

Policy Name/Number: Conflict of Interest Disclosure / ADMIN-0719-8

Committees, Departments, or Individuals Responsible for Implementation: Beth Fox, MD / Vice Dean for Academic	
Affairs	
Original Approval Date/ By: 7/30/2019 / William Block,	Effective Date: 5/23/2024
Jr., MD - Dean of Medicine	
Most Recent Revision Date: 5/23/2024	Policy Advisory Committee Review Date: 5/23/2024

(A) Policy Statement:

- 1. Quillen College of Medicine (COM) faculty members and senior administrative staff will complete a COM *Conflict of Interest Disclosure* form annually. See attached form.
- 2. Conflicts of interest are generally described in the University's Conflicts of Interests or Commitments Policy https://www.etsu.edu/policies/human_resources_policies_webpage/conflicts_interests_commitments_policy.php and in the COM *Conflict of Interest Disclosure* form.
 - a. When a potential conflict is identified, the initial level of review is by the individual's immediate supervisor based on the principles outlined in the University's Conflicts of Interests or Commitments Policy and the COM *Conflict of Interest Disclosure* form.
 - b. If the reviewing supervisor determines that a significant conflict of interest does **not** exist, no further action is required.
 - c. If the reviewing supervisor determines that a potentially significant conflict of interest **does** exist, then the issue(s) will be referred to the review group as outlined in the University's Conflicts of Interests or Commitments Policy procedures section, https://www.etsu.edu/policies/human resources policies webpage/conflicts interests commitments policy.ph
 - p. The immediate supervisor must provide a description in the comments section as to why a perceived conflict of interest exists.

(B) Purpose of Policy:

To define the process of managing potential conflicts of interest identified on annual disclosures.

(C) Scope of Policy (applies to):

All faculty and senior administrative staff members.

(D) Policy Activities:

Conflict of interest defined: A conflict of interest occurs when the personal interests, financial or otherwise, of a person who owes a duty to East Tennessee State University actually or potentially diverge from the person's professional obligations to, and from the best interests of, the University.¹

Exploring examples of conflicts of interest: Employees must balance their University responsibilities with any *V. May 2021*

external activities they choose to participate in (e.g. consulting, public service, patenting and licensing an invention, being involved in or owning a business, etc.). In general, employees should avoid situations where the self-interests of the employee depart from the best interests of the University. When a conflict of interest arises, the employee must disclose the conflict so that the University can manage the conflict appropriately. Unmanaged conflicts of interest may give rise to legal liability for the employee and the University, and may result in a loss of the public trust.

The Quillen College of Medicine has a policy that explains how employees must disclose conflicts of interest and how it will review those conflicts. Disclosure of conflicts of interest do not necessarily imply inappropriate conduct. The disclosure process allows the employee and the University to engage in a transparent process to manage or eliminate the conflict as needed.

Examples of Conflicts of Interest in Teaching and Educational Activities:

- Use of educational materials (e.g. a textbook) which the employee has authored, or in which they otherwise stand to benefit financially from such use
- An external entity supplies financial support to a faculty member or a faculty member's graduate students, postdocs, etc.

Examples of Conflicts of Interest in Research:

- A research study that includes use of a pharmaceutical or medical device manufactured by an entity in which the researcher has a financial interest
- An employee holding equity interests, including stock options, in an entity which supports their University research
- A researcher serves as a consultant for an entity that funds their research

Examples of Conflicts of Interest in Clinical Care:

- A physician prescribes pharmaceuticals manufactured or distributed by an entity in which the physician has a financial interest
- A physician utilizes a medical device or implant created or supplied by an entity in which the physician has a financial interest
- A physician refers patients to a healthcare facility in which the physician has a financial interest

Examples of Conflicts of Interest in Administrative Responsibilities:

- Purchase of state-owned property by an employee absent fair and open bidding.
- Solicitation or acceptance of a gifts/gratuities/favors from a person or entity that is seeking to obtain contractual or other business or financial relations with the University
- University contracts with businesses or non-profit organizations in which an employee or the employee's immediate family members stand to realize a personal financial benefit.

Additional ETSU Policies Regarding Conflicts of Interest

PPP-72 Conflict of Interest Disclosure Review Committee:

https://www.etsu.edu/policies/human_resources_policies_webpage/conflict-of-interest-disclosure-review-committee.php

FP-30 Institutional Conflict of Interest:

https://www.etsu.edu/policies/employment/institutional financial conflicts interests.php

Financial Conflict of Interest and the Promotion of Objectivity in Sponsored Program: https://www.etsu.edu/research/orspa/researchcompliance/conflictofinterest.php

Guidelines on the Education of Researchers and Research Staff regarding Responsibilities and Disclosures Related to Researcher Conflict of Interest:

https://www.etsu.edu/irb/how-to/disclosures related to coi.php

State and Federal Laws Regarding Conflicts of Interest

This list is not exhaustive. Additional laws, regulations and policies may apply in a given conflict of interest situation.

