FP-30: Institutional Conflict of Interest

Institutional conflict of interest may occur when East Tennessee State University (ETSU) or the East Tennessee State University Research Foundation forms relationships with profit-making entities; holds equity interest in a business entity in which university employees propose to conduct research that may affect the value of the equity interest; or when the University or the Research Foundation holds a patent or license. Such relationships may put the University into actual or apparent conflict of interest situations when accepting grants or contracts from the profit making entities for research or other activities. (See exclusion at the end of this section for certain types of relationships.) To assure that these grants, contracts and research projects are performed with the highest level of integrity by University employees and to assure that the public maintains it trust in University activities, the following procedures shall be followed:

I. Disclosure
II. Process
III. Human Subjects Research
IV. Excluded Relationships

I. Disclosure
By the end of July the Vice President for Finance and Administration and the Vice Provost for Research and Sponsored Programs shall prepare a disclosure listing all profit-making entities in which the East Tennessee State University (ETSU) or the East Tennessee State University Research Foundation (ETSURF) have a significant financial interest. This disclosure shall be updated during the year as new relations develop and old ones terminate. This disclosure and its updates will be submitted to the President, the Provost/Vice President for Academic Affairs, the Vice President for Health Affairs, the Vice President for Finance and Administration, the College Deans, the Director of the Human Subjects Research Protection Program, the Director of Research and Sponsored Programs Administration and the Chair of the Academic Freedom and Faculty Ethics Committee.

Units submitting proposals for external funding to commercial entities may not be aware of possible institutional conflict of interest issues. Thus, the Office of Sponsored Programs Administration shall have the primary responsibility of notifying Vice Provost for Research and Sponsored Programs and the submitting unit of the University's conflict of interest as part of its regular procedures for the review and approval of such applications.

II. Process
The Vice Provost for Research and Sponsored Programs (VPR) has the responsibility for overseeing the process for the review, the development of management plans for resolution and monitoring the conflict of interest. In consultation with the Academic Freedom and Faculty Ethics Committee. The VPR shall develop a plan to manage the institutional conflict of interest after consultation with the submitting unit and other relevant university offices. University acceptance of grants and contracts related to a management plan is contingent upon approval of the management plan by the Academic Freedom and Faculty Ethics Committee. A negative decision of the Committee may be appealed to the President of ETSU. An institutional conflict management plan may range from a simple disclosure of the University's interest in publications and reports emanating from the grant or contract to complete University divestiture of the financial interest. The institutional conflict of management plan shall be separate from and in addition to any conflict management plans for conflicts of interests of individuals (e.g., the principal investigator) involved in the grant or contract.

When considering an institutional conflict of interest management plan, the Academic Freedom and Faculty Ethics Committee shall a) include as voting members, one or more individuals from the general public who have no direct or indirect relationship with the University, i.e., the
individuals and their spouses or other dependents must not be current employees or students of the University; and b) recuse from the deliberations of the Committee any ETSU member of the Committee who has been involved in the negotiation, approval, or implementation of the relationship that is the basis of the actual or perceived conflict of interest. The general public members of the Committee should be individuals that have sufficient education or experience to understand both the issues before the Committee and the possible impacts of the Committees decisions on the general public.

Arrangements for plan implementation and oversight shall explicitly be part of an institutional conflict management plan. Implementation and oversight will usually be the joint responsibility of the submitting unit and the Office of the Vice Provost for Research and Sponsored Programs. However, other arrangements shall be made for plan implementation and oversight if, in the judgment of the Academic Freedom and Faculty Ethics Committee, such arrangements are necessary for the effective management of the conflict.

III. Human Subjects Research
The University will pay special attention to potential institutional conflicts of interest involving human subjects to ensure that the welfare of subjects is protected. Any financial interest of the University or the Research Foundation must be disclosed at the time of submission of the clinical study for initial review by the ETSU Institutional Review Board (IRB). The VPR will assess the potential conflict of interest, develop a plan to manage the conflict and refer to the Academic Freedom and Faculty Ethics Committee for review and approval. Any interest of the University must be disclosed during the informed consent process to any human research participant with oversight by the ETSU IRB. The ETSU IRB must review and approve any management plan prior to approval of the clinical study.

IV. Excluded Relationships
A relationship with a profit making organization for the purposes of this institutional conflict of interest policy shall not include ordinary investments of the university's endowment that are managed by the Board of Directors of the ETSU Foundation or ordinary client-vendor relationships where the University contracts for specific goods or services from a profit-making organization.

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