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ORGANIZATION(S):

- North Carolina Baptist Hospital (NCBH)
- Lexington Medical Center (LMC)
- Davie Medical Center (DMC)
- Wilkes Medical Center (WMC)
- High Point Medical Center (HPMC)
- Wake Forest Health Network (WFHN)
- Wake Forest University Health Sciences (WFUHS)
- Wake Forest University School of Medicine
- NCBH Outpatient Endoscopy
- Wake Forest Baptist Imaging, LLC (WFBII)

PURPOSE

The purpose of this policy is to establish the principled use of professional time and personal time used for professional endeavors by Individuals employed by Wake Forest Baptist Health (Institution, WFBH), defined as Wake Forest University Health Sciences (WFUHS) and North Carolina Baptist Hospital (NCBH) and their controlled affiliates.

The Institution supports principled personal relationships with industry and other organizations in which its 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 Individuals who expend personal effort outside the Institution while also maintaining the reputations of all employees, and their professional commitment to the Institution.

SCOPE

This policy applies to all faculty members, clinical providers, trainees, or exempt employees of NCBH, WFUHS, or WFBH controlled affiliate who owe a primary duty of loyalty and support to the Institution. Individuals, in recognizing that their primary professional responsibility is to the Institution, must devote their energies to external activities in congruence with the Institution’s mission and comply with each section of this policy, including the request for approval prior to engaging in an outside activity.

DEFINITIONS

- A. **Policy:** A statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities. A policy may help to ensure compliance with applicable laws and regulations, promote one or more missions, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors, and others are expected to operate.
- B. **WFBH:** Wake Forest Baptist Health (WFBH) is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical

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Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Wake Forest Baptist Imaging, LLC (WFBI), NCBH Outpatient Endoscopy, Wake Forest Health Network (WFHN), and Premier Surgery Center.

- C. **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
Non-Clinical Dept. 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 WFBH or designee
Department Managers:	VP or designee
Exempt or Special Exempt Staff:	Department Manager/Director
House Staff:	Associate Dean for GME or CMO
Faculty:	Department Chair or designee
Non-Clinical Dept. Chair:	Dean or designee
Clinical Department Chair:	Dean or designee, and President of WFBH or designee

- D. **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.

1. 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.
2. 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.

- 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).

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- G. **Exempt Employees:** Refers to monthly-paid Individuals, including certain special-exempt hourly pay groups of clinical providers such as pharmacists, physical therapists, dieticians, etc. at NCBH, WFUHS, and WFBH's controlled affiliates.
- H. **Individual:** A faculty member, clinical provider, trainee, or exempt employee of NCBH, WFUHS, or WFBH controlled affiliate who owes a primary duty of loyalty and support to the Institution.
- I. **Institution:** Wake Forest Baptist Medical Center, defined as Wake Forest University Health Sciences and North Carolina Baptist Hospital and their controlled affiliates.
- J. **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.
- K. **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.
- L. **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, charitable foundation or an unvalued start-up company.
- M. **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 WFBH.

POLICY GUIDELINES

A. Conflict of Commitment and Disclosure

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.

Individuals are required to seek prior approval for outside commitments, whether paid or unpaid, and also to disclose such commitments annually through an electronic reporting process administered by the Conflict of Interest (COI) Office upon new hire and each April during employment. For clarifications of reportable and non-reportable Conflicts of Commitment, see *Definition D – Conflict of Commitment*.

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For this policy, Leadership is defined in accordance with Definition C – Authority. Leaders are responsible for reviewing, evaluating, approving and managing any outside commitments observed in job performance or identified in the annual disclosure for their direct reports. The COI Office serves in an advisory role to relevant leadership concerning the disclosed conflicts of commitment.

