

**Financial Conflict of Interest Policy  
for Research Undertaken at TUD Dresden University of Technology  
Funded by Agencies of the United States Public Health Service (PHS) or the  
United States National Science Foundation (NSF)**

dated May 23, 2023

*Please note that the English translation is provided for information purposes only. The English text is not legally binding. Only the original German document has legal validity. The official language at TU Dresden is German. German jurisdiction applies.*

**Section I:**

**General Provisions**

**§ 1**

**Scope**

- (1) This Financial Conflict of Interest Policy (hereinafter: "Policy") applies to all staff members of TUD Dresden University of Technology (TUD) who are responsible for the design, conduct, or reporting of research projects funded by Agencies of the United States Public Health Service (PHS), e.g. the National Institutes of Health (NIH), or the United States National Science Foundation (NSF). They are referred to hereinafter as "Investigators". Every Investigator is obliged to abide by the stipulations of this Policy.
- (2) This Policy applies to all staff members of TUD who have primary responsibility (TUD is Main Awardee) as well as to all staff members who responsibly participate to PHS or NSF projects for which another institution has primary responsibility, but in which TUD is involved as a subrecipient (TUD is Subawardee).

**§ 2**

**Compliance with PHS, NIH and NSF Regulations**

- (1) In addition to this Policy, Investigators must also comply with the regulations and provisions stipulated by the funding body for the research project in question. Where PHS-funded projects are concerned, this typically includes the NIH Grants Policy Statement, and where NSF-funded projects are concerned, this includes the NSF Proposal and Award Policies and Procedures Guide.
- (2) Where NSF-funded projects are concerned, the financial conflict of interest policies described in the NSF Proposal and Award Policies and Procedures Guide, Part II. Award and Administration Guide, Chapter IX A, must be observed; where PHS- and NIH funded projects are concerned, compliance with the stipulations of the US Code of Federal Regulation (CFR) Title [42 Chapter I Subchapter D Part 50 Subpart F](#) regarding financial conflicts of interest is required.

### § 3

#### Notification Prior to Proposal Submission

TUD staff who are planning to submit a proposal for funding to the NSF, NIH or an Agency of the PHS will have to notify the responsible Unit at TUD – Directorate 5 Research, Unit 5.1 Research Promotion (or the Research Department of the Carl Gustav Carus (CGC) Faculty of Medicine) – in a timely manner.

#### Section II:

#### Financial Conflicts of Interest

### § 4

#### Definitions

- (1) Financial Conflict of Interest (FCOI) means a significant financial interest held by an Investigator or his/her spouse or partner within the meaning of the German Registered Civil Partnership ACT (*in German: Lebenspartnerschaftsgesetz - LPartG*) as well as dependent children or foster children that TUD determines could affect the design, conduct or reporting of PHS, NIH or NSF-funded research. Financial interest is an all-encompassing term, irrespective of monetary value.
- (2) U.S. financial conflict of interest requirements under Title 42 Code of Federal Regulation ([CFR](#)) [Part 50.603](#) apply. A Significant Financial Interest (SFI) is 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, see §4 section 1 and 3) that reasonably appears to be related to the Investigator's institutional responsibilities:
  - a) Publicly traded entity: Value of any remuneration (e.g., salary, consulting fees, honoraria, paid authorship) received from the entity in the twelve months preceding the disclosure and value of any equity interest (e.g., stock, stock option, or other ownership interest) in the entity as of the date of disclosure that when aggregated exceeds \$5,000;
  - b) Non-publicly traded entity: Value of any remuneration received in the twelve months preceding the disclosure that when aggregated exceeds US\$5,000, or any equity interest;
  - c) Intellectual property (IP) rights and interests (e.g., patents, copyrights) in excess of \$5,000 upon receipt of income (see [FAQ E.20.](#)). IP rights assigned to the Institution and agreements to share in royalties related to such rights are excluded from the SFI definition; and
  - d) Any Reimbursed or Sponsored Travel related to the Investigator's institutional responsibilities for which the value exceeds US\$5,000, excluding travel that is reimbursed or sponsored by the following:
    - A federal, state, or local government agency located within the United States
    - A United States Institution of higher education
    - An academic teaching hospital
    - A medical center, or

- A research institute that is affiliated with a United States Institution of higher education
- (3) The SFI definition excludes the following types of interests:
- a) Generally, payments the Investigator receives from or through TUD if the Investigator is currently employed or otherwise appointed are excluded, specifically:
    - salary, royalties, or other remuneration, including travel reimbursement;
    - IP rights assigned to TUD and agreements to share in royalties related to such rights;
  - b) Income from investments, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions;
  - c) Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a federal, state, or local government agency located within the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education.<sup>1</sup>
- (4) Suspicion of a Financial Conflict of Interest also applies to those whose family members fulfill the stipulations of Paragraph 1. This includes fiancé(e)s, spouses, civil partners within the meaning of the German Registered Civil Partnership Act (*Lebenspartnerschaftsgesetz – LPartG*), dependent children and foster children.

