Conflict of Time and Interest

Institutional Training for KSU Faculty and Staff



University Research Compliance Office

Conflict of Interest

For research universities to retain their standing as independent arbiters of knowledge, research must be conducted according to the highest ethical standards.



Conflict of Interest (COI)

A key goal for universities is to segregate decision making about financial activities and research activities, so that decisions can be made about one without undue influence from the other. **Financial and research activities** should be separately and independently managed.

Conflict of Interest (COI)

The partnership between research universities and their principal research sponsors – including the federal government – must be based on the conviction that universities are accountable for the research they perform. If research universities do not demonstrate their ability to maintain accountability for individual and institutional COI, more prescriptive approaches may well be pursued by either the executive or legislative branches of government, or both.

Conflict of Interest

- **COI** is a divergence between private interests, and professional obligations to the university so that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal benefit, gain or advantage.
- *The mere appearance of a COI can be as damaging as an actual conflict.* Thus, report potential conflicts so that appearances can be separated from reality.
- Potential COI are not unusual in a modern university. COI can arise since the university promotes public good by fostering transfer of knowledge gained to the private sector.
- Two important means of accomplishing this transfer include consulting and commercialization of technologies derived from research. University personnel should be rewarded for participation in these activities through consulting fees and sharing in royalties from the commercialization of their work.
- It is wrong, however, for an individual's actions or decisions to be determined by considerations of personal financial gain.

Research universities are concerned about financial conflict of interest (COI) because it strikes to the heart of the integrity of the institution and the public's confidence in that integrity.

Universities want to protect the key values identified below from such conflicts of interest:

- their commitment to *educating students*;
- their commitment to academic freedom;
- their commitment to advancing the range and depth of knowledge and understanding of the natural world and our human condition;
- their commitment to the *safety of patients* and *participants in research*;
- their commitment to *open and timely communication and dissemination of knowledge*; and
- their commitment to protect the appearance and integrity and objectivity of research, instruction, and public service.

Report of Task Force on Research Accountability - Association of American Universities - October 2001

Conflict of Interest (COI)

Transferring university-developed knowledge to the private sector is one of the goals of federally funded research, by bringing the fruits of research to the benefit of society. With technology transfer comes increasingly close relationships between industry and universities, which provide benefits - but also increases the risk of academic research being compromised in two ways:

1. Individual Financial Conflict of Interest (COI) in Science

2. Institutional Conflict of Interest (COI)



Conflict of Interest (COI)

- COI is rarely a particular conflict itself rather it is the question about what is *done* with the specific conflict.
- In most cases, problems arise when the <u>COI is not made apparent</u>, or when it is not assessed or managed.
- Other than in the particular case of research involving human subjects, much of the challenge is for universities to develop robust systems so that conflicts are disclosed, assessed, and managed.
- With *individual* COI, the focus is on improving existing management systems and regulatory compliance
- With *institutional* conflict, the focus is on developing policies and principles, since no regulations guide this area. *This presentation*



This presentation will focus on individual COI)

Individual Financial COI in Science or Research

Situations may occur in which financial considerations may compromise, or *have the appearance of compromising*, an investigator's professional judgment in conducting or reporting research.



The bias such conflicts may impart not only affects collection, analysis, and interpretation of data, but also hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants, and the use of statistical methods

What is **Individual Conflict of Interest?**

- Individual COI should be *considered across all academic fields*, not just biomedical ones (though biomedical conflicts have some unique aspects and invoke a special intensity and interest);
- This definition centers on financial conflicts of interest in research, and excludes conflicts of commitment and non-research and non-financial conflicts, which bear separate scrutiny
- **COI for individuals primarily concerns faculty**, but also applies to other officials and staff involved in research administration



Individual Conflict of Interest

The 1995 requirements established by the National Science Foundation (NSF) and the Public Health Service (PHS) require federally supported investigators to *disclose* to their institution significant financial interests that would reasonably appear to affect research funded by PHS or NSF.

Institutions are required to determine if a COI exists, and if so, how the COI can be managed, reduced, or eliminated.





