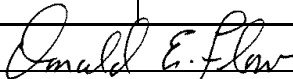
	<b>Policy on Institutional Conflicts of Interest in Research and Clinical Care</b>	<b>Type:</b>	<b>Tier I</b>
		<b>Effective Date:</b>	<b>05.07.15</b>
		<b>Revised Date:</b>	<b>03.06.19</b>
		<b>Contact:</b>	<b>WFBMC Conflict of Interest Office</b>
<b>Approval Signature:</b> 		<b>Date Approved</b>	<b>03.06.19</b>
<b>Typed Name and Title:</b> Donald E. Flow, Chair, Board of Directors			

## I. General Purpose

Wake Forest Baptist Medical Center (WFBMC) engages in relationships with a variety of for-profit and not-for-profit external entities that may lead to financial benefit for the institution in many forms, including gifts, business ventures, performance milestones, royalty payments and equity from licensing intellectual property, contracts to perform research services, as well as sponsored educational and research activity. In addition, institutional relationships with external entities for research and development services are essential for advancing scientific frontiers leading to the commercial development of academic discoveries for the benefit of the public. Nonetheless, while legitimately part of educational, research and business activities, relationships with external entities or individuals cannot be allowed to compromise, or appear to compromise, the integrity of the WFBMC primary missions, including the safety and integrity of its research, education and clinical care.

The purpose of this policy is to establish principles for a) the identification of institutional conflicts of interest that could, actually or potentially, influence or introduce bias into research-related activities and clinical care at WFBMC; b) the establishment of a committee to implement the policy; and c) the management of institutional conflicts of interest to:

1. Protect human subjects and clinical patients from risks related to institutional conflicts of interest;
2. Maintain the highest possible standards in research and clinical care;
3. Adhere to all applicable federal and state regulations;
4. Maintain the integrity of the WFBMC educational and clinical missions; and
5. Protect the reputation and credibility of WFBMC, its faculty and staff.

### A. Scope of Policy

The Policy on Institutional Conflict of Interest in Research and Clinical Care applies to key officials at WFBMC (as defined in this policy) and requires review of conflicts of interest in research and clinical care involving the institution and its key officials.

This policy does not replace or supersede any other WFBMC policy relating to conflict of interest.

### B. Responsible Parties

Policy Owner: Conflict of Interest Office

Procedure: Conflict of Interest Office

Supervision: Board of Directors of Wake Forest University Baptist Medical Center

Implementation: Audit and Compliance Council

## II. Definitions

- A. Institutional Conflict of Interest in Research and Clinical Care ( “Institutional COI”):** A divergence between an institution’s private interests and its research and patient care obligations such that an independent observer might reasonably question whether research or clinical care activities conducted by the institution or by one of its key officials may potentially be influenced or biased by consideration of significant financial interest.
- B. Key Officials:** Individuals at WFBMC in roles such as institutional officers; presidents; vice-presidents; general counsel; controllers; deans; advisors to the dean; department chairs; section heads; institute, center and division directors; other individuals responsible for oversight of research; Institutional Review Board chairs; COI committee chairs; the chair of the Medical Biosafety Committee; the chair of the Radiation Safety Committee; and chairs of other committees that have been or may be created to ensure additional protection of human subjects. For this policy, the definition also includes the spouse or domestic partner and immediate children of the key official.
- C. Individuals Responsible for Oversight of Research or Clinical Care:** WFBMC employee(s) with the authority and responsibility for the supervision of faculty, staff and trainees participating in research conducted at or under the auspices of WFBMC, or providing clinical care at WFBMC. The supervisory roles of particular importance in defining an “official with oversight of research or clinical care” include the evaluation and management of promotion, pay raises, and the assignment of job responsibilities, as well as academic assignments to students or other trainees and clinical assignments to students, residents and fellows.
- D. Significant Financial Interest (institutional):** The following relationships between WFBMC and/or its key officials and external entities may create significant financial interests:
1. *Royalties:* When WFBMC has agreements to receive milestone payments and/or royalties from the sales of a product that is the subject of research or clinical trials conducted at, or under the auspices of WFBMC;
  2. *Non-publicly traded equity:* When, through its technology licensing activities or investments related to such activities, WFBMC has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a non-publicly traded entity that is:
    - a. the sponsor of research or clinical trials at WFBMC; or
    - b. the manufacturer of a product to be studied or tested, at or under the auspices of WFBMC;
  3. *Publicly traded equity:* When, through technology licensing activities or investments related to such activities, WFBMC has obtained a direct ownership interest (not including equity interest held in a mutual fund or other non-discretionary account) or an entitlement to equity (including options or warrants) exceeding \$100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a publicly-traded entity that is a) the sponsor of research or clinical trials at WFBMC, or b) the manufacturer of a product to be studied or tested, at or under the auspices of WFBMC; and
  4. *Gifts from sponsors:* When WFBMC has received gifts exceeding \$100,000 in value, including gifts in kind, from a potential commercial sponsor of research or clinical trials, or from an entity that owns or controls products being studied or tested, or from an individual affiliated with these companies. The following circumstances should be evaluated:

- a. Whether a gift is of sufficient magnitude that even when held in the general endowment for the benefit of the entire institution, it might affect, or appear to affect, oversight of research or clinical trials at WFBMC;
  - b. Whether a gift is held for the express benefit of the hospital, school, department, institute or other unit where the research or clinical trial is to be conducted; or
  - c. Whether any key official who has the authority, by virtue of his or her position, to affect or appear to affect the conduct, review or oversight of the proposed research or clinical trial has been involved in solicitation of the gift.
5. *Fiduciary responsibilities for key officials with an outside entity*: When through an ownership interest or board membership a key official has a fiduciary responsibility to an external entity that can create competing motives with WFBMC's research and/or clinical care.

