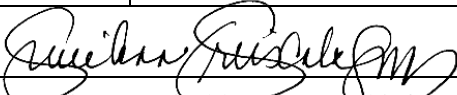
	Policy on Conflict of Interest	Type:	Tier II
		Effective Date:	July 1, 2018
		Revised Date:	May 22, 2018
		Contact:	WFBMC Conflict of Interest Office
Approval Signature: 		Date Approved:	May 23, 2018
Typed Name and Title: Julie A. Freischlag, M.D., Chief Executive Officer and Dean			

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I. General Purpose

The purpose of this policy is to provide guidelines for establishing principled personal outside relationships with industry and other organizations and to establish rules for personal interactions with Industry, health care industry 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, clinical providers and staff collaborate. The Institution has adopted this policy to promote the public's trust in the Institution's role in healthcare, research, and education. The policy supports the highest level of patient care, integrity of research, safety of human subjects, objectivity of education and the reputations of faculty, clinical providers and staff.

A. Scope of Policy

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

Faculty, clinical providers and exempt employees are required to disclose to the Institution any outside interests, including financial relationships with Industry or other outside organizations, that are related to Institutional duties. This includes disclosure of family members' outside interests with entities that do business with WFBMC. The Conflict of Interest Office will assist Individuals to determine if there is an appearance of conflict of interest, to manage any associated conflicts of interest which might arise in personal outside relationships, and to eliminate those conflicts that cannot be effectively managed.

B. Responsible Parties

- | | | |
|------|-----------------|--|
| i. | Policy Owner: | Conflict of Interest Office |
| ii. | Procedure: | Conflict of Interest Office |
| iii. | Supervision: | CEO, Dean |
| iv. | Implementation: | Department Chair, Supervisor, Director, VP, etc. |

II. Conflict of Interest and Disclosure

The institution requires faculty, clinical providers and exempt employees to disclose both research and non-research related outside interests, regardless of the value or income received. Disclosures are collected upon new hire and each April through an online process and 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 Individual's department chair/section head/director/manager as defined by HRIS. In the case of department chairs, the Dean of the Medical School will perform the review. Please note that leaders are expected to disseminate information about significant conflicts of interest for their direct reports to the appropriate superior leadership.

Upon disclosing outside interests, the Individual will cooperate with the COI Office to mitigate potential conflicts of interest, and the CIRC to manage significant conflicts of interest. Individuals must update their disclosure within 30 days of a substantial change in external relationships or activities.

Additional required disclosures:

- Disclosure of project specific relationships is required with submission of grants, contracts, and regulatory protocols.

- Disclosure of outside relationships is required when submitting requisitions to Institutional procurement committees.
- Significant conflicts of interest in clinical research require disclosure of the conflicting relationship 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 an Individual's outside relationship or financial interests.
- Prior to sponsored 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) should disclose relationships to patients when such a relationship might appear to be a significant conflict of interest.
- Disclosure of all financial interests will be made by standing committee members to their committee(s). 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.

III. Conflict of Interest in Research

On behalf of the Conflict of Interest Review 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 a 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, clinical providers 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 to protect the credibility and integrity of the Institution and its faculty, clinical providers and staff.

A. Human Subject Research

If a conflict of interest is identified in research involving human subjects, the Institutional Review Board (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.

B. 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. Designate an Institutional official(s) to solicit and review disclosures of Financial Interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research. The designated official is responsible for determining if a Significant Financial Interest exists, and whether or not it constitutes a Financial Conflict of Interest per PHS Regulations 42 CFR, Part 50, Subpart F and 45 CFR, Part 94.
3. 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.
4. 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.
 5. 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.
 6. 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).
 7. The Institution provides initial and ongoing FCOI reports to the PHS awarding component as required pursuant to § 94.5(b).
 8. 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.
 9. The Institution maintains enforcement mechanisms and provides sanctions and other administrative actions to ensure Investigator compliance as appropriate.
 10. 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
 11. The information available via written response to any requestor within five business days of a request shall include, at a minimum, the following: Investigator's name,
 - a. Investigator's title and role with respect to the research project,
 - b. Name of the entity in which the SFI is held,
 - c. Nature of the SFI, and
 - d. 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.

IV. Permitted Outside Employment/ External Professional Relationships Requiring Prior Approval

- Outside employment is evaluated primarily by departmental leadership through prior

approval requests and in compliance with the Policy on Conflicts of Commitment. See section A.

