

Financial Conflict of Interest Policy
for Research Funded by Agencies of the United States Public Health Service (PHS) or the
United States National Science Foundation (NSF)

That Is Being Undertaken at Julius-Maximilians-Universität Würzburg

Dated 21 April 2021

*(This document is available for download at
<https://www.uni-wuerzburg.de/forschung/service/richtlinie-zu-finanziellen-interessenkonflikten/>)*

Part I:

General Provisions

Section 1 Scope

- (1) This Policy applies to all staff members of Julius-Maximilians-Universität Würzburg (JMU) who are working on 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 has an obligation to abide by the provisions of this Policy.
- (2) This Policy applies to all PHS- or NSF-funded research JMU carries out as the prime awardee institution or as a subrecipient.

Section 2 Compliance With PHS and NSF Regulations

- (1) In addition to this Policy, Investigators must also comply with the regulations 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 complied with; where PHS-funded projects are concerned, compliance with the requirements of CFR (Code of Federal Regulation) Title 42, Part 50 Subpart F is required.

Section 3 Notification Prior to Proposal Submission

JMU staff who are planning to submit a proposal for funding to the NSF or an Agency of the PHS will have to notify the competent Unit at the JMU Service Centre Finance - currently, this is Unit 3.4. The English text in this document is intended solely as a convenience to non-German-reading staff members. Any discrepancies or differences that may arise in the translation of the official German version shall not be legally binding.

Third-Party Funds and Donations - in a timely manner.

Part II:

Financial Conflicts of Interest

Section 4 Definitions

- (1) Financial Conflict of Interest (FCOI) means a significant financial interest held by an Investigator, their spouse or registered civil partner within the meaning of the German *Lebenspartnerschaftsgesetz* (Registered Civil Partnership Act, LPartG) or their children that JMU determines could affect the design, conduct or reporting of PHS- or NSF-funded research. Financial Interest includes all financial interests irrespective of their monetary value.
- (2) Significant Financial Interest (SFI) includes equity interests, e.g. shares or intellectual property rights, remunerations and sponsored travel related to the PHS- or NSF-funded project. SFI does not include Financial Interests arising from an Investigator's contractual relationship with JMU. SFI does not include income from teaching activities engaged in at, or consultancy services provided to, public or not-for-profit institutions either.

Section 5 Procedures for the Disclosure and Review of Financial Interests

- (1) All Investigators must disclose their Financial Interests as defined in Section 4 hereof using the Disclosure Form of Financial Interests (disclosure form), which can be downloaded from the WueTeams portal.
- (2) Disclosures must be submitted to Unit 3.4 Third-Party Funds and Donations at the Service Centre Finance:
 - a) before a proposal for funding is submitted;
 - b) on an annual basis during the project award period (usually prior to the renewal of an award from the NSF or the Agency of the PHS) and
 - c) within 30 calendar days if an FCOI arises during the project award period.
- (3) Unit 3.4 Third-Party Funds and Donations at the Service Centre Finance will retain records relating to Investigator disclosures of Financial Interests (disclosure forms) for at least three years from the end date of the NSF- or PHS-funded project. 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.
- (4) The Service Centre Finance at JMU will promptly report any Financial Interest disclosed to it to the University Board. If the University Board determines that the Financial Interest appears to be biasing the NSF- or PHS-funded research, an FCOI will be deemed to exist and the Service Centre Finance at JMU will report the FCOI, within 60 days of the University Board's discovery of it, to the NSF Office of the General Counsel or the NIH Chief Grants Management Officer or

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the competent Agency of the PHS, as appropriate (if JMU is the prime awardee institution) or to the prime awardee (if JMU is a subrecipient).

For those purposes, the records relating to the disclosure of the Financial Interest (disclosure forms) may be made available to the bodies mentioned above as well as to JMU staff whose input is indispensable for the review of the matter.

- (5) The University Board will ask the Investigator to manage, reduce or eliminate the FCOI and to make a report to it, within 60 days, about the actions taken to address the FCOI.
- (6) If the University Board determines that the FCOI has been managed, reduced or eliminated adequately, the Service Centre Finance at JMU will make a report to the competent bodies mentioned in Section 5 (4) hereof.
- (7) If the University Board determines that the FCOI continues to bias the NSF- or PHS-funded research or if the Investigator fails to comply with its duty to report, the Service Centre Finance at JMU will notify the competent bodies mentioned in Section 5 (4) hereof. The JMU University 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.

Section 6 Public Accessibility of Information

After an award has been granted by the PHS or the NSF, but prior to the University's expenditure of any funds under a PHS- or NSF-funded research project, JMU will make available, via a publicly accessible website the information listed in Section 6 b) hereof concerning any SFI that meets the following criteria:

a)

- The SFI was disclosed and is still held by the Investigator;
- JMU determines that the SFI is related to the PHS- or NSF-funded research;
- JMU determines that the SFI is a FCOI.

b)

The University must post on the publicly accessible website and make available within five days of receiving a written request the following minimum information:

- Investigator's name,
- Investigator's position with respect to the research project,
- nature of the SFI,
- approximate dollar value of the SFI:
 - US\$0 - US\$4,999;
 - US\$5,000 - US\$9,999;

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- US\$10,000 - US\$19,999;
- amounts between US\$20,000 - US\$100,000 by increments of US\$20,000;
- amounts above US\$100,000 by increments of US\$50,000 or
- a statement that a value cannot be readily determined;
- the entity with which the Investigator has a FCOI, to enhance transparency and accountability.

c)

JMU will update the above-noted information within 60 days when there are changes to the information and, at a minimum, will update the above-noted information annually.

Section 7 FCOI Training

- (1) Each Investigator must complete the web-based financial conflict of interest training course ('FCOI Online Tutorial') of the NSF or, respectively, of the Agency of the PHS prior to engaging in research funded by the NSF or the PHS and at least every four years thereafter.
- (2) In addition, Investigators must promptly complete the training course mentioned in Section 7 (1) hereof in the event that
 - a) this Policy is amended in a manner that changes the requirements of Investigators;
 - b) the Investigators are new to JMU or
 - c) in the circumstances described in Section 5 (7) Sentence 1 hereof.
- (3) Investigators must submit a copy of the 'Certificate of Completion' to Unit 3.4 Third-Party Funds and Donations at the JMU Service Centre Finance as evidence of completion of the training course mentioned in Sections 7 (1) and (2) hereof. They will be issued with that Certificate upon having successfully completed the FCOI Online Tutorial.

Section 8 JMU as the Prime Awardee Institution

- (1) If JMU is the prime awardee of NSF or PHS funds, it will ask the subrecipients to enter into written undertakings to comply with the requirements of Section 510 of the NSF Grant Policy Manual or CFR (Code of Federal Regulation) Title 42, Part 50 Subpart F (PHS), as appropriate.

- (2) The subrecipients will need to have their own NSF- or PHS-compliant FCOI policy in place. The subrecipients will be expected to undertake to report any existing FCOI related to NSF- or PHS-funded research to Unit 3.4 Third-Party Funds and Donations at the JMU Service Centre Finance within 30 days of their becoming aware of the existence of that FCOI. Unit 3.4 will then notify the University 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 rely on this Policy of JMU for the NSF- or PHS-funded project. The subrecipients will be expected to undertake to report any existing Financial Interest related to NSF- or PHS-funded research to JMU 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 Unit 3.4 Third-Party Funds and Donations at the JMU Service Centre Finance 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.

Section 9 Entry into Force

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