Federal Regulations on Conflicts of Interest

- I. The National Science Foundation (NSF) and the Department of Health and Human Services (HHS), acting through the Public Health Service (PHS) (which includes the National Institutes of Health (NIH)), have promulgated policies and regulations regarding conflicts of interest and disclosure of financial interests by investigators who receive funding from these Federal agencies.
- II. The NSF policy regarding researcher conflicts of interest is contained in Section 510 of NSF Publication 95-26, the Grant Policy Manual. The PHS regulations, upon which the NSF policy is modeled, are contained in the Code of Federal Regulations at 42 CFR 50.601 et seq. and 45 CFR 94.1 et seq.
- III. Other Federal agencies (e.g., the Veterans' Administration or the Food and Drug Administration) may require as a condition to a contract, disclosure and management of conflicts of interest (see, for example, Veterans' Administration Acquisition Regulation 852.209-70).

State Laws, Rules, and Regulations on Conflicts of Interest

- I. Accepting rebates, gifts, or other things of value. T.C.A. §12-3-106 prohibits employees who are responsible for initiating requisitions from directly or indirectly accepting or receiving any rebate, gift, money, or other thing of value from any person, firm, or corporation to whom a contract for the purchase of materials, supplies, or equipment may be awarded. This statute also prohibits accepting or receiving any promise, obligation, or contract for future rewards of compensation from a contractor.
- II. Having a personal interest in any contract in which the University is or may be interested. T.C.A. §12-4-101 prohibits employees who are in a position to select a contractor, to oversee work under a contract, or in any manner to superintend a contract in which the University is or may be interested from being directly interested in the contract. An employee is directly interested if the contract is with:
 - The employee,
 - A business in which the employee is the sole proprietor,
 - A business in which the employee is a partner, or
 - A business in which the employee has a controlling interest, i.e., owns or controls the largest number of outstanding shares owned by any single individual or corporation.

Violation of this statute carries a civil penalty requiring forfeiture of all pay and compensation received under the contract, dismissal from the employee's position, and ineligibility for the same or a similar position for ten years.

Exceptions:

- Any interest that does not fall within the definition of a direct interest is an indirect interest and is also prohibited unless it is publicly acknowledged at the time of contracting.
- If the employee, proprietorship, partnership, or corporation is the sole supplier of required goods or services in the county, the employee's interest will not violate this statute if it is publicly acknowledged at the time of contracting.
- III. Selling goods to the University or any other State agency. T.C.A. §12-4-103 prohibits all University employees from bidding on, selling, or offering to sell any merchandise, equipment or material, or similar commodity to the University or any other State agency. This prohibition applies to sales by:
 - The employee,

- A business in which the employee is the sole proprietor,
- A business in which the employee is a partner, or
- A business in which the employee has a controlling interest (see II, above).

This prohibition continues for six months after employment with the University terminates. Violation of this statute carries both civil and criminal penalties:

- Civil. The employee must refund to the University or the State all amounts paid for the goods, plus 8 percent interest.
- Criminal. Violation of §12-4-103 is a Class E felony. Exceptions:
 - O Sales by a business in which an employee owns less than a controlling interest are also prohibited unless the employee's interest is publicly acknowledged at the time of the sale.
 - o If the employee, proprietorship, partnership, or corporation is the sole supplier of required goods in the county, the sale will not violate this statute if the employee's interest is publicly acknowledged at the time of the sale.
- IV. Providing personal, professional, or consultant services to the University or any other State agency.

T.C.A. §12-4-109 requires that all personal, professional, and consultant services to the University and other State agencies be procured as prescribed by the regulations of the State Department of Finance and Administration. Under those regulations, all employees are prohibited from contracting with the University or another State agency to provide personal, professional, or consultant services. The prohibition applies to contracts with:

- The employee,
- A business in which the employee is the sole proprietor,
- A business in which the employee is a partner, or
- A business in which the employee has a controlling interest (see II, above). This

prohibition continues for six months after employment with the University terminates.

- V. **Interests of spouse or minor child.** For the purpose of applying every statute and regulation described above, the interest of a spouse or minor child with whom the employee commingled asset is treated as the employee's interest.
- VI. **Nepotism.** T.C.A. §8-31-103 prohibits employees who are relatives from working within the same direct line of supervision whereby one relative is responsible for supervising the job performance or work activities of the other. "Relative" means a parent, foster parent, parent-in-law, child, spouse, brother, foster brother, sister, foster sister, grandparent, grandchild, son-in-law, brother-in-law, daughter-in-law, sister-in-law, or any other family member who resides in the same household.