### **III. Identification of Potential Institutional Conflicts of Interest in Research and Clinical Care**

The following interests of WFBMC require formal review for institutional COI with respect to research and clinical care:

- A. Significant financial interests of the institution;
- B. Significant financial and/or fiduciary interests of key officials involved with the research or clinical trial; and
- C. Situations in which a key official involved in research or clinical care participates in procurement or purchasing decisions involving major institutional purchases from, or non-routine supply contracts with, an entity that sponsors research at WFBMC, whose product is being studied or tested in human subjects research at WFBMC, or whose product is used in clinical care at WFBMC.

In addition to those circumstances indicated above, other financial relationships with research sponsors or providers of clinical care products could require formal scrutiny, depending on the circumstances. In general, WFBMC will assess the potential for any conflict of interest and weigh the magnitude of any potential influence or bias. Primary consideration will be given to the potential impact of the institutional conflict on the safety and welfare of human research subjects or patients. The potential impact on the integrity of research data that could affect future clinical use will be carefully considered.

Although the listed circumstances are potential areas of concern, the goal of this policy is not to preclude WFBMC from accepting philanthropy from external entities that sponsor research, or that provide products that are being studied or tested at or by WFBMC, including clinical care products. Rather, this policy is intended to provide a means to (a) identify and examine potential institutional conflicts of interest, (b) manage potential conflicts of interest through disclosure and separation of responsibilities, and (c) as otherwise appropriate, mitigate any actual or apparent conflicts of interest that may result. All philanthropical gifts should be accepted in compliance with this policy through the office of Development and Alumni Affairs.

### **IV. Establishment of an Institutional Conflict of Interest Review Committee**

In order to review and manage institutional COIs, an Institutional Conflict of Interest Review Committee (I-CIRC) will be appointed by the Chief Executive Officer (CEO). The I-CIRC will be charged with promoting the highest ethical standards in conducting business and academic affairs of WFBMC by ensuring that the research and clinical care activities will not be influenced by consideration of the significant financial interests of WFBMC or financial and/or fiduciary interests of one of its key officials. The I-CIRC will review, monitor, and facilitate the development of management for institutional conflicts of interest and make policy and standard operating procedure decisions related to institutional relationships with external entities.

If the COI Office or the Conflict of Interest in Research Committee (CIRC) identifies a potential institutional conflict of interest during a review, recommendations for management will be sent to the I-CIRC for review and approval.

**Membership:** The I-CIRC shall consist of:

- a. Three members appointed by the CEO
- b. The CEO, who will chair the I-CIRC;
- c. At least one independent member of the public with no active institutional relationship and whose family members shall not be on the WFBMC payroll.
- d. Six ex-officio members with advisory, but not voting power, consisting of representation from the Legal Department, the Office of Sponsored Programs, the Institutional Review Board, Wake Forest Innovations, the Office of Compliance and the COI Office.
- e. The Director of the COI Office will act as Executive Secretary for the I-CIRC to (a) provide administrative support for I-CIRC meetings, and (b) provide administrative duties on behalf of the I-CIRC, including the maintenance of records, policy and standard operating procedures.

Committee decisions shall require a 2/3 vote of the total voting membership. Membership length of term will be reviewed annually and approved by the CEO. An I-CIRC member may advise the committee, but shall not vote on management of a research proposal or clinical concern with which he/she has a personal COI and/or involvement in the institutional COI under review.

## **V. Management of Potential Institutional COI in Research**

The following basic principles will be applied in the management of actual or potential institutional COI:

### **A. When WFBMC itself has a significant financial interest that could potentially influence or bias research outcomes:**

1. **Human Subjects Research:** In situations where WFBMC faculty members have unique capabilities, or where there are unique staff and resources at the institution, the research may be performed at WFBMC after the establishment of a formal institutional management plan that includes appropriate independent oversight and monitoring to ensure the safety, rights, and welfare of research subjects, as well as minimizing risk to the reputation and/or mission of WFBMC.
2. **Non-Human Subjects Research:** If the I-CIRC determines that the potential value of a non-human subjects research project exceeds the potential risks related to institutional COI, a management plan will be developed to provide independent oversight to ensure research integrity and to minimize risk to the reputation and/or mission of WFBMC.

### **B. When a key official is responsible for oversight of a research project and has a significant financial interest (including fiduciary role):**

The I-CIRC should review the role of the key official in relation to the research and to any other researchers, and the nature of his/her financial interest to determine if it creates a conflict of interest. If a conflict of interest exists, the I-CIRC will develop a plan to ensure that an appropriately objective individual can oversee the research for WFBMC to manage potential bias that could affect the research. In some cases alternative independent supervision of the research project may be required by the Committee.

## **VI. Review/Revision/Implementation**

### **A. Review Cycle**

This policy shall be reviewed by the Conflict of Interest Office at least every seven (7) years from the effective date.

### **B. Office of Record**

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

### **C. Implementation**

The Conflict of Interest Office shall implement this policy on behalf of, and with guidance from, the Institutional Conflict of Interest in Research Committee (I-CIRC).

## **VII. Related Policies**

### **A. [Risk Management - Insurance](#)**

### **B. Office of Research Policies:**

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

### **C. Conflict-of-Interest Procedure for News Releases and News Media Contact**

### **D. Wake Forest Innovations:WFBMC Intellectual Property Policy**

## **VIII. 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/text-idx?c=ecfr&tpl=/ecfrbrowse/Title37/37cfr401\\_main\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title37/37cfr401_main_02.tpl)

### **C. AAMC Reports on Individual and Institutional Financial Conflict of Interest Policies**

### **D. Institutional Conflict of Interest in Human Subject Research and Clinical Care- Management Guidelines (standard operating procedure)**