

# University Senate Meeting

## December 8, 2010

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# Changes to Federal Conflict of Interest Regulations

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# Outline

- Background
- Goals
- What is Changing?
- What Does it Mean?
- Going Forward

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# Background

- Last major revision in federal regulations impacting disclosure & management of conflicts of interest was in 1995
- Senate Policy/Faculty Handbook Appendix revised then with the latest revision in 2003:  
Conflict of Interest [1-67](#); [23-95](#); [4-96](#); [11-96](#); [9-01](#); [22-01](#); [2-03](#)]
- In '95, NIH took the lead, issued initial regulations, and other agencies followed. This same pattern is emerging again.

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- **Grassley Hearings** – Identified numerous examples of questionable disclosures of conflicts by university faculty around the country
- **Physician Payment Sunshine Act of 2008** – Requires new standards of disclosure of conflicts and transparency (public accessibility)
- **America COMPETES Act** – Imposes new training requirements on recipients of federal funding

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- **Chronicle of Higher Education** – June, 2008; October, 2009
- **NIH**
  - Notice of Proposed Rulemaking - May 21, 2010
  - Supplemental Notice - July, 2010
  - Public Comment Period – October, 2010
  - Final rules expected no later than March, 2011
- **NSF** – surveying institutional COI compliance and beginning process

# Goals

- Maintain objectivity and prevent the introduction of bias into research
- Transparency

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# What is Changing?

- Responsibility for determination of conflicts will shift from individual researcher to their institution
- Will require annual individual disclosure updates
- Public access to financial conflict of interest information
- Will mandate increased training



# What Does it Mean?

- Investigators will be required to disclose significant financial interests [SFI] to their institution on an annual basis and any changes or new SFIs within 30 days
- Thresholds for significant financial interests will be lowered to any payments and/or equity of \$5,000 or greater annually [consulting, royalties, speaker fees, etc.] and any equity in non-publicly traded companies. Likely will exclude income from seminars, lectures, etc. and service on advisory or review panels for government or higher education

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- Institution must have a written management plan for each identified financial conflict of interest [FCOI] and must monitor the plans
- NIH will likely require reporting to NIH of each FCOI that will at least include name, value, nature, and management plan
- Posting of all FCOIs on a publically accessible web site, including name, position, value, and nature of FCOI before expenditure of funds

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- Disclosure requirements will apply to at least PIs, co-PIs, senior personnel, and key personnel
- Scope will be increased to include SBIR/STTR Phase I activities
- NIH will require documented FCOI training before engaging in PHS funded research with updated training every two years thereafter

# Going Forward

- After NIH rules published in early 2011, we will probably have at least one year, but not more than two years, for implementation
- NSF will likely issue their rules at least one year, but probably not more than two years, after NIH
- Some universities have already started – for example, see <http://med.stanford.edu/coi/> [including Individual Faculty Member's Industry Relationships]

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- We have maintained an approach that only requires the minimum disclosure necessary to be in compliance with federal regulations. Universities that currently require more are much further ahead in implementation of these new requirements.
- Senate, Provost, and VPR need to begin process of policy revision and procedure development

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- We should begin discussions prior to issuance of NIH rules. Suggest separation of policy and procedures, with a goal of a new policy by May, 2011.
- Implementation of new procedures may be as soon as early 2012, but might extend to 2013. If 2012, they need to be developed by December, 2011

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