

Guidelines of the Medical Faculty of the University of Münster (MFM) on Financial Conflicts of Interest in Grants from U.S. Public Health Service (PHS) Agencies and the National Science Foundation (NSF)

First Section: General Provisions

§ 1 Scope of Application

- (1) This directive applies to all MFM staff involved in projects funded by U.S. Public Health Service (PHS) agencies (e.g., the National Institutes of Health - NIH) or the U.S. National Science Foundation (NSF) as funding providers. They are hereinafter referred to as project staff.
- (2) Project staff are obligated to comply with the requirements of this directive.
- (3) This directive applies to all PHS or NSF projects for which the MFM has primary responsibility (MFM as Main Awardee) or to projects for which another institution has primary responsibility (MFM as Subawardee).

§ 2 Applicable Legal Framework

- (1) Project staff must comply not only with this directive but also with the regulations and requirements specified by the funding provider for each respective project. For PHS projects, this typically includes the NIH Grants Policy Statement, and for NSF projects, the NSF Proposal and Award Policies and Procedures Guide.
- (2) For PHS projects, the requirements regarding financial conflicts of interest are summarized in [42 Code of Federal Regulations \(CFR\) Part 50 Subpart F](#).
For NSF projects, the requirements regarding financial conflicts of interest must comply with the [NSF Proposal and Award Policies and Procedures Guide, Part II: Award and Administration Guide, Chapter IV A](#).

§ 3 Preliminary Information on Project Applications

MFM staff must inform the Service Point for Scientific Staff (SerWiM) at least four weeks before the submission deadline if they intend to apply for project funding from a PHS agency or the NSF.

Second Section: Financial Conflicts of Interest

§ 4 Definitions

- (1) A financial conflict of interest exists when a significant financial interest of project staff, their spouses, domestic partners (as defined by the Civil Partnership Act), or their children is present and appears likely to influence the design, conduct, or publication of the results of a PHS or NSF project. Financial interests include any monetary value.
- (2) Indications of a significant financial interest include the presence of assets such as shares or intellectual property rights, compensation payments, or sponsored travel that are substantively related to the PHS or NSF project. Financial interests arising from contractual relationships with the University of Münster (UM) do not constitute a significant financial interest. Similarly, compensation for teaching activities or advisory work for public or nonprofit institutions is excluded.

§ 5 Obligation to Disclose Financial Interests (Conflicts)

- (1) Project staff must disclose, via self-reporting using the Disclosure Form of Financial Interests (Disclosure Form) attached as an annex, whether and which financial interests exist pursuant to Section 4.
- (2) The disclosure must be submitted to SerWiM:
 - a. at least four weeks prior to project application submission;
 - b. annually during the project duration (usually before a contract extension with the PHS agency or NSF); and
 - c. within 30 calendar days if a financial conflict of interest arises during the project duration.

- (3) The Disclosure Form is available for download in the MFM website's download section
- (4) Reports on financial interests (Disclosure Forms) are confidential documents. In the event of a report of financial interests, they may be disclosed to the MFM Dean's Office, as well as to UM staff or third parties commissioned by UM, whose involvement is essential for clarifying the matter. If a conflict of interest is identified, the reports may be disclosed to the relevant PHS agency, the NIH Chief Grants Management Officer, or the NSF's Office of the General Counsel (in cases where MFM is the Main Awardee), or to the institution with primary responsibility for the project (in cases where MFM is the Subawardee)
- (5) SerWiM retains the reports on financial interests (Disclosure Forms) for at least ten years after the completion of a PHS or NSF project. In the event of an audit or legal dispute within the retention period, the reports will be retained beyond the end of the period until the conclusion of the proceedings. period, reports may be kept beyond this period until the matter is resolved.

§ 6 Procedures for Reporting Financial Interests

- (1) In the event of a report of significant financial interests, SerWiM promptly informs the MFM Dean's Office. If the Dean's Office concludes that the objective execution of the PHS or NSF project appears to be compromised due to the significant financial interests, a financial conflict of interest exists. The project leader, in collaboration with SerWiM, reports the financial conflict of interest within 60 days of its determination by the MFM Dean's Office to the relevant PHS agency, the NIH Chief Grants Management Officer, or the NSF's Office of the General Counsel if MFM is the main project leader (MFM as Main Awardee), or to the institution with primary responsibility for the project (MFM as Subawardee).
- (2) the MFM Dean's Office instructs the project staff member to address, mitigate, or eliminate the financial conflict of interest and to report back within 60 calendar days.

- (3) If the MFM Dean's Office concludes that the financial conflict of interest has been adequately addressed, mitigated, or resolved, the project leader, in collaboration with SerWiM, reports this to the relevant authorities in accordance with Section 6(1), Sentence 3.
- (4) If the MFM Dean's Office concludes that the objectivity of the PHS or NSF project continues to be compromised due to the financial conflict of interest, or if project staff fail to meet their reporting obligations within the specified deadline, SerWiM informs the relevant authorities in accordance with Section 6(1), Sentence 3. To address the conflict of interest, the MFM Dean's Office takes the necessary measures. Possible actions include excluding individual project staff from the project, terminating the project prematurely, or, in the case of clinical studies, requiring the project staff member to disclose the financial conflict of interest in publications.

§ 7 Training on Financial Conflicts of Interest

- (1) All project staff participate in the web-based training on financial conflicts of interest (['FCOI Online Tutorial'](#)) provided by the respective PHS agency or NSF before the start of a PHS or NSF project and repeat this training at least every four years.
- (2) Furthermore, all project staff shall immediately participate in the training pursuant to Section 1, provided that:
 - a. an amendment to this directive affects the duties of a project staff member,
 - b. a new project staff member joins the MFM, or
 - c. Section 6(4), Sentence 1, applies.
- (3) The project staff confirm their participation in the training pursuant to Sections 1 and 2 to the project manager and SerWiM in writing using the 'Certificate of Completion' form. This certificate is issued at the end of the online tutorial.

§ 8 MFM as Primary Awardee

- (1) If the MFM conducts a PHS or NSF project as the main responsible party (MFM as Main Awardee), it requires the participating institutions (subawardees) in writing to comply with the U.S. regulations outlined in 42 Code of Federal Regulations Part 50 Subpart F (PHS) and the NSF Grant Policy Manual, Section 510 (NSF).
- (2) For this purpose, the participating institutions must either:
 - a. apply their own regulations on financial conflicts of interest that meet the requirements of Section 2, or
 - b. comply with the regulations outlined in this directive.
- (3) At the request of the project leader, the participating institutions confirm to SerWiM in writing, using the Subrecipient Financial Conflicts of Interest Certification Form, which of the options described in Section 2 applies to them.
- (4) The participating institutions commit, at the request of the MFM project leader, to report any existing financial conflicts of interest related to a PHS or NSF project in writing to SerWiM within 30 days of becoming aware of them. SerWiM will then notify the MFM Dean's Office, the NSF's Office of the General Counsel, the Chief Grants Management Officer of the NIH, or the relevant PHS agency, as applicable.

Third Section: Effective Date

§ 9 Effective Date

These guidelines take effect on September 28, 2022.