1. Commitment of Time to Consulting and Other Outside Employment

The use of time for consulting and other outside employment activities is a privilege and not a right. 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.*

Activities that involve an Individual's personal effort, such as consulting and advisory agreements, expert witness testimony and publication of books and payment of related royalties are not subject to sharing of income with the Institution, however, written approval must be received by the Individual's departmental leadership on the *Outside Employment Request* prior to any such activity in accordance with guidelines in Appendix A (Outside Employment Requirements). Final review of personal consulting agreements for Conflict of Interest (COI) Policy compliance is available through the Conflict of Interest Office, at the request of the department leader.

The *Outside Employment Request* document may be found in the Forms Library on the Conflict of Interest website: <http://intranet.wakehealth.edu/Departments/COI/Resources/>.

2. Authority in Assignment of Duties

Leaders, as defined in Definition C – Authority, will review and consider *Outside Employment Requests* along with contracts/agreements for external employment or external personal professional relationships. This must be provided by Individuals prior to their participation in the activity. Leaders, as defined in Definition C – Authority, are also expected to disseminate approvals of significant outside commitment by their own direct reports to their senior leadership.

3. Allowed Time Away and Approvals

Approvals will be made by leadership based on the appropriateness of the activity within the context of professionalism and ethics, compliance with Institutional policies, and the amount of time proposed for the activity. The maximum amount of time allowed for outside employment will be determined by each department leader, as defined in Definition C – Authority, and may vary from department to department. In case of a dispute, departmental leadership may appeal to the Committee on Outside Activity (COA) for adjudication.

To review policy on allowable vs. prohibited activities, including requesting prior approval for industry-funded activities which do not require a personal agreement, please refer to the Conflict of Interest Policy, sections C and D.

4. Clinical and Adjunct (Volunteer) Appointments at Other Institutions

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Any Individual's clinical or medical practice occurring outside the Institution, unless otherwise specifically directed, is not permitted within the rules of a faculty member's non-compete agreement. Any exception must have written prior approval from the department leadership, as defined in *Definition C – Authority*, must be in line with the business needs of the institution, and copies must be maintained by applicable leadership.

5. Use of the Institution's Resources

Individuals may not use institutional resources for personal gain or to generate personal income.

Prior approval must be obtained and approved by the Individual'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.

The Office of Sponsored Programs (OSP) policies and Wake Forest Innovation (WFI) policies govern an Individual's participation in any agreement under which an outside entity will profit from WFBH resources (including information). Examples include but are not limited to start-up companies, inventions and patent ownership, data ownership, authorship and copyright ownership.

6. 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 independently of their affiliation with the Institution, therefore the Individual should be clear that opinions are their own and not the Institution's.

If an outside entity wishes to use any of the names, symbols or logos belonging to WFBH or its affiliates, written approval from Communications, Marketing and Media (CMM) must be obtained prior to such use. To request approval for use of the Institution's names, symbols or logos, e-mail a request to: Brand Center (brandchampion@wakehealth.edu).

7. 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 WFI Policies and OSP Policies.

8. Submission of Research Proposals

Individuals acting as Investigators must comply with all institutional and federal requirements regarding management of conflicts of commitment as specified in

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institutional policies and/or *PHS Regulations 2 CFR, 200*. Institutional policies on research proposals and professional effort may be found in OSP policies.

9. Employment of Relatives (Nepotism)

Individuals who intend to employ or collaborate on research with a relative or individual with whom they have a consensual relationship are required to report to Human Resources (HR) as outlined in the *Nepotism and Consensual Relationships Policy*. Individuals will cooperate with the appropriate departments to minimize or eliminate the appearance of bias that may be created by collaborating or working directly with a relative or individual with whom they have a consensual relationship.

B. Committee on Outside Activities (COA)

The Committee on Outside Activities is an ad hoc committee appointed jointly by the Dean, or designee, and President of the Health System. The purpose of the COA is to provide guidance to Chairs and provide management for their faculty members who may request outside employment that exceeds the expectations of time and/or income that the Chair determines is appropriate to carry out the mission of WFBH. The committee will consist of five Faculty Chairs with votes, and 1 ex-officio member from Faculty Affairs and 2 ex-officio members from the Compliance Office, with no vote.

