

Contractual Agreements

Faculty cannot conduct research projects at Wake Forest Baptist Medical Center without the involvement of the Office of Research, which protects the rights of 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 the department chair with the assistance of the Conflict of Interest administrator.
- Projects involving human subjects will be communicated to the IRB and projects involving animals will be communicated to the Institutional Animal Care and Use Committee.

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

Medical Center Conflict of Interest Office

Conflict-of-interest processes, committee support and policy development are managed and supported in a central office at WFBMC. Questions about potential conflicts of interest may be addressed to the Conflict of Interest Office at 336-716-9300.

The Conflict of Interest in Research Committee (CIRC) determines if the conflicted research or other activity may proceed. It also reviews plans for management and oversight of potential conflicts when it is appropriate.

The Conflict of Interest with Industry in Clinical Care and Education Committee (Co-ICE) determines if activities involving education, clinical care and other Medical Center functions are allowable in accordance with current COC/COI policies.

Conflict of Interest/Conflict of Commitment Policies for Research

The comprehensive COC/COI policy may be found on the Medical Center's COI Office website, <http://intranet.WakeHealth.edu/Departments/COI/Policies-and-Supporting-Documents/Policies-and-Supporting-Documents.htm>.

Medical Center Conflict of Interest Website

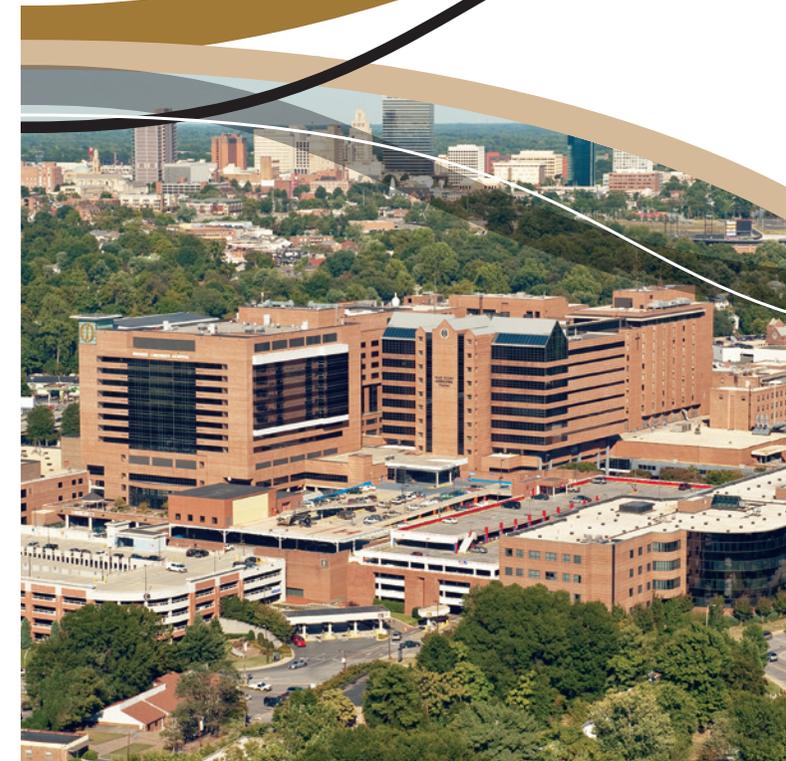
<http://intranet.WakeHealth.edu/Departments/COI/>

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 all faculty and staff is to WFBMC. Outside activities shall complement, not compromise, institutional responsibilities.

This brochure is for the faculty and staff of Wake Forest Baptist Medical Center (WFBMC) and contains guidelines consistent with institutional policies on conflict of interest and commitment. These guidelines are not a substitute for the actual WFBMC policies.

Guidelines on Conflict of Interest and Commitment



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 institutional 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, procurement of materials and education of trainees. An institution may have a conflict of interest whenever the financial interests of the institution, or institutional officials acting within their authority, on behalf of the institution, might affect (or reasonably appear to affect) institutional decisions involving research, purchasing, accepting gifts, clinical care and education.

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 if a conflict of interest exists, individuals may direct questions to the medical center's COI Office.

Examples of Conflicts:

- Investigators who earn remuneration speaking for a pharmaceutical company that sponsors research in which they participate may have a significant financial conflict of interest.
- Research performed by medical center employees, if sponsored by a medical center spin-off company, would constitute an institutional conflict of interest.
- A potential conflict of interest may exist if any medical center employees receive financial benefits from an entity with which they do medical center business.

Significant Conflicts of Interest

Any of the following interests that you or a spouse or children may have with your research sponsors or a vendor whose products you order or prescribe may represent a significant conflict:

- **Income from Speaking/Consulting:** Compensation greater than \$5,000 per year from the same entity.
- **Equity:** Greater than 5 percent of an entity or \$5,000 value, including stock options, or any equity in non-publicly traded entities.
- **Royalties:** Current and potential future payments.
- **Fiduciary Service:** Officer or board member of an outside entity, whether for-profit or non-profit.
- **Intellectual Property Rights:** Patents, copyrights and royalties from licensing such rights.
- **Travel:** Airfare, lodging, meals and other travel expenses reimbursed or paid on behalf of an individual by an outside entity.

Disclosure

- **Annual:** WFBMC faculty and exempt employees must disclose online all existing and potential personal interests that may result in a conflict of interest, regardless of value.
- **Project-related:** Individuals must disclose financial interests 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, publications and agents for media release.

Additional disclosure may be necessary at any time if there is a substantial change in external activities.

COI Training

All PHS-funded investigators must complete an online financial conflicts of interest training course provided by WFBMC at least every 4 years to remain in compliance with federal regulations. The training may be found in the investigator's PeopleSoft self-service under Learning and Development.

What is 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 institution. The individual's department chair or supervisor must determine how much time is allowable. 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 each new activity undertaken by a faculty member that may conflict with the primary commitment to WFBMC requires approval in advance by the department chair or supervisor.

Outside Employment

Faculty members or exempt employees must notify their department chair or supervisor and receive written approval in advance to engage in external personal contractual activities involving the use of professional competence to receive direct or indirect compensation from a non-WFBMC source. Consulting and expert testimony agreements are personal contracts between the individual and the outside entity, not involving WFBMC. Because WFBMC does not provide insurance or indemnification for most external activities, individuals are encouraged to retain their own attorney to advise and prepare consulting contracts. They should also make sure that an agreement does not conflict with primary obligations to WFBMC or its policies.