- Certified continuing education is either evaluated through the institution's CME Office or must adhere to their same policies if certified outside the institution. See section B.
- Under the guidance of the Conflict of Interest Review Committee (CIRC), the COI Office evaluates
 - requests for non-certified education funded by Industry, see section C.
 - requests for travel funding received by Industry, see section D
 - other reported outside relationships, including equity in faculty start-up companies, see section E.

For prior approvals the COI Office may grant approval based on guidelines established by the CIRC, or may determine that a request needs additional review by the CIRC.

A. **Outside Employment**

Individuals who wish to undertake outside employment (generally requiring considerable effort, earning equity or income, and/or related to institutional responsibilities), including but not limited to consulting, expert witness activities, personal businesses and advisory boards must consult the Policy on Conflicts of Commitment, complete an *Outside Employment Request* for each separate entity, and obtain prior approval from his or her departmental leadership.

Specific requirements for undertaking Outside Employment are found in the Policy on Conflict of Commitment. Departmental leadership will review Outside Employment Requests for the appropriateness of the activity, if the activity serves the mission of the Medical Center, and the time to be spent outside of institutional responsibilities. Final review for COI policy compliance is available through the Conflict of Interest Office, at the request of the department leader.

B. **Certified Continuing Education (CCE) Activities**

To ensure that potential for bias is minimized and that CCE programs are not a guise for marketing or off-label promotions, all CCE 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), All such Industry supported activities 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).

C. **Attending, Organizing or Speaking for Non-Certified Educational (non-CE) Events Sponsored by Industry**

Unless covered under a contractual agreement previously approved by his/her supervisor, an Individual who wishes to attend, organize or conduct speaking for a non-CE meeting, conference, or other activity that is fully or partially sponsored by Industry must follow the guidelines for the specific activity found in Appendix B and complete the appropriate prior approval request documents.

D. **Receiving Travel Funding from an Industry Sponsor for Special Circumstances**

Any Individual who has been offered travel funding from an Industry sponsor to view capital equipment or for specialized training on capital equipment/devices must obtain prior approval from his or her supervisor and the COI Office.

Prior approval is required if the travel meets one of the following circumstances:

1. To view capital equipment in situ if the equipment is being considered for purchase by WFBMC; must submit request for prior approval by the Chair/Section Head/VP/Director (*Industry-Funded Travel to View Capital Equipment or for Specialized Training*).
2. 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 the Chair/Section Head/VP/Director (*Industry-Funded Travel to View Capital Equipment or for Specialized Training*).

Prior approval is not required if the travel meets one of the following requirements:

1. For reimbursement for travel to provide contractual services, such as approved consulting that has been approved by Chair/Section Head/VP/Director through an Outside Employment Request.
2. To participate in meetings directly related to the initiation of sponsored research or ongoing sponsored research covered under a research agreement.
3. Receipt of travel funds from scientific societies, even if Industry is the source of the funds, provided that the society controls the selection of the recipient of the travel support.

E. **Licenses, Royalties, and Equity and Engaging in a Start-up Company**

Individuals must report proposed outside professional relationships with Industry and other entities related to their areas of expertise and professional duties, including start-up companies, in which they expect to receive royalties or equity, regardless of the value, or under which they or WFBMC is expected to license WFBMC-owned technology or copyrights, as defined in Wake Forest Innovations Policy on Intellectual Property. 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.

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

A. **Speaker's Bureaus**

Individuals may not participate in promotional speakers' bureaus or other promotional events for Industry designed to influence purchasing or prescribing decisions (see additional speaking guidelines in Appendix B, Section C.). This includes advising on creating promotional and marketing materials for Industry to sell 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 educational activities that meet the allowable Speaking guidelines.

B. **Advising for Investment Companies**

Individuals are prohibited from advising representatives of investment companies (including but not limited to investment firms, hedge funds, investment bankers, venture capital firms, and brokerage houses) on the status of areas of research and development, especially non-public information within the realm of the individual's professional expertise or collaborative knowledge, whether by telephone or email, in meetings, or otherwise. Directly or indirectly disclosing material or confidential information from a clinical trial prior to publication to individuals or companies that trade stock or advise such companies based on such information is prohibited. In addition, individuals must exercise caution in the relationships that are formed through memberships in expert networks (e.g., Gerson Lehman, Primary Global Research, Coleman Research Group, etc.).

