

Business Directive

**Financial Conflict of Interest Directive
related to grants of the
US National Science Foundation (NSF)
and the
National Institutes of Health (NIH)**

dated: 1 Juli 2019

HZI **HELMHOLTZ**
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§ 1 Principle

1) HZI staff members, hereinafter referred to as investigators, who are involved in projects funded by the US National Science Foundation or the National Institutes of Health (NSF or NIH projects) are required to comply with these regulations.

2) An NSF or NIH project can be managed by HZI (HZI as Main Awardee) or it can be an HZI project managed by a university or other institution (HZI as Subawardee).

§ 2 Applicable Legal Provisions

1) In addition to these regulations, investigators must also comply with the NSF and NIH regulations set out in the *NSF Proposal and Award Policies and Procedures Guide* and the *NIH Grants Policy Statement*.

2) For NSF projects, the provisions on financial conflicts of interest in the *NSF Proposal and Award Policies and Procedures Guide, Chapter IV A* must be observed. For NIH projects, the US provisions on financial conflicts of interest must be observed, *42 Code of Federal Regulations Part 50, Subpart F*.

§ 3 Duty of Notification

HZI investigators must notify the Third Party Funding department (DMC) when applying for NSF or NIH project funding.

§ 4 Financial Conflicts of Interest

1) A financial conflict of interest is defined as the existence of assets, income or sponsored travel of investigators, their spouse or dependent children, who are related to the NSF or NIH project in terms of content or who could influence the design, conduct or reporting of the results of the NSF or NIH project.

2) Investigators must disclose to HZI any financial interests that could be identified as financial conflicts of interest under this regulation.

3) Financial interests arising from a contractual relationship with HZI are excluded from this rule. Remuneration from teaching engagements or advisory activities in favour of public or non-profit institutions is also excluded.

§ 5 Reporting Financial Interests

1) When concluding or renewing a contract with the NSF or the NIH, the investigators declare by means of the disclosure form of financial interests (*disclosure form*) whether and which

financial interests exist pursuant to § 4. If financial interests arise during the term of the project, the investigators shall report them within 30 days using the *disclosure form*.

2) The reports on financial interests (*disclosure form*) are confidential documents. If financial interests are declared, they may be disclosed by the DMC department to Management and to HZI employees, whose involvement is essential for establishing the facts. If a conflict of interest is identified, the reports may be disclosed to the NSF's Office of the General Counsel or to the NIH Chief Grants Management Officer (HZI as Main Awardee) or to the university or institution with primary responsibility for the project (HZI as Subawardee).

3) The DMC department keeps the disclosure reports for at least three years after the completion of an NSF or NIH project.

§ 6 Procedure for Reporting Financial Interests

1) If financial interests are reported, the DMC department informs Management immediately. If Management determines that the objectivity of the NSF or NIH project is compromised due to the financial interests involved, a financial conflict of interest exists and the HZI DMC department reports the financial conflict of interest to the NSF's Office of the General Counsel or to the NIH