David Tvildiani Medical University

Financial Conflict of Interest Policy

Last Reviewed: August 6, 2026

1. Purpose

David Tvildiani Medical University LLC (DTMU), located in Tbilisi, Georgia, is a higher educational institution operated under the institutional policies and regulations, national laws, and international standards for higher education and research. DTMU is committed to maintaining the highest standards of integrity, transparency, and accountability in all research activities conducted under its auspices. The University recognizes that financial relationships held by investigators may create actual or perceived conflicts of interest that could compromise, or appear to compromise, the objectivity of research.

The purpose of this policy is to establish a framework for identifying, disclosing, reviewing, and managing financial conflicts of interest in research. This policy ensures that all research remains free from bias and is conducted in a manner that upholds public trust.

The policy is applied to any research conducted at DTMU, whether conducted without specific financial support, funded by the University itself, or supported through national funding agencies. It also applies to DTMU-based research supported by international and foreign donors, including the European Union (e.g., through the Horizon Europe framework), and funded by the United States government, among others.

<u>Donor specific considerations:</u>

For research funded by the U.S. Public Health Service (PHS), including the National Institutes of Health (NIH), additional regulatory requirements as set forth in 42 CFR Part 50 Subpart F shall apply. In such cases, DTMU will ensure full compliance with all applicable USA federal requirements.

For research funded by the European Union, including Horizon Europe and related programmes, DTMU will comply with applicable European Commission requirements concerning ethics, transparency, and the management of conflicts of interest, as defined in relevant grant agreements and regulations.

2. Scope and Applicability

This policy applies to all investigators participating in research projects administered through DTMU. It covers all stages of research, including proposal development, conduct of research, and reporting of results. DTMU shall apply this policy in a manner proportionate to the nature, scale, and risk of the research activity, ensuring that administrative requirements do not unduly burden low-risk or small-scale studies. For the purposes of this policy, an Investigator is defined as the Principal Investigator (PI) as well as any other individual, regardless of title or position, who is responsible for the design, conduct, or reporting of research. This definition includes collaborators, consultants, and other key personnel involved in the research activities.

3. Definitions

A Significant Financial Interest (SFI) refers to a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities.

For the research supported by the US government agencies, this includes remuneration received from a publicly or non-publicly traded entity in the preceding twelve months that, when aggregated, exceeds USD 5,000; any equity interest in a non-publicly traded entity; equity interests in publicly traded entities that exceed USD 5,000 in value; income related to intellectual property rights and interests, such as patents and copyrights; and reimbursed or sponsored travel, except when such travel is funded by government agencies, academic institutions, or recognized research organizations.

For all other research activities, "Financial and Other Interests" include any financial, personal, professional, or institutional interests that could directly and significantly affect, or reasonably appear to affect, the design, conduct, or reporting of research.

A Financial Conflict of Interest (FCOI) exists when DTMU reasonably determines that a Significant Financial Interest is related to NIH-funded research and could directly and significantly affect the design, conduct, or reporting of that research.

4. Disclosure of Significant Financial Interests

All Investigators are required to disclose their Significant Financial Interests in a timely and complete manner. When applying for funding, initial disclosure must be made at the time of application for funding. Thereafter, Investigators must submit updated disclosures on an annual basis for the duration of the project.

In addition, Investigators are required to disclose any new Significant Financial Interest within thirty (30) days of acquiring or discovering such interest. Disclosures must include sufficient detail to allow for an informed institutional review, including the nature of the interest, its monetary value (where applicable), and its relationship to the Investigator's institutional responsibilities.

To disclose Significant Financial Interests, Investigators must fill – in the Significant Financial Interests disclosure form, sign and date it, and send it via email to the research integrity officer – lawyer@dtmu.edu.ge

DTMU shall maintain a secure record of all submitted disclosure forms and related reviews Upon receipt of a disclosure, the research integrity officer shall review whether the disclosed interest is related to the investigator's research activities and whether additional assessment or management measures are required.

A designated review committee can be established when decisions cannot be made by the research integrity officer. The committee then will be responsible for the review of all disclosed Significant Financial Interests. The review process shall determine whether the disclosed interest is related to a particular study and whether it constitutes a Financial Conflict of Interest.

This determination shall be made based on whether the financial interest could directly and significantly affect the design, conduct, or reporting of the research. The review process shall be documented and conducted in a consistent and transparent manner. Where no relevant interests are identified, the disclosure shall be recorded as reviewed and no further action shall be required unless circumstances change. Where a potential conflict is identified, DTMU shall conduct an institutional review and, if necessary, develop and implement a management plan.