VI. Gifts from Industry (including medication samples) - see Appendix C

VII. Industry Access to Facilities, Staff and Trainees - see Appendix D**VIII. Other Considerations for Faculty and Key Officials****A. Administrative Actions by Key Officials**

Key officials in the Institution include presidents, vice presidents, officers, directors, student advisors, deans, department chairs, and section heads. Because of their leadership roles, authority to make important decisions, fiduciary duty to act in the best interests of the Institution, and 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 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 disclose any potentially conflicting relationships in open meeting to be documented in the meeting minutes.

C. Faculty Participation in Student Affairs

Identifying and managing potential conflicts of interest involving students and faculty where a personal financial or fiduciary relationship may exist preserves and maintains academic integrity. Matters involving COI in student assessment may be found in the "WFBMC Conflict of Interest Related to Student Assessment Policy." Matters involving COI in appeals of student dismissal, may be found in the Student Appeal of Dismissal Policy. Program specific policies related to COI in admissions or mentoring of students are maintained by the applicable program and/or in the Student Handbook.

IX. Penalties for Breach of Policy

Individuals have an obligation to comply with this policy. Examples of conduct that violates this policy includes, but is not intended to be exhaustive:

- Failure to comply with the annual disclosure process by refusal to respond
- Intentional deception or dishonesty in disclosures
- Omission of industry relationship disclosures
- Failure to remedy conflicts of interest
- Failure to comply with management plan requirements, or
- Repeated failure to seek prior approval for speaking or for organizing or attending non-certified outside activities funded by Industry.

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 leadership in accordance with Appendix A, Definition of *Authority*.

Penalties for deliberate violations of this policy will be adjudicated in accordance with applicable disciplinary policies and procedures. Penalties for failure to comply will be commensurate with the breach and may include, but are not limited to:

- Reimbursement to the Institution for misused resources, including salary and/or other forms of institutional compensation and other applicable fines imposed by outside entities
- Written admonition for placement in Individual's employee file indicating that the individual's good standing has come into question
- Ineligibility to participate in grant applications, IRB or IACUC applications or on committees
- Ineligibility to work with graduate students
- Dismissal from an educational or training program
- Performance improvement counseling
- Dismissal 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 found in BRSA Policies. 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 misconduct investigation may consult with the Conflict of Interest Office to determine the need for any additional course of action.

X. Review/Revision/Implementation

A. Review Cycle

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

B. Office of Record

The Conflict of Interest Office shall maintain this policy on behalf of the Conflict of Interest Review Committee and be the office of record.

XI. Related Policies

A. Risk Management - Insurance

B. Research Policies:

1. Authorship Policy
2. Data Ownership Policy
3. Institutional Oversight of Animal Research and Teaching Policy
4. Institutional Oversight of Human Research Policy
5. Research Integrity Policy

C. Communications, Marketing, and Media's Media Relations Policy

D. Human Resources Nepotism Policy

E. Wake Forest Innovations Policies:

1. Copyright Ownership Policy
2. Inventions and Patent Policy

F. Resource Management's Health Care Industry Policy

G. Pharmacy Policy on Medication Samples

XII. 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/>

XIII. Appendix A - Definitions

XIV. Appendix B - Prior Approval and Guidelines for Attending, Organizing or Speaking for Non-Certified Educational Events Sponsored by Industry

XV. Appendix C - Guidelines on Specific Types of Gifts

XVI. Appendix D - Guidelines on Industry Access to Faculty, Clinical Providers, Staff, and Trainees

Definitions

- A. **Authority:** reviews, management determinations, final approvals and sanctions regarding conflicts of commitment will be made in accordance with the table below.

Faculty:	Department Chair or designee
Department Chair:	Dean or designee
Clinical Department Chair:	Dean or designee, and President of WFBH or designee
Network Physicians:	CMO, Network Physicians
Departmental Directors:	Dean or designee, or appropriate VP
Vice Presidents:	President of WFBH or designee or CEO of WFBMC or designee
Department Managers:	VP or designee
Staff:	Department Manager/Director
Students:	Associate Dean for Academic Affairs
Graduate Students:	Dean of the Graduate School
Postdoctoral:	Dean of the Graduate School
House Staff:	Associate Dean for GME Policy/CMO