State of Tennessee Executive Order by the Governor, No. 2, issued by Governor Lee on January 29, 2019

I. Conflict of Interest Transactions. State of Tennessee Executive Order by the Governor, No. 2, issued by Governor Lee on January 29, 2019, orders executive branch employees to avoid any action that might result in or create the appearance of using public office for private gain, giving preferential treatment to any person, impeding government efficiency or economy, losing complete independence or impartiality, making a government decision outside of official channels, or affecting adversely the confidence of the public in the integrity of the government. With respect to financial interests, the order prohibits employees from:

- entering into or deriving any benefit, directly or indirectly, from any contractual arrangement with the State or any of its agencies; and
- having a direct or indirect financial interest that conflicts substantially, or appears to conflict substantially, with his or her government duties.

https://publications.tnsosfiles.com/pub/execorders/exec-orders-lee2.pdf

- II. **Use of government property.** State of Tennessee Executive Order by the Governor, No. 2, issued by Governor Lee on January 29, 2019, prohibits state employees from using the facilities, equipment, personnel, or supplies of the State or its agencies for private use or gain, except to the extent that the use is incidental or de minimis or is lawfully available to the general public.
- III. **State Code of Conduct.** The State of Tennessee's Code of Conduct instructs state employees to "avoid situations that involve conflicts of interests." The Code of Conduct explains: "A conflict of interest is a situation where your personal interests or activities could influence your judgment or decisions, and therefore, your ability to act in the best interests of the State of Tennessee ... State employees may not engage in outside employment activities that conflict with their official State duties and responsibilities.

East Tennessee State University Contracts Policy

- I. Conflict of Interest. Contracts should contain the following provisions: "The Contractor warrants that no part of the total Contract Amount shall be paid directly or indirectly to an employee or official of the State of Tennessee as wages, compensation, or gifts in exchange for acting as an officer, agent, employee, subcontractor, or consultant to the Contractor in connection with any work contemplated or performed relative to this Contract. The Contractor acknowledges, understands, and agrees that this Contract shall be null and void if the Contractor is, or within the past six months has been, an employee of the State of Tennessee or if the Contractor is an entity in which a controlling interest is held by an individual who is, or within the past six months has been, an employee of the State of Tennessee.
 - This provision is not applicable and should be omitted from agreements between TBR Institutions or between a TBR Institution and another state entity.

Reference: The State and Federal Laws Regarding Conflicts of Interest listing was adapted from the Tennessee Board of Regents Conflict of Interest Policy: 1.02.03.10 and accompanying materials.



Conflict of Interest Disclosure Form

Definitions:

- A. <u>Conflict of Interest:</u> Occurs when the personal interests, financial or otherwise, of a person who owes a duty to East Tennessee State University actually or potentially diverge from the person's professional obligations to, and from the best interests of, the University.
- B. <u>Family Member:</u> Includes the parent, spouse, and children (both dependent and non-dependent) of a person covered by this policy. Other ETSU policies may have definitions of "family member" and those definitions apply in the instances covered by the relevant policy.
- C. <u>Immediate Family</u>: For purposes of General Disclosure Requirements section of T.C.A. § 12-4- 103, immediate family means spouse, dependent children or stepchildren, or relatives related by blood or marriage.

This Conflict of Interest Disclosure Form should indicate whether the faculty member has an economic interest in, or acts as an officer or a director of, any outside entity whose financial interests would reasonably appear to be affected by the individual's responsibilities as an ETSU faculty member. The faculty member should also disclose any personal, business, or volunteer affiliations that may give rise to a potential or actual conflict of interest. Potential or actual conflicts of interest must be disclosed, monitored and managed by the appropriate University official.

Date:
Name of Faculty Member:
Department/Position:
Please describe below any relationships, transactions, positions you hold (volunteer or otherwise), or circumstances that you believe could give rise to a potential or actual conflict of interest:
I have no conflict of interest to report.
I have already reported conflicts of interest on either the ETSU Significant Financial Interest Disclosure Form for research or an ETSU Continuing Medical Education conflict of interest disclosure and have no other disclosures to report.
I have the following conflict(s) of interest to report:
Please list all relationships or business affiliations where you are or a member of your immediate family is an officer director, trustee, partner, employee or agent of such organization.
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2

Conflict of Interest Disclosure Form

Please list all relationships or business affiliations where you or a member of your immediate family is the actual or beneficial owner of more than 4% of the voting stock or controlling interest in such organization.	
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Please list all relationships or business affiliations where you have or a member of your family has any direct or indirect dealings with such organization (not listed above) from which you knowingly materially benefit (i.e., through receipt directly or indirectly of cash or other property in excess of \$4,000 per year exclusive of dividends or interest).	
ADDITIONAL INFORMATION: List any additional information you wish to disclose. (Examples: financial or other interest in a business which manufactures medical devices or equipment, pharmaceuticals, or other health care products; royalties paid in connection with intellectual property rights such as patents and copyrights; business or financial relationships with research sponsors.)	
I hereby certify that the information set forth above is true and complete to the best of my knowledge.	
Faculty Signature:Date:	
I have reviewed this reported conflict of interest and determined that a significant conflict of interest does not exist.	
I have reviewed this reported conflict of interest and determined that a potentially significant conflict of interest does exist, and that it should be referred to the East Tennessee State University (ETSU) Conflict of Interest Disclosure Review Committee.	
Comments:	_
Supervisor Signature:Date:	