Individual Conflict of Interest

In 1998, the Food and Drug Administration (FDA) established regulations requiring companies filing a New **Drug Application to certify that no financial** arrangements with an investigator have been made where study outcomes could affect compensation, and requiring disclosure to FDA of any pertinent investigator financial arrangements and steps taken to minimize the potential for bias.



KSU Policy for Conflict of Interest and Conflict of Time

The following slides are based on the University Handbook, Appendix S: KSU Policy on Conflict of Interest and Conflict of Time Commitment



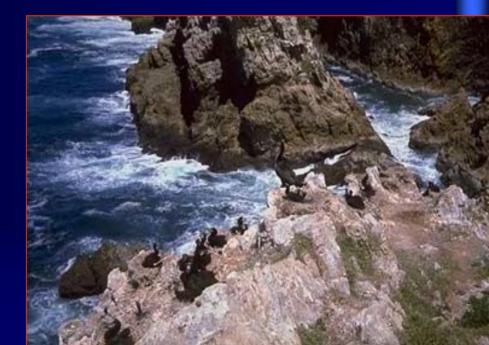
For a comprehensive explanation of KSU policies regarding Conflict of Interest and Conflict of Time, please refer to the complete policies at http://www.k-state.edu/conflict/

KSU Policy for Conflict of Interest and Conflict of Time

The KSU policy concerning conflicts of interest and time commitment was developed by a university task force in to ensure compliance with Kansas laws and mandates from the Board of Regents and federal funding agencies - the latter as a prerequisite for their future support. Policies are found in the University Handbook, Appendix S: KSU Policy on Conflict of Interest and Conflict of Time Commitment

Main topics in the Handbook include:

- 1. Conflict of Time Commitment
- 2. Conflict of Interest
- 3. Consulting or Other Employment
- 4. Reporting Requirements
- 5. Use of University Name
- 6. Kansas State University Review Process
- 7. Sanctions



Conflict of Time Commitment

- Conflicts of commitment usually involve issues of time allocation
- Whenever a faculty or staff member's **external activities exceed reasonable time limits**, or whenever an unclassified staff or faculty member's primary professional responsibility is not to the institution, a conflict of time commitment exists.
- Faculty members and unclassified staff owe their primary professional responsibility to their employing institutions, and their primary commitment of time and intellectual effort should be to the KSU missions
- Faculty and unclassified staff should maintain a presence on campus commensurate with their appointments.



Consulting or Other Employment

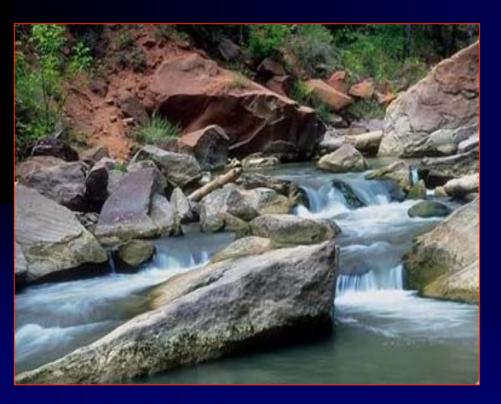
For a comprehensive explanation of KSU policies regarding consulting or other employment, please refer to the complete policies at http://www.k-state.edu/conflict/

- Consulting for Other State of Kansas Agencies: Must be approved in advance by the institution or agency seeking these services and approved by the employee's home institution.
- Consulting Outside the University: Without prior approval, faculty members or unclassified professionals on full-time appointments must not have significant outside managerial responsibilities nor act as principal investigators on sponsored projects that could be conducted at their institution but instead are submitted and managed through another organization.
- Other Employment: Faculty and unclassified staff should give full professional effort to their assignments. It is inappropriate to engage in gainful outside employment that is incompatible with institutional commitments. (Participation in academic conferences, workshops and seminars does not usually constitute consulting or outside employment).