## § 5

### Procedures for the Disclosure and Review of Financial Interests

- (1) All Investigators must disclose their Financial Interests as defined in Section 4 using the Disclosure Form: [Self-disclosure of financial interests related to PHS/NIH/NSF projects](#).
- (2) Disclosures must be submitted to Directorate 5 Research, Unit 5.1 Research Promotion (or the Research Department of the CGC Faculty of Medicine):
  - a) Before submitting a proposal for funding
  - b) On an annual basis during the project period on June 01 and
  - c) Within 30 calendar days if an FCOI arises during the project term
- (3) Directorate 5 Research, Unit 5.1 Research Promotion (or the Research Department of the CGC Faculty of Medicine) will retain disclosure forms and all records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or Retrospective Review (see §5 section 8), if applicable, for at least three years from the date the final expenditures report is submitted to the PHS, NSF or NIH. If any litigation or audit is started before the expiration of the three-year period, the records will be retained at least until all litigation or audit findings involving the records have been resolved and final action taken.

<sup>1</sup> updated with decision of the rectorate on July 11, 2023

- (4) Directorate 5 Research, Unit 5.1 Research Promotion (or the Research Department of the CGC Faculty of Medicine) will promptly report any Financial Interest disclosed to it to the University Executive Board via the Vice-Rector Research. Should the University Executive Board determine that the Financial Interest significantly affect the design, conduct, or reporting of the NSF or PHS-funded research, an FCOI will be deemed to exist and Directorate 5 Research, Unit 5.1 Research Promotion (or the Research Department of the CGC Faculty of Medicine) will report the FCOI within 60 days of the University Executive Board having identified it to the NSF Office of the General Counsel or the NIH Chief Grants Management Officer or the competent Agency of the PHS, as appropriate (if TUD is the main awardee institution), or to the main awardee (if TUD is a subrecipient). This report follows the U.S. requirements under 42 Code of Federal Regulation ([CFR\) Part 50.605\(b\)](#).
- (5) The University Executive Board will ask the Investigator to manage, reduce or eliminate the FCOI and may impose appropriate measures in this regard (e.g. full public disclosure, appointment of an independent monitor, modification of the research plan, etc.). A report on the actions taken to address the FCOI is to be submitted to the University Executive Board within 30 days.
- (6) If the University Executive Board determines that the FCOI has been managed, reduced or eliminated adequately, Directorate 5 Research, Unit 5.1 Research Promotion (or the Research Department of the CGC Faculty of Medicine) will submit a report to the competent bodies mentioned in Section 5 (4).
- (7) If the University Executive Board determines that the FCOI continues to compromise the objectivity of the NSF or PHS-funded research, or if the Investigator fails to comply with their duty to report, Directorate 5 Research, Unit 5.1 Research Promotion (or the Research Department of the CGC Faculty of Medicine) will notify the competent bodies mentioned in Section 5 (4). The University Executive Board will then take appropriate action to address the FCOI. The following actions may be taken: disqualification of specific Investigators from participating in the project or discontinuation of the project or, if the FCOI is related to a clinical trial, obligating the Investigator to disclose the FCOI in each publication of the clinical trial.
- (8) A Retrospective Review is mandatory whenever a FCOI is not identified or managed in a timely manner, including:
  - a) Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;
  - b) Failure by the Institution to review or manage such a Financial Conflict of Interest; or
  - c) Failure by the Investigator to comply with a Financial Conflict of Interest management plan;the TU Dresden shall (within 120 days of the determination of noncompliance) complete a "Retrospective Review" of the Investigator's activities and the PHS, NSF or NIH-funded research project to determine whether any PHS, NSF or NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research. This Retrospective Review follows the U.S. requirements under 42 Code of Federal Regulation ([CFR\) Part 50.605\(a\)](#). Based on the results of the Retrospective Review, if appropriate, the TUD will update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias

is found, the TUD will notify the PHS; NSF or NIH Awarding Component promptly and submit a mitigation report. The mitigation report follows the U.S. requirements under 42 Code of Federal Regulation ([CFR Part 50.605\(a\)](#)) and the NIH [FAQs I. sections 1-4](#).<sup>1</sup>

