

OVERVIEW AND BACKGROUND of Conflict of Commitment and Conflict of Interest

(Revised January, 2010)

I. BACKGROUND

Requirements set forth in 42 CFR, Part 50, Subpart F and other Federal guidelines (National Science Foundation, National Institutes of Health, Food and Drug Administration) call for disclosure of personal financial interests by Principal Investigators, Clinical Investigators (co- or sub-investigators), and others involved in the conduct of research in any way that could bias the design, conduct or implementation, management, and reporting of research data. The regulations further require that the University have a mechanism for the investigators to disclose real or potential conflicts and for the development of a management plan that manages, eliminates, or reduces the potential conflict, if necessary. The disclosure and management of the conflict must occur before any funds are released to the grantee institution and contractors (investigator) for expenditures, and before any human subject research may occur.

II. OVERVIEW

Conflict of Commitment: Faculty members and exempt employees, including key administrators (as defined in the WFUHS Employee Human Resources Manual) owe a primary duty of loyalty and support to the Medical School. The professional time and efforts of the Individual are expected to be devoted, as appropriate to each appointment, to patient care, teaching, counseling students, pursuing research and other scholarly work, serving on School committees, performing necessary administrative duties, and carrying out such other duties as are expected in the department of which they are members. Outside activity may not distract from these primary responsibilities.

Conflict of Interest: The School has the responsibility to evaluate all potential conflicts of interest that may be created by a financial or fiduciary interest of an Individual. Reports of conflicts based on appearances can undermine public trust in ways that may not be adequately restored even when mitigating facts of a situation are brought to light. The appearance of a conflict may be serious and as potentially damaging as the presence of an actual conflict. Potential conflicts, therefore, should be evaluated and managed with the same vigor as known conflicts.

III. DEFINITIONS

1. a. For conflict of commitment ***Individual*** means the faculty member or exempt employee who owes a primary duty of loyalty and support to the Medical School, including part-time appointments.
- b. For conflict of interest ***Individual*** means the principal investigator/project director, co-investigators, and any other person who is responsible for the design, conduct, or reporting of research for which extramural funding is sought, or the person conducting educational or other academic activities such as consultation. The principal investigator is responsible for identifying

to the Office of Research other persons who are responsible for the design, conduct, and reporting of the research for which extramural funding is sought, or involved in educational or other academic activities. *Individual includes spouse and dependent children.*

2. A ***conflict of commitment*** exists when a faculty member or exempt employee of Wake Forest University School of Medicine (WFUSM) has a relationship that requires a commitment of time or effort to outside activities that may potentially result in the Individual's failure to meet his or her obligations to the School. Any relationship with an outside entity that requires frequent and/or prolonged hours of effort spent outside WFUSM may present a conflict of commitment, *regardless of amount of remuneration, number of days, time of day or day of the week.*

3. The term ***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, or carrying out or directing other types of School programs. The bias that may result from such conflicts could have impact not only on the collection, analysis, interpretation and reporting of data, but also on the hiring of staff, procurement of materials, or other activities influencing the course of the School's programs. WFSUSM follows the Public Health Service (PHS) regulations' definition for significant financial interest set forth in 42 CFR, Part 50, Subpart F ([http://grants.nih.gov/grants/compliance/42 CFR 50 Subpart F.htm](http://grants.nih.gov/grants/compliance/42%20CFR%2050%20Subpart%20F.htm)).

4. ***Reportable conflicts of commitment*** include, but are not limited to ongoing or repetitive arrangements with outside entities include consulting, speaking, expert opinion, paid court appearances, research, laboratory testing, and teaching, regardless of the amount of remuneration, the number of days, the time of day, or day of the week.

5. ***Non-reportable conflicts of commitment*** include writing, membership on peer review panels, and membership on advisory groups/councils for not-for-profit organizations.

6. ***Reportable significant financial interest***, meaning receiving anything of value, including, but not limited to:

- All payments for services (e.g., consulting fees, lecture payments, or honoraria) regardless of value.
- Equity interests (e.g., stock ownership, stock options, or other ownership interests) regardless of value.
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights) regardless of value.
- Fiduciary services (e.g., officer or board member of an outside entity), even if unpaid.

7. Some examples of ***non-reportable significant financial interest*** include:

- ownership of mutual funds;
- salary or reimbursements from the school;
- income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- income from service on advisory committees or review panels for public or nonprofit entities (e.g., NIH). Disclosure *is* necessary when a foundation is supported by industry.

IV. SANCTIONS

Disclosure-Related Violations:

The Dean/President will review all alleged breaches of the disclosure process, including

- a) failures to comply with such process, whether by virtue of an Individual's refusal to

respond or by his/her responding with incomplete or knowingly inaccurate information, b) failures to remedy conflicts, and (c) failures to comply with a prescribed management plan. Such cases may, if appropriate, be forwarded to an appropriate *ad hoc* Medical School Committee for investigation. The committee will provide the Individual an opportunity to respond to allegations of a breach in the disclosure process, first in writing and then in person if appropriate. Any such written response will be appended to the committee's report for review by the Dean/President.

Instances of deliberate breach of policy – including failure to file a required disclosure form, knowingly filing an incomplete, erroneous, or misleading disclosure form, or failure to comply with prescribed monitoring procedures – will be handled in accordance with applicable disciplinary policies and procedures of the School of Medicine as described in other sections of the Organization and Policies Handbook, including the potential for dismissal.

Management-Related Violations:

If an Individual has violated this policy or the terms of the management plan, the CIRC shall recommend sanctions, which may include disciplinary action ranging from a letter of reprimand, to suspension of access to funds, to termination of employment. If the violation results in a collateral proceeding under School policies regarding misconduct in science, then the CIRC shall defer a decision on sanctions until the misconduct in science process is completed. The CIRC's recommendations on sanctions shall be presented to the Dean/President, or designee, who will propose sanctions to the Dean/President. The Dean/President shall approve and implement any disciplinary action. In addition, the School shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Individual has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Individual, until the matter is resolved.

V. THE APPEALS PROCESS

In order to appeal the decision of a department chair or supervisor, an Individual may request that the department chair or supervisor submit the conflict of interest and/or commitment review to the Senior Associate Dean for Research for an initial ruling. The Senior Associate Dean for Research will then seek concurrence and final decision from the Dean/President.