- B. **Individual:** a faculty member, clinical provider, student, trainee, volunteer or employee of NCBH, WFUHS, or WFBMC controlled affiliate who owes a primary duty of loyalty and support to the Institution, including part-time appointments. *Family members related by blood, adoption, or marriage are included when considering financial or fiduciary interests.*
- C. **Institution:** Wake Forest Baptist Medical Center, defined as Wake Forest University Health Sciences and North Carolina Baptist Hospital and their controlled affiliates.
- D. **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:** ownership interest of shareholders in a corporation, partnership, or similar organization (includes ownership in non-valued start-up companies)
- G. **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, education, 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 the hiring of staff, the procurement of materials, or the conduct of other activities supporting the institution's objectives.
- a. Reportable outside activities include, but are not limited to ongoing or repetitive arrangements with outside entities (e.g. consulting, speaking, expert testimony, paid court appearances, laboratory testing, teaching, etc.). 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, charitable foundation, or academic society.

b. Non-reportable outside activities 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, and textbook editorships.

- H. **Industry-Sponsored Travel:** the occurrence of any reimbursed or industry-sponsored travel (i.e., that which is paid on behalf of the Individual so that the exact monetary value may not be readily available), related to the Individual's institutional responsibilities. This 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.
- I. **Travel Authorization:** a form that serves as the disclosure for Industry-Sponsored Travel and is completed prior to any professional travel. Reimbursed or Industry-Sponsored travel information must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of travel.
- J. **Conflict of Interest Review Committee (CIRC):** a committee of faculty/administrators/directors responsible for ensuring that individual and institutional conflicts of interest in research, clinical care, education, purchasing, intellectual property transfers and other institutional missions are identified, managed, or eliminated, in accordance with federal regulations and in the best interests of patients, research subjects, trainees, researchers, employees and the Institution.
- K. **Outside Employment:** personal contractual services provided for entities outside the Institution for which an individual spends considerable time and/or receives a regular retainer or income. Outside Employment 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 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 or an unvalued start-up company.
- L. **Outside Interest:** a personal professional relationship with any entity, domestic or foreign, public or private, for-profit or non-profit (excluding a Federal agency) with which an Individual has a financial interest or regular time commitment. This includes disclosure of family members' interests with entities that do business with WFBMC.
- M. **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.
- N. **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 family member):
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 family member) 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.
- O. **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.
- P. **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.
- Q. **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.
- R. **Exempt employees:** refers to monthly-paid Individuals, including certain special-exempt hourly pay groups of providers such as pharmacists, physical therapists, dieticians, etc. at NCBH, WFUHS, and WFBMC's controlled affiliates.

Prior Approval and Guidelines for Attending, Organizing or Speaking for Non-Certified Educational (non-CE) Events Sponsored by Industry

Payments by Industry for travel, meals, registrations, honoraria, etc. for an Individual to attend, organize, or speak at a non-CE educational event can compromise the appearance of the integrity in our clinical care. Prior approval promotes awareness of the policy guidelines for each activity, promotes discussion between the individual and his/her supervisor and ensures compliance with the Policy on Conflicts of Interest.

Individuals who wish to attend, organize or speak/provide leadership at a non-CE meeting, conference, or other activity that is fully or partially sponsored by Industry must obtain prior approval from his or her supervisor and the COI Office by completing the document that corresponds to the activity from the Forms Library on the Conflict of Interest website:

<http://intranet.wakehealth.edu/Departments/COI/Resources/>

A. Attending:

All attendees should follow the guidelines on the document, obtain approval from the appropriate leader, and obtain approval from the Conflict of Interest Office to mitigate the potential for perceived or real conflicts of interest (a departmental individual may complete one document for a group of attendees):

1. The main reason for attending the Industry-sponsored or supported educational event should be to advance knowledge in the attendee's area of institutional responsibilities with the intention of adding value to patient outcomes and/or institutional service excellence.
2. The attendee does not believe the event is a dedicated marketing and promotions program designed by Industry solely to influence purchasing or prescribing decisions, and the educational value outweighs any marketing influence.
3. Attendees may accept invitations to receptions and meals of modest value provided in conjunction with a legitimate educational event when incidental to the education and available for all attendees. 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 event.
4. The attendee believes the event contains didactic lecture and/or case based discussion and/or hands on lab sessions with recognized independent experts in the field who are not primarily employed by the sponsoring vendor.
5. The attendee believes that sufficient time is allowed for each activity to advance knowledge and/or train in technique and/or procedure.
6. Attendees may not receive a gratuity for attending the educational event, including material gifts, entertainment expenses or honoraria.
7. When attending an approved certified educational event and an unanticipated non-CE 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. Attendees understand that travel expenses do not extend beyond a reasonable arrival and departure period.
9. Attendee(s) do not solicit funding for the activity from vendor representative(s).
10. Attendees must obtain approval from their leader and the COI Office prior to attending the educational event.