5. Management of Financial Conflicts of Interest

In cases where a Financial Conflict of Interest is identified, DTMU shall implement a management plan designed to mitigate or eliminate the potential bias. Management plans will be tailored to the specific circumstances of the conflict and may include, but are not limited to, public disclosure of the conflict, monitoring of the research by independent reviewers, modification of the research plan, disqualification of the Investigator from certain aspects of the research, or divestiture of the financial interest. Investigators are required to comply fully with any management plan imposed by the institution. Failure to do so may result in corrective actions.

When a Financial Conflict of Interest (FCOI) is identified, DTMU will implement appropriate management strategies to ensure the objectivity, integrity, and transparency of research activities. The specific management measures will be determined based on the nature and extent of the conflict and may include, but are not limited to, the following:

- ✓ Public disclosure of the FCOI: The investigator(s) will disclose relevant FCOIs in research presentations, publications, abstracts, and other public communications related to the research, where appropriate.
- ✓ Disclosure to human research study participants: Where applicable, information regarding the identified FCOI will be disclosed directly to human subject research participants as part of the informed consent process or through other appropriate communication mechanisms.

- ✓ Independent monitoring of research activities: DTMU may require oversight of the research by an independent reviewer or monitoring committee to ensure that the research is conducted objectively and in accordance with approved protocols and applicable requirements.
- ✓ Modification of the research plan: The research protocol, procedures, or operational approach may be modified to minimize or eliminate the impact of the FCOI on the conduct, analysis, or reporting of research.
- ✓ Adjustment of personnel roles and responsibilities: DTMU may require changes to the involvement of conflicted individuals, including modification of assigned duties, limitation of participation in specific research activities, reassignment of responsibilities, or disqualification from participation in all or part of the research.
- ✓ Reduction or elimination of financial interest: Where appropriate, steps may be taken to reduce or eliminate the financial interest contributing to the conflict, including the sale or divestiture of equity interests or other relevant financial arrangements.
- ✓ Severance of conflicting relationships: In circumstances where other management measures are insufficient, DTMU may require termination or restructuring of relationships, agreements, or activities that create the FCOI.

DTMU will document all identified FCOIs, the management actions implemented, responsible parties, and monitoring requirements. The effectiveness of the management plan will be reviewed periodically and adjusted as necessary to ensure continued compliance and protection of research integrity.

In the event of noncompliance with this policy, DTMU shall conduct a retrospective review of the Investigator's activities to determine whether any bias has occurred in the design, conduct, or reporting of the research. The review will be conducted within 120 days to determine any noncompliance related bias in the research. When a bias is found, appropriate mitigation actions will be taken. Based on the findings, the University shall implement appropriate mitigation actions and, where required, report such actions to the NIH (in case of NIH-supported research).

6. Training Requirements

All Investigators must complete training on Financial Conflict of Interest requirements. This training must be repeated at least once every four (4) years and immediately when any of the following circumstances apply: the institution revises its FCOI policy in a manner that affects Investigator requirements; an Investigator is new to the institution; or an Investigator is found to be noncompliant with this policy or a management plan. Further training requirements apply for studies supported by donor organizations which apply specific FCOI training requirements. DTMU shall ensure that appropriate training resources are made available to all Investigators. This may include access to institutional training (in-person or online), or supporting access (including financial coverage of training, when considered necessary) for recognized and accepted external training opportunities. DTMU will also recognized training obtained through the key funding agencies, such as the FCOI training module offered by NIH, USA.

7. Reporting to Donor Organizations

DTMU is responsible for reporting identified Financial Conflicts of Interest to the donor organizations, as required by these organizations, using the policies, rules, mechanisms and procedures established by these donor organizations.

In case of the National Institutes of Health, United States, DTMU will report FCOIs to the NIH in accordance with the US federal requirements. Initial FCOI reports shall be submitted prior to the expenditure of funds under the award. For newly identified conflicts, reports shall be submitted within sixty (60) days. Annual updates regarding the status of previously reported conflicts shall also be submitted. All reporting shall be conducted through the appropriate NIH electronic systems, including eRA Commons. Upon request, the University shall also provide information regarding identified Financial Conflicts of Interest held by senior/key personnel, within five (5) business days.

When DTMU collaborates with subrecipients on externally funded projects, the University shall ensure that subrecipient Investigators comply with applicable Financial Conflict of Interest regulations. This shall be achieved through written agreements specifying whether the subrecipient will follow its own FCOI policy or that of DTMU. Where applicable, DTMU shall obtain sufficient assurances and reports from subrecipients to meet funding agency reporting obligations.

8. Administrative considerations

DTMU shall maintain records of all Investigator disclosures, institutional reviews, and management plans for a period of at least three (3) years from the date of submission of the final expenditure report or from other dates specified by applicable regulations.

The up-to-date version of the policy shall be published at the official DTMU website – www.dtmu.ge.

Approved by:

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