## § 6

### Publication of Information

- (1) After an award has been granted by the PHS, NIH or the NSF, but prior to the University's expenditure of any funds under a PHS, NIH or NSF-funded research project, TUD will make available via a publicly accessible website the information listed in Section 6 (b) concerning any SFI that meets the following criteria:
  - a) The SFI was disclosed and is still held by the Investigator
  - b) TUD has determined that the SFI is related to the PHS, NIH or NSF-funded research
  - c) TUD has determined that the SFI is a FCOI.
- (2) TUD must post on the publicly accessible website and make available within five days of receiving a written request at least the following information:
  - a) The name of the concerned Investigator
  - b) Investigator's position with respect to the research project
  - c) The nature of the SFI
  - d) The approximate value of the SFI (in USD): (i) USD 0–4,999; (ii) USD 5,000–9,999; (iii) USD 10,000–19,999; (iv) amounts between USD 20,000 and 100,000 by increments of 20,000; (v) amounts above USD 100,000 by increments of 50,000 or a statement that a value cannot be readily determined
  - e) The entity with which the Investigator has a FCOI, to enhance transparency and accountability
- (3) TUD will update the above information within 60 days if and whenever changes are made to the information and, at a minimum, will update the above information annually.
- (4) In any case in which it is determined that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, planned, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Investigator as required, the TUD will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations and publications.

## § 7

### FCOI Training

- (1) Each Investigator must complete the web-based financial conflict of interest training course ("FCOI Online Tutorial") of the NSF, NIH or of the PHS Agency as applicable prior to engaging in research funded by the NSF, NIH or the PHS and at least every four years thereafter.
- (2) In addition, each Investigator must promptly complete the training course mentioned in Section 7 (1):

<sup>1</sup> updated with decision of the rectorate on July 11, 2023

- a) In the event that this Policy is amended in a manner that changes the requirements of Investigators
  - b) If the Investigators are new to TUD
  - c) In the circumstances described in Section 5 (7) Sentence 1.
- (3) Investigators must confirm their completion of the training course mentioned in Sections 7 (1) and (2) unprompted via submission of the PHS/NIH/NSF FCOI Disclosure Form to Directorate 5 Research, Unit 5.1 Research Promotion (or the Research Department of the CGC Faculty of Medicine). This form will be issued to participants upon successful completion of the FCOI Online Tutorial.

## § 8

### TUD as the Main Awardee Institution

- (1) If TUD is the main awardee of NSF, NIH or PHS funds, it will bind the subrecipients in writing to comply with the requirements of Section 510 of the NSF Grant Policy Manual or CFR (Code of Federal Regulation) [Title 42 Chapter I Subchapter D Part 50 Subpart F](#) (PHS&NIH), as appropriate.
- (2) The subrecipients must have their own NSF, NIH or PHS-compliant FCOI policy in place. The subrecipients will be expected to report any existing FCOI related to NSF, NIH or PHS-funded research to Directorate 5 Research, Unit 5.1 Research Promotion (or the Research Department of the CGC Faculty of Medicine) within 30 days of their becoming aware of the existence of that FCOI. Unit 5.1 (or the Research Department) will then notify the University Executive Board and will report the FCOI to the NSF Office of the General Counsel or the NIH Chief Grants Management Officer or the competent Agency of the PHS, as appropriate.
- (3) If a subrecipient does not have an adequate FCOI policy in place, it may assume this Policy of TUD for the NSF, NIH or PHS-funded project. The subrecipients will be expected to report any existing Financial Interest related to NSF, NIH or PHS-funded research to TUD within 30 days of their becoming aware of the existence of that Financial Interest. Further action will then be taken in accordance with this Policy.
- (4) The subrecipients will be expected to provide to Directorate 5 Research, Unit 5.1 Research Promotion (or the Research Department of the CGC Faculty of Medicine) a written statement ("Subrecipient Financial Conflicts of Interest Certification Form") confirming which of the options described in Section 8 (2) and (3) hereof applies to them.

## § 9

### Entry into Force

This Policy will enter into force one day after its publication.

Dresden, dated May 23, 2023

Prof. Dr. Ursula M. Staudinger

The Rector