B. Organizing:

All individuals organizing a non-CE event should follow the guidelines on the document,

obtain approval from the appropriate leader, and obtain approval from the Conflict of Interest Office to mitigate the potential for perceived or real conflicts of interest:

1. The organizer will not allow vendor sales representatives to conduct the educational activity.
2. For medical products or services used in the education, introductory comments by the organizer should include the following information:
 - a. The selection of the product or service is an evidence-based decision;
 - b. The educational activity does not imply an endorsement of the product or service by WFBMC or by the Individual;
 - c. Faculty or clinical provider participants have no personal financial interest in the activity.
3. The organizer will work with a business manager to ensure that the vendor will pay reasonable compensation for the use of WFBMC facilities, personnel, and resources.
4. The setting should allow critical interaction and evaluation among the participants.
5. Vendor representatives should be instructed that they cannot engage in sales, marketing, and promotional activities during the educational activity. Vendor displays must meet 2004 Updated Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of CME: Standards to Ensure the Independence of CME Activities and must be separate from the educational space.
6. Vendor representatives should be instructed not to provide material gifts of any value (pens, magnets, raffle tickets, etc.). Attendees are prohibited from accepting gifts or entertainment expenses of any kind as a gratuity for attending the training.
7. Receptions and meals of modest value may be provided if incidental to a legitimate, non-routine, educational activity (i.e. proposes to advance research, education, and/or clinical care using evidence based scientific principles). Receptions and meals should promote discussions among those attending. Meals should not be served in the same vicinity as vendor displays.
8. The organizer and WFBMC personnel may not provide mailing lists, email address lists, or other group contact information to vendor for use in inviting WFBMC personnel to an educational activity or for distribution of promotional material to WFBMC personnel. The sponsoring Department is responsible for communications pertaining to the educational event.
9. The organizer may not incorporate Industry sales or marketing information into any flyers, advertisements, or training materials. Educational materials should be restricted to the appropriate and necessary training documentation.
10. Individuals must obtain approval from their leader and the COI Office prior to organizing the educational event.

C. Speaking and Leadership

All speakers and leaders should follow the guidelines on the document, obtain approval from the appropriate leader, and obtain approval from the Conflict of Interest Office to mitigate the potential for perceived or real conflicts of interest:

1. The Speaker will design the activity to promote evidence-based clinical care, advance scientific research and/or teach desirable clinical skills or service excellence.
2. The Speaker is expected to provide a fair and balanced assessment of the subject and to

promote objective scientific and educational activities and discourse.

3. The Speaker's purpose at the event is not to act as a company's agent, spokesperson, or marketing representative for the purpose of disseminating company or product information.
4. The Speaker prepares the meeting or lecture content and does not use a pre-determined slide set or presentation dictated by the Industry sponsor to promote or market their product(s) and the company has no contractual right to control the content, excluding FDA required language, review for proprietary information or to grant final approval of the educational presentation. Exceptions to this rule may be granted with prior approval by the COI Office
 - a. to allow Individual participation in FDA-mandated training of providers for a new device or procedure
 - b. to allow the use of industry-developed illustrative slides that cannot be reasonably duplicated at the institution or
 - c. to allow an Individual to utilize an unbranded industry slide library to determine and prepare his/her own educational content.
5. Financial support by Industry will be fully disclosed to the attendees by the Speaker.
6. The Speaker makes clear that content reflects individual views and not the views of WFBMC.
7. The use of the names of WFBMC and/or its component affiliates is limited to the identification of the Speaker by his or her title and association with the institution.
8. The speaker may accept compensation or honoraria only for the services provided and the compensation must be reasonable and reflect fair market rates. Reasonable reimbursement for related travel and meals may also be accepted by the Speaker.
9. The Speaker will instruct vendor representatives not to give material gifts, entertainment expenses, or other compensation to any individuals as a gratuity for attending the activity.
10. The Speaker and WFBMC personnel may not provide mailing lists, email address lists, or other group contact information to vendor for use in inviting WFBMC personnel to the presentation or for distribution of promotional material to WFBMC personnel. The sponsoring Department is responsible for communications pertaining to the presentation.
11. Individuals must obtain approval from their leader and the COI Office prior to speaking or providing leadership for the educational event.