The COA is administratively supported by the Conflict of Interest Office, which will be available to provide general guidance, consult with Faculty Affairs, and organize ad hoc meetings. The Director of the COI Office will serve as ex-officio Executive Secretary. Ex-officio members will conduct an annual review of disclosures for potential conflicts of commitment.

C. Penalties for Breach of Policy

Individuals have an obligation to comply with this policy. Examples of conducts that violate this policy include, but are not intended to be exhaustive:

- a. Failure to comply with the annual disclosure process by refusal to respond
- b. Intentional deception or dishonesty in disclosures
- c. Omission of industry relationship disclosures
- d. Repeated failure to seek prior approval for outside employment activities

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 *Definition C – 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:

- a. Reimbursement to the Institution for misused resources, including salary and/or other forms of institutional compensation and other applicable fines imposed by outside entities
- b. Written admonition for placement in Individual's file indicating that the individual's good standing has come into question
- c. Ineligibility to participate in grant applications, Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) applications or on committees

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- d. Ineligibility to work with graduate students
- e. Dismissal from an educational or training program
- f. Performance improvement counseling
- g. Dismissal of employment

REFERENCES

- Conflict of Interest Policy
- Nepotism and Consensual Relationships Policy
- Public Health Service (PHS) Regulations on Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 C.F.R. Part 200) – <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=19907435889953500f76cd52d011e52a&mc=true&n=pt2.1.200&r=PART&ty=HTML#sq2.1.200.a.sg0>

ATTACHMENTS

- Appendix A – Outside Employment Requirements

REVISION DATES

9/2006, 8/2012, 5/2016, 5/2018, 8/2018, 8/2021

Appendix A: Outside Employment Requirements

Any Individual who wishes to undertake outside employment (generally requiring considerable time and/or earning a retainer or income), including but not limited to consulting, expert witness activities, and advisory boards must attach the personal Agreement to a completed *Outside Employment Request* for each separate entity agreement and obtain prior approval from his or her supervisor as defined in *Definition C – Authority*.

Consulting agreements are personal agreements between an Individual and a separate Industry Entity, and do not include the Institution as a party to the consulting agreement.

- A. The Institution does not provide legal review or insurance coverage for personal Agreements; therefore, an Individual who considers entering into a consulting arrangement may wish to seek the advice of an attorney retained at his or her own expense.
- B. The Conflict of Interest (COI) Office will not negotiate with outside parties to personal consulting agreements, but will make policy compliance recommendations to the Individual who is consulting.
- C. Individuals must remember that their primary commitment is to the Institution. Annual reporting of outside time commitments and prior approval for each outside employment opportunity is required in accordance with the *Conflict of Commitment Policy*.
- D. Individuals may consult with Industry to contribute expert advice, provided any compensation for consulting services is reasonably related to specified services and is at fair market value. The activity must be 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.
- E. The following principles, adapted to the specific written agreement, should be included in all personal consulting agreements and will be subject to prior approval by appropriate leadership:
 1. The Industry Entity acknowledges in the written Agreement that Consultant's primary obligation is to WFBH.
 2. Efforts and specific responsibilities under the written Agreement must be separate and distinct from those duties performed for WFBH.
 3. Terms of employment between the consultant and WFBH will be specifically addressed, including work responsibilities and ownership of any resulting intellectual property, in accordance with Wake Forest Innovation (WFI) policies.
 4. Personal consulting agreements that address ownership of resulting intellectual property must be reviewed and approved by Wake Forest Innovations prior to execution.
 5. The following paragraph should be included in all personal consulting agreements:
Entity acknowledges that Consultant's primary obligation is to Wake Forest Baptist Health (WFBH). It is the intent of the parties that efforts and specific responsibilities under this Agreement be separate and distinct from those duties performed for WFBH. In the event of any conflict between this Agreement and any terms of employment between the Consultant and WFBH, including work

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responsibilities and ownership of any resulting intellectual property, the terms and conditions of the Consultant's employment with WFBH will take precedence unless specific written arrangements have been made in advance between Entity and WFBH.