
Guidelines of Friedrich-Alexander-Universität Erlangen-Nürnberg on financial conflicts of interest affecting grants from the US Public Health Service (PHS) Agencies and the National Science Foundation (NSF)

Part I: General provisions

Section 1 Scope of application

- (1) ¹These guidelines shall apply to all members of Friedrich-Alexander-Universität Erlangen-Nürnberg (FAU) conducting scientific work who are involved in projects financed by the US [Public Health Service \(PHS\) Agencies](#) (e.g. the [National Institutes of Health](#) - NIH) or the US [National Science Foundation](#) (NSF). ²As well as research staff, this includes students and administrative employees involved in research. ³They shall be referred to hereinafter as investigators.
- (2) ¹FAU may lead a PHS or NSF project (FAU as *main awardee*) or it may be involved in a project led by another institution (FAU as *subawardee*).

Section 2 Applicable legal framework

¹In addition to these Guidelines, investigators shall also comply with the relevant US regulations governing financial conflicts of interest:

- a) For PHS projects, these regulations are summarised in [the US Code of Federal Regulations \(CFR\) Title 42 Part 50 Subpart F](#);
- b) For NSF projects, the [NSF Award and Administration Guide Chapter IV.A](#) shall be complied with.

Section 3 Preliminary information on project applications

¹Investigators at FAU shall inform the Department of Research Services and Research Development (hereinafter Department F1) in advance if they apply for funding from a PHS Agency or the NSF.

Part II Financial conflicts of interest

Section 4 Definitions

- (1) ¹A financial conflict of interest shall be deemed to apply if investigators, their spouses, life partners as defined by the German Act on Registered Life Partnerships ([LPartG](#)) or children have a considerable financial interest which may influence the planning, conducting or publishing of the results of a PHS or NSF project. ²All types of financial value shall be classed financial interests.
- (2) ¹A considerable financial interest shall be deemed to apply in the case of assets such as shares or intellectual property rights, remuneration or sponsored travel relating to the subject of the PHS or NSF project. ²Financial interests derived from the contractual relationship with FAU are not defined as a considerable financial interest. ³Payment for teaching at or providing consulting to public or charitable organisations is also excluded.

Section 5 Duty to disclose (conflicting) financial interests

- (1) ¹Investigators shall disclose any financial interests to FAU which may potentially be classed as a financial conflict of interest within the meaning of Section 4 (1)(1).
- (2) ¹The declaration shall be submitted
- a) Before the application for the project is filed
 - b) Once a year whilst the project is ongoing (as a rule before the contract with the PHS Agency or the NSF is extended)
 - c) Within a period of 30 days if a financial conflict of interest arises while the project is ongoing.

- (3) ¹For this purpose, Department F1 shall supply investigators with declaration forms complying with current US requirements.
- (4) ¹The declaration shall be confidential. ²Department F1 shall be entitled to report to the following individuals/institutions:
- a) On considerable financial interests
 - i. The Executive Board of the University
 - ii. Other staff members of the University Administration, if they have to be consulted in order to clarify the situation.
 - b) On financial conflicts of interest
 - i. The PHS Agency or the NSF before the start of the project, once a year whilst the project is ongoing and within 60 days if a new project member has a relevant financial interest or in the case of Section 6 (4)(1).
 - ii. The institution responsible for leading the project (FAU as *subawardee*).

Section 6 Procedure for declaring financial interests

- (1) ¹Department F1 shall inform the Executive Board immediately if considerable financial interests are reported. ²A financial conflict of interest shall be deemed to apply if the Executive Board comes to the conclusion that the objectivity of the PHS or NSF project may be jeopardised as a result of the considerable financial interests. ³Within 60 days of the financial conflict of interest being recognised by the Executive Board, Department F1 shall inform the NSF's Office of the General Counsel, the Chief Grants Management Officer of NIH or the applicable PHS Agency if FAU is the *main awardee* and the institution which is leading the project if FAU is the *subawardee*.
- (2) ¹The Executive Board shall instruct the investigator to resolve, reduce or remove the financial conflict of interest and to report back within a period of 60 days.
- (3) ¹If the Executive Board comes to the conclusion that the financial conflict of interest has been sufficiently resolved, reduced or removed, Department F1 shall report to the bodies responsible pursuant to section 6 (1)(3).
- (4) ¹If the Executive Board comes to the conclusion that the objectivity of the PHS or NSF project is still jeopardised due to the financial conflict of interest or if investigators fail to

meet the deadline for reporting, Department F1 shall inform the bodies responsible pursuant to Section 6 (1)(3). ²The Executive Board shall take the necessary measures. ³Possible measures include excluding individual investigators from the project, ending the project earlier than planned or, in the case of [clinical trials](#), requiring the investigator to include a reference to the financial conflict of interest in publications.

- (5) ¹Department F1 shall keep all records concerning financial interests for at least three years after the final report has been submitted to the PHS Agency or NSF. ²In the event of an audit or legal dispute, reports shall be kept at least until proceedings have been completed.

Section 7 Training on financial conflicts of interest

- (1) ¹Before commencing a PHS or NSF project, all investigators shall take part in the web-based training course offered by the PHS Agency or NSF on financial conflicts of interest (*FCOI Online Tutorial*) and shall retake this course at least once every four years.
- (2) ¹In addition, all investigators shall take part immediately in the course stated in subsection 1 if
- a) Any amendments to these Guidelines affect the duties of an investigator
 - b) An investigator moves to FAU
 - c) In the case of Section 6 (4)(1).
- (3) Investigators shall provide Department F1 with written confirmation of having completed the training course pursuant to subsections 1 and 2 by submitting the *Certificate of Completion*. ²This is issued at the end of the online tutorial.

Section 8 FAU as main awardee

- (1) ¹If FAU is responsible for leading a PHS or NSF project (FAU as *main awardee*), it shall require written confirmation from the other institutions involved (*subawardees*) that they shall comply with the requirements set in the US Code of Federal Regulations Title 42 Part 50 Subpart F (PHS) or the NSF Grant Policy Manual, Section 510 (NSF).
- (2) ¹The involved institutions must either

- a) Use their own regulations governing financial conflicts of interest which meet the requirements pursuant to Section 2 or
 - b) Use the regulations stipulated in these guidelines.
- (3) ¹The involved institutions shall provide Department F1 with written confirmation of which of the options described in subsection 2 apply in their case by completing the *Subrecipient Financial Conflicts of Interest Certification Form*.
- (4) ¹The involved institutions agree to report any existing financial conflicts of interest affecting a PHS or NSF project to Department F1 within a period of 30 days of becoming aware of their existence. ²Department F1 shall then inform the NSF's Office of the General Counsel, the Chief Grants Management Officer of NIH or the relevant PHS Agency.

Part III: Legal validity

Section 9 Legal validity

These Guidelines shall enter into force on 1 January 2019.

Approved by the Executive Board on 24 April 2019.

Erlangen, 25 April 2019

Prof. Dr.-Ing. Joachim Hornegger

President