Guidelines on Specific Types of Gifts

A. Gifts to Individuals

Personal gifts from Industry may not be accepted by Individuals. Examples of personal gifts include pens, notepads, food baskets, flowers, gift cards, and entertainment, regardless of the value.

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

Personal gifts from patients or patient family members may not be received during ongoing care. If you have questions about such a gift, please contact the COI Office.

B. Gifts of Food

Industry Supplied or supported food and drinks are prohibited in the following circumstances: (Not an all-inclusive list)

1. In conjunction with an invitation-only meal provided offsite by an Industry Representative for the purpose of promoting or marketing their products.
2. In conjunction with routine medical center departmental or committee meetings.
3. In conjunction with in-services, new product information presentations or any other onsite activity that appears to be promotional or marketing in content.

Industry Supplied or supported food and drinks are permissible in the following circumstances: (Not an all-inclusive list)

1. In conjunction with sponsored research meetings for research that is covered by a formal agreement.
2. In conjunction with a certified education activity funded by industry through the WFUSM Office of Continuing Medical Education (per section IV. B.).
3. In conjunction with attending a legitimate educational activity when incidental to the education and available for all attendees. Formal request and prior approval is required (per section IV.C.).
4. In conjunction with a didactic educational lecture or meeting organized for a sizable audience by WFBMC faculty, clinical providers or staff which proposes to advance research, education, and/or clinical care using evidenced based scientific principles. Formal request and prior approval is required (per section IV. C.).

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

1. 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 this fund to pay for reasonable travel expenses and registration fees as determined by the Department Chair/ VP/Director.
2. Gifts of educational materials for the benefit of medical trainees such as textbooks, practice models and other materials are permissible if received by departmental leadership for distribution to trainees. Vendor representatives should not be allowed to distribute materials directly to trainees.
3. Gifts of educational materials for the benefit of patient care, 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, if feasible.

4. Gifts to support non-ACGME/ABMS fellowships will not be designated to the salary of any specific fellow. In addition, funds will not be used to support the salary of any fellow who provides and bills for their professional services (e.g. a 4th year therapeutic fellow).

D. Gifts of Medications and Pharmaceutical Samples

1. Medication samples will not be routinely supplied in the WFBMC ambulatory clinics.
2. Individual clinics may request an exception to the policy for use of samples in the following situations:
 - Patient education (for example, education in the use of inhaled drugs for pediatric asthma)
 - Appropriate patient trials to determine tolerance and efficacy
 - Hardship situations

To request an exception and for other procedures regarding samples, see the Pharmacy Policy on Medication Samples.

E. In-Kind Gifts to the Institution

Gifts 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 adhere to Office of Development & Alumni Affairs policies.

F. Donations to Institution for Philanthropic Events

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, clinical providers and faculty of WFBMC who are participating in the approved event.

Guidelines on Industry Access to Faculty, Clinical Providers, Staff, and Trainees

A. Access of Health Care Industry Representatives (HCIRs)

1. Faculty, clinical providers, staff, and student interactions with HCIRs must comply with the Health Care Industry Representative Management Policy found in Resource Management Policies, which requires HCIRs to properly register and prohibits their access to patient care areas.
2. HCIRs must have an appointment with a specified individual in order to visit the Medical Center, and they may not market products or services with Individuals over meals.
3. HCIRs may not place promotional materials in any area of the medical center for nonspecific distribution.

B. Access of Marketing Representatives

Marketing Representatives are individuals who:

1. Do not conduct business directly with WFBMC or any of its affiliates
2. Request access to meet with or provide promotional information to our faculty, clinical providers, staff, and/or trainees, or
3. Seek to do business with these Individuals.

Marketing representatives, individuals that meet the above criteria, will not be provided access by WFBMC to phone contacts, emails, or other personal information of its employees or trainees. Marketing Representatives may not offer gifts, meals, or incentives to WFBMC employees for referrals to their business. This does not include the representatives for companies which have been endorsed by Human Resources and have a contract to provide services for Medical Center employees and trainees.

C. Commercial Exhibits (Vendor Fairs)

Vendor fairs are prohibited at the Medical Center. 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 to 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.

D. 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 Appendix C, section C.3.

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

E. News Releases and News Media Contact

Prior to participating in a media event Individuals must disclose to Communications, Marketing and Media (CMM) 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 COI Office in compliance with CMM policies.