

## Contractual Agreements

Faculty cannot conduct research projects at WFUHS without the involvement of the Office of Research, whose interest is to protect the rights of the researchers. Contractual agreements are necessary for all industry projects, and faculty may not accept payments outside the study contract.

## Managing Conflicts

- Conflict management always begins with disclosure and may require a management plan.
- Conflict management is situation specific; the goal is to achieve the simplest effective means of managing the conflict.
- The management plan is drafted by the conflicted investigator and his/her department chair with the assistance of the Conflict of Interest Administrator.
- Projects involving human subjects will be communicated to the Institutional Review Board.

**The key to managing all conflicts of interest is full disclosure to WFUHS.**

## Conflict of Interest Review Committee (CIRC)

- Reviews personal interests of employees that are potential conflicts of interest
- Determines if the conflicted research or other activity may proceed
- Reviews plans for management and oversight of the potential conflict when it is appropriate

Questions about potential conflicts of interest may be addressed to the Assistant Director of Conflict of Interest at 713-2990.

## COI/COC Policies

The COI/COC policies and related policies may be found on the Office of Research website:

**<http://www1.wfubmc.edu/OR/Conflict+of+Interest/COI+Policy.htm>**

- Overview and Summary-Conflict of Commitment and Conflict of Interest IV-46-48
- Policy on Conflict of Commitment and Disclosure IV-49-51
- Policy on Conflicts of Interest and Disclosure IV-52-53
- Procedures on Disclosure and Management for COC and COI IV-54-55
- Personal Consulting IV-56
- Nepotism IV-99

## COI Integrity Principles

- Investigators have a responsibility to conduct scientific activities objectively and with the highest professional standard.
- Consulting and advisory board relationships shall be carried out in a transparent and accountable manner and be disclosed as they are initiated.
- Investigators shall regard all significant financial interests in research involving human subjects as potentially problematic and requiring close scrutiny.
- Faculty mentors and institutions should make trainees aware of their rights and responsibilities in industry relationships.
- The primary responsibility of full-time faculty is to WFUHS. Outside activities shall complement, not compromise, school responsibilities.



## **GUIDELINES ON CONFLICT OF INTEREST AND COMMITMENT**

### **WHAT YOU SHOULD KNOW ABOUT**

**CONFLICTS OF INTEREST  
DISCLOSING AND  
MANAGING CONFLICTS  
CONFLICTS OF COMMITMENT  
CONTRACTUAL  
AGREEMENTS  
PROFESSIONAL CONSULTING  
CONFLICT OF INTEREST  
INTEGRITY  
CONFLICT OF INTEREST  
REVIEW COMMITTEE**

This brochure is for the Faculty and Exempt Employees, including Key Administrators of Wake Forest University Health Sciences (WFUHS) and contains guidelines consistent with WFUHS policies on conflict of interest and commitment listed on the back panel with other related policies. These guidelines are not a substitute for the actual WFUHS policies.

## What is Conflict of Interest?

**Conflict of interest** refers to a situation in which financial or other personal considerations may compromise, or have the appearance of compromising, an individual's or institution's professional judgment in conducting or reporting research, protection of human subjects, or carrying out or directing other types of school programs.

**Individual** conflicts may result in bias during the collection, analysis and interpretation of data in clinical protocols, as well as clinical decision-making, hiring of staff, and procurement of materials.

An **institution** may have a conflict of interest whenever the financial interests of the institution, or of an institutional official acting within his or her authority, on behalf of the institution, might affect (or reasonably appear to affect) institutional processes for the conduct, review, or oversight of research.

The **mere appearance** of a conflict of interest may be just as serious and potentially damaging as an actual lack of objectivity and should be evaluated and managed with the same consideration as known conflicts of interest. When in doubt whether or not a conflict of interest exists, individuals may direct questions to the Office of Research.

### Examples:

**Researcher**— an investigator who earns remuneration speaking for a pharmaceutical company that sponsors research in which he participates may have a significant financial conflict of interest.

**Institution**— research performed by WFUHS employees, if sponsored by a WFUHS spin-off company, would constitute an institutional conflict of interest.

**Business**— a potential conflict of interest may exist if any WFUHS employee receives financial benefits from an entity with which he/she does WFUHS business.

## Significant Conflicts of Interest

Any of the following interests that you *or a relative* may have with your research sponsors:

- **Income from Speaking/Consulting**—compensation >\$10,000 per year from the same entity
- **Equity**— > 5% of an entity or \$10,000 value, including stock options
- **Royalties** - current & potential future payments
- **Fiduciary Service**- officer or board member of an outside entity
- **Intellectual Property Rights** - patents, copyrights, and royalties from such rights

## Disclosure

- **Annual**- WFUHS faculty and exempt employees must disclose online all existing and potential personal interests that may result in a conflict of interest.
- **Project-related**— individuals must disclose conflicts of interest related to the sponsor of each research application.
- **Public**— individuals must disclose conflicts of interest to human subjects involved in their research, and to audiences of their presentations and publications.

**Additional disclosure may be necessary throughout the year if there is a substantial change in external activities or when required by granting agencies or WFUHS.**

## Conflict of Commitment

Interaction between faculty members and exempt employees and external entities for reasonable periods of time and for personal remuneration is desirable and encouraged when the relationship enhances the professional skills of the individual and is a benefit to the University. The individual's Department Chair or Supervisor may allow the equivalent of up to *26 days per year*.

The time allowable will vary among individuals, from discipline to discipline, from one type of proposed activity to another, and will be affected by specific departmental needs to meet teaching, research, service, and governance functions. Such released time is not an automatic entitlement and requires prior written approval by the Department Chair or Supervisor.

**Each new activity undertaken by a faculty member that may conflict with the primary commitment to WFUHS requires approval in advance by the Department Chair or Supervisor.**

## Professional Consulting

A faculty member or exempt employee **must notify his/her Department Chair or Supervisor** and receive necessary approval to engage in most external activities involving the use of personal professional competence to receive direct or indirect compensation from a non-WFUHS source. Consulting and speaker's bureau agreements are personal contracts between the individual and the outside entity, not involving WFUHS. Since WFUHS does not provide insurance or indemnification for most external activities, the individual is encouraged to retain his/her own attorney to advise and prepare consulting contracts. He/she should also make sure that an agreement does not conflict with primary obligations to WFUHS.