

Summary of Proposed Changes to Policy 11-01-03

Conflict of Interest Policy for Research

The following are some of the important elements of the proposed new policy.

- Changes to the policy were made with respect to faculty and inventor equity ownership in companies licensing University owned inventions. Under current policy the maximum equity that a faculty member can hold in a licensed start-up company is 49%. The new policy places no limit on equity ownership by faculty.
- Faculty members will be allowed to have management positions in start-ups, provided they have the prior approval of their supervisors and agree to a Conflict of Interest (COI) management plan. This significantly broadens the current policy which allows Principal Investigators (PIs) to have management positions in start-ups only for two years or until there is \$500,000 in product sales and only for companies with options to license, and not an active license to University Intellectual Property (IP). Except in cases of human subject research, holding a management position would not automatically preclude a faculty member from being the PI on a project at the University that is related to company interests.
- Faculty will continue to be allowed to pursue outside activities (for example, consulting) for 20% of their time (1 day/week).
- Faculty members will now be allowed to conduct research benefiting outside entities as part of their 20% outside activity time. This has not been allowed to date. In the new proposed policy, when research benefiting an outside entity is conducted as an outside activity, this research must be performed at an outside facility.
- Outside activities still require approval by the faculty member's supervisor and compliance with the existing policy on outside activities. (**Policy 02-06-01**)
- Faculty members with a Significant Financial Interest (SFI) related to research involving animals will now be permitted to serve as PI on that research project. This must be approved by the Institutional Animal Care and Use Committee (IACUC) and the COI Committee (COIC). The PI must agree to a COIC-approved conflict management plan. Previous policy prohibited a faculty member with a SFI from serving as PI on an animal study when that study was related to their financial interests.
- No changes were made from the current policy prohibiting, in almost all cases, faculty members with a SFI from serving as PI on research involving human subjects when the SFI is related to the research. Exceptions are made rarely, and final authority rests with the Institutional Review Board, a component of the Human Research Protection Office.
- Research funded by a company will be allowed in designated university facilities when appropriate University agreements are in place. For example, University research, funded by a company and conducted in University space, will be allowed under an executed sponsored research agreement (no change in policy). Research funded by a company and conducted by company personnel in university-owned space may be allowed under a situation-appropriate agreement that has been approved by the

University, department and COIC (change in policy; previously, this situation was not allowed).

- No change was made from current policy regarding faculty members being allowed to conduct sponsored research when the PI has a SFI in the sponsoring company. COIC approval and COI management is required.

Under the new policy, an SFI and associated disclosure and oversight requirements arise only if royalty income exceeds \$5,000 (PHS) or \$10,000 (non-PHS) over a 12-month period. Under current policy, simply being an inventor of patented technology constitutes an SFI.

- Oversight and enforcement of this new COI policy continues to rest with the academic unit of the primary appointment of the researcher and with the unit where the research is being conducted.
- COI training has been modified to be consistent with new less-burdensome training requirements. Re-training in COI will be required every four years and not every three years as presently required by policy.
- The draft specifically addresses conflicts of commitments, in addition to COI, in order to capture the full universe of potential outside activity undertaken by faculty. For instance, this broadens COI away from solely addressing equity bearing companies whose outcome is a liquidity event, as not all outside activity by faculty concerns this type of work.
- An overarching goal in preparing this draft was to develop a policy that is simple and stresses clarity. The intent is to have the policy be a standalone document, meaning that someone who is not familiar with COI could read it and understand COI and the University's position.
- Another overarching goal was to separate the policy components from the procedural components of COI governance to the extent possible. The current policy consists of an intermix of policy and procedure. Accordingly, a significant change found in this version is that many procedural aspects found in the current policy are removed and instead there are references to websites or other publications and authorities that provide that type of procedural detail.
- In preparing this draft, other universities' policies were reviewed and gaps in our existing policy's coverage were identified. Accordingly, new information, including a fuller set of definitions, is included in this draft to appropriately describe the policy's coverage. For instance, this draft includes a definition of "incidental use," based on definitions the Federal government uses, which we believe to be workable and enforceable.