpatient areas when such requests are considered to be in the best interest of patient care. Samples may be permitted when provided for patient education (for example, education in the use of inhaled drugs for pediatric asthma), for appropriate patient trials to determine tolerance and efficacy, and for hardship situations. Any ambulatory/outpatient area which receives approval from AMMSC to stock sample medications must agree to follow all guidelines associated with the handling of sample medications. The Department of Pharmacy or representatives designated by the AMMSC may inspect sample areas at any time and may revoke sampling privileges if non-compliance is identified. Requests may be submitted via the Request for Samples form found on the intranet under the forms section.
2. The NCBH Pharmacy may continue to accept pharmaceutical samples, as it has previously done to develop patient assistance programs.

E. **In-Kind Gifts to the Institution**

Gifts and loans to the Institution of equipment, devices, supplies and similar items from Industry for use in education, research or clinical care cannot suggest the expectation of return benefit to the donor, or "quid pro quo". The gift transaction will be documented on the Gift In-Kind Donation form and submitted to the Office of Development & Alumni Affairs.

F. **Donations to Institution for Philanthropy for External Non-Profits**

This policy applies only to philanthropic events that have been approved by WFBMC executive leadership for the purpose of raising funds for external non-profit organizations. Donations of items intended for raffle or prizes to raise money during philanthropic events must be well-documented and received from the vendor by WFBMC's chief organizer of the event. The chief organizer will assure all vendors that their business is not dependent on making donations for such events. Tickets for the charitable event and other reasonably valued items for the event, such as shirts and hats, may be received by employees and faculty of WFBMC who are participating in the approved event.

VIII. Industry Access to Facilities and Staff

A. **Access of Medical Service Representatives (MSRs)**

Industry access to the Medical Center occurs primarily through Medical Service Representatives (MSRs), including, but not limited to, pharmaceutical products MSRs and medical device MSRs. Pharmaceutical products MSRs are defined as vendors' representatives who promote

pharmaceutical products and provide information and services to health care providers on behalf of manufacturers and suppliers. Medical device MSRs are defined as vendors' representatives who promote medical devices and products and provide information and services to health care providers and researchers on behalf of manufacturers and suppliers, but do not include health science associates or liaisons, who do not act in the capacity of MSRs.

Faculty, staff, and student interactions with MSRs must comply with the Medical Center policies on *MSR for Pharmaceutical Products* and *Medical Devices and Products*, which require MSRs to properly register and prohibits their access to patient care areas.

The policy on *Medical Devices and Products* makes a limited exception for MSRs invited to provide in-service assistance regarding devices or equipment. MSRs providing in-service assistance must be accompanied by Medical Center staff or faculty at all times and patient consent for the MSRs attendance must be obtained. In these limited circumstances, an MSR may be allowed to offer technical advice to a surgical team regarding their equipment or devices but may not give advice concerning patient care. MSRs are restricted from manipulating their equipment or devices while in use on a patient and MSRs are not to touch patients at any time, nor may they scrub on any procedures. Exceptions to this restriction are extenuating circumstances (e.g., equipment malfunction) or specialized training (e.g., pacemaker representatives) under the direction of a Medical Center physician and in accordance with the applicable departmental guidelines.

MSRs must have an appointment with a specified individual in order to visit Medical Center staff or faculty.

B. **Commercial Exhibits (Vendor Fairs)**

Vendor fairs shall be prohibited at the Institution. A vendor fair is an event intended to promote drugs, devices, or other products to be prescribed for/used in the care of patients. This policy is not intended to preclude any materials management and/or purchasing department from coordinating vendor displays where several brands of medical devices or medical materials are displayed simultaneously for key decision makers to compare them in order make purchasing or standardization decisions. This policy is not intended to preclude Human Resources or any other medical center department from coordinating vendor displays for benefits or services offered exclusively to employees.

C. **Advertising Materials**

Industry advertising and Industry advertising materials are prohibited at programs provided or sponsored by the Institution. For purposes of this policy, Industry advertising does not include advertisements for clinical trials or Industry sponsored patient education materials such as those permitted under section *VII C*.

Advertising materials (for example, print, radio, and television) designed to promote physician practices or clinical services that are funded directly or indirectly by Industry and include advertising for Industry or Industry products may not be purchased or accepted.

D. **Ghostwriting and Guest Authorship**

Individuals may not be listed as authors on any materials ghostwritten by Industry representatives or someone acting on behalf of Industry. Individuals must always be responsible for the content of any publications or presentations, including slides. See also *WFSM Authorship Guidelines*, Page IV-70 of t5he WFUHS Operations and Policy Manual, which provides guidance for scholarly publications.

E. **News Releases and News Media Contact**

Prior to participating in a media event Individuals must disclose to Communications, Marketing and Media any potential or actual COI related to personal outside interest in the sponsor of his/her research or in the ownership of a related entity or intellectual property, such as new or experimental drugs, devices or therapies, or of a start-up business. All such disclosures will be reported to the Medical Center COI Office in compliance with Communications Marketing and Media's policy section on conflict of interest.

F. **Free Services to Clinical Departments**

Clinical departments may not accept free services provided by Industry representatives. Examples include Industry representatives obtaining insurance preauthorization for their drugs or devices, conducting coding audits, and appealing denied claims or reimbursing departments for denied claims. Exceptions may be appropriate if the primary purpose of the service is to benefit the patient, and the benefit to the clinical department is de minimus. For example, frequently providing a free service that is ordinarily performed by department staff is not acceptable. Requests for exceptions should be made to the Audit & Compliance Office as appropriate.