Use of University Name

The name of the Board of Regents, a Regents institution or the Regents System may never be used as an endorsement of a faculty member or unclassified staff member's external activities without expressed and advance written approval of the University chief executive officer and/or the Board's Executive Director



Faculty members or unclassified staff members may list their institutional affiliation in professional books, articles and monographs they author or edit and in connection with professional workshops they conduct or presentations they make without securing approval

Reporting Requirements

For a comprehensive explanation of KSU policies regarding consulting or other employment, please refer to the complete policies at http://www.k-state.edu/conflict/

- Annual Reporting: Faculty and unclassified staff must disclose whether they, their family, or associates have consulting arrangements, significant financial or managerial interest, or employment that would reasonably appear to be directly and significantly affected by their research or other university activities.
- Reporting Significant Ad Hoc Current or Prospective Conflicts As They Occur: Faculty and unclassified staff must disclose to department chair, dean or supervisor, current or prospective situations that may raise questions or conflict of commitment or interest.
- **Reporting of Consulting:** Faculty members or unclassified professionals must report proposed arrangements for personal professional activities and secure approval prior to engaging in the activities.
- Faculty must inform the provost of all external personal, professional activities. For faculty members only, personal, professional activities that occur within a single 24-hour period need not have prior approval but must be reported annually in writing on the Annual Declaration and Disclosure.
- Unclassified professionals must inform the appropriate vice president / provost of all external personal professional activities, and obtain approval prior to engagement external personal professional activities



KSU Policy for Conflict of Interest and Conflict of Time

- In general, university resources may not be used in external activities unless written approval has been received from the institution's chief executive officer or his/her designee
- Proprietary or other information confidential to KSU may never be used in external activities unless written approval has been received in advance
- Faculty or unclassified staff may not involve students, classified staff, unclassified staff or faculty in their external activities if such involvement is in any way coerced or in any way conflicts with the involved participants' required commitment of time to their university
- A college or unit, in consultation with the Provost, may clarify definitions of conflict or apparent conflict leading to COI or time commitment unique to the unit's mission



Kansas Governmental Ethics Commission – Statement of Substantial Interests Form

To facilitate disclosure and management of Financial conflict of interest (COI), K.S.A. 46-248 requires that all state employees file an annual **Statement of Significant Financial Interests Form** with the Secretary of State between 15-30 April.

The forms are available at <u>www.accessKansas.org/ethics.</u>



KANSAS STATE UNIVERSITY ANNUAL DECLARATION AND DISCLOSURE

- In order to comply with federal regulations and Board of Regents (BOR) policy, Kansas State University (KSU) requires all unclassified faculty and Staff with 100% or fractional time appointments to file an Annual Declaration and Disclosure form. Unclassified faculty and staff with fractional appointments who have potential or possible conflicts of time or conflicts or interest are also required to file disclosure forms.
- The disclosure forms assess any perceived, real or potential conflicts of time or financial interest that are related to faculty research and other university activities.



KSU Review Process

Reporting procedures reflect requirements in the policy adopted by the Board of Regents. Two forms have been developed to implement this policy, the Annual Declaration and Disclosure (developed by Board of Regents) and the Consulting Request.



The Annual Declaration and Disclosure will be attached to each annual contract and is to be returned every year to the unit head with the signed contract.

The Consulting Request form must be filed with and approved by the unit head, dean, and provost in advance of undertaking any consulting activity.

Sanctions

In the event a faculty or unclassified staff member fails to comply with this policy, he or she could be subject to sanctions ranging from:

- loss of the privilege of submitting grant proposals and receiving extramural support, to
- dismissal for cause in extreme cases, (University Handbook C161.1).



KSU Policy for Conflict of Interest and Conflict of Time

The University Handbook, Appendix S: KSU Policy on Conflict of Interest and Conflict of Time Commitment is the definitive reference for policies and guidance about COI. You should refer to the handbook if you have questions.





This presentation has been prepared by the University Research Compliance Office (URCO). If you have questions or comments about this training module, please contact us at 785-532-3224, comply@ksu.edu, or visit the Research Compliance home page at http://www.ksu.edu/research/compliance