IX. Administrative Actions by Faculty and Staff Related to Their Relationships with Industry

A. **Administrative Actions by Key Officials**

Key officials in the Institution include presidents, vice presidents, officers, directors, advisors, deans, department chairs, and section heads. Because of their leadership roles, their authority to make important decisions, their fiduciary duty to act in the best interests of the Institution, and their positions as role models for other Individuals, key officials are held to an even higher standard of ethics, integrity, professionalism, and objectivity in their decisions and conduct. Key officials might not be permitted to engage in some personal, professional relationships with industry that are allowable for others, when actual or perceived conflicts of commitment or interest would result, or may have restrictions on their ability to make certain decisions. Key officials should always be aware that their decisions may create institutional conflicts of interest in all missions.

B. **Committee Participation When Members Have Personal External Relationships with Industry**

Individuals who serve as voting members on Medical Center committees that recommend purchases and utilization of pharmaceutical and medical devices shall recuse themselves from participation in voting and similar decision-making processes when the decision or discussion may pose a real or perceived conflict of interest. In addition, the Chair of the committee may remove a member from the committee in the event the Chair reasonably determines that the member cannot substantially contribute to and participate in the work on the committee due to the member's actual or perceived conflict of interest. Additionally, committee members are required to verbally update any potentially conflicting relationships in open meeting to be documented in the meeting minutes.

X. Sanctions for Breach of Policy

Individuals have an obligation to comply with this policy. Examples of conduct that violate this policy include:

- Failure to submit required outside interest disclosure statements
- Intentional deception or dishonesty in disclosures,
- Repeated omission of industry relationships in disclosures, or
- Failure to comply with management plan requirements.
- Repeated failure to submit required travel and/or education related forms

These examples are not intended to be exhaustive. Reports of suspected violations may be made to any of the Individuals listed below, or anonymously through the Compliance Hotline (1-877-880-7888). Suspected violations will be investigated and referred to the following for sanctioning as appropriate:

Students:	Associate Dean for Student Services
Graduate Students:	Dean of the Graduate School
Postdoctoral:	Dean of the Graduate School
Staff:	Human Resources
Faculty:	Dean of the School of Medicine or Senior Associate Dean and President/COO or CMO
House Staff:	Dean of the School of Medicine/Associate Dean for GME Policy/ President/COO or CMO

Possible sanctions may include:

- Reimbursement to the Institution for misused resources
- Written advisory for placement in employee or student file
- Ineligibility to participate in grant applications or on committees
- Dismissal from an educational or training program.
- Termination of employment

If the failure of a research investigator to comply with this policy has, or appears to have, biased the design, conduct, or reporting of PHS-funded research, in accordance with 42 CFR Part 50 Subpart F, Section 50.606 (a) and 45 CFR, Part 94, the Institution must promptly notify the PHS Awarding Component of the findings and corrective action taken or to be taken. The PHS Awarding Component will consider the situation and may take appropriate action or refer the matter to the Institution for further action, such as determining how to maintain appropriate objectivity in the funded project.

Allegations of research misconduct are addressed by a separate policy entitled *Research Integrity Policy*. If, in the course of investigating allegations of research misconduct, evidence of violations of the Conflict of Commitment and Conflict of Interest Policy is discovered, the Research Integrity Officer conducting the research misconduct investigation may consult with the Conflict of Interest Office to determine the need for any additional course of action.

XI. Review/Revision/Implementation

A. **Review Cycle**

This policy shall be reviewed by the Medical Center Conflict of Interest Office at least every three (3) years from the effective date.

B. **Office of Record**

The Medical Center Conflict of Interest Office shall maintain this policy and be the office of record.

XII. Related Policies

A. Expert Medical Witness Testimony Policy Section IV-57 of the WFUHS Organization and Policies Handbook

B. Risk Management - Insurance

C. WFBMC Organization and Policies Handbook- Office of Research Section.

D. Conflict-of-Interest Procedure for News Releases and News Media Contact
E. Human Resources Nepotism Policy
F. WFSM Authorship Guidelines
G. Research-Integrity-Policy
H. IRB Standard Operating Procedure
I. Copyright Ownership Policy
J. Inventions and Patent Policy
K. Medical Devices and Products
L. MSR for Pharmaceutical Products

XIII. Governing Law of Regulations/Guidelines

A. **Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought** (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94)
http://grants.nih.gov/grants/policy/coi/

B. **Bayh-Dole Act (1980),** 37 CFR 401.1-16
http://ecfr.gpoaccess.gov/cgi/t/text/textidx?c=ecfr&tpl=/ecfrbrowse/Title37/37cfr401_main_02.tl

C. **Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)**
http://oig.hhs.gov/fraud/enforcement/cmp/index.asp

D. **"Stark Law" Section 1877 of the Social Security Act 42 U.S.C. 1395nn,**
https://www.cms.gov/PhysicianSelfReferral/

E. **Accreditation Council for Continuing Medical Education (ACCME)** Standards for Commercial Support of CME: Standards to Ensure the Independence of CME Activities

F. **PhRMA**
http://www.phrma.org/

G. **AdvaMed**
http://www.advamed.org/MemberPortal/

XIV. Attachments

A. Travel Authorization
B. Brand Champion
C. Annual Request for Outside Employment
D. Offsite Industry-Funded Non-Certified CE Training Request
E. Onsite Industry-Funded Non-Certified CE Training Request
F. Offsite Industry-Funded Speaking Request
G. Industry-Funded Travel to View Capital Equipment of for Specialized Training
H. Gift In-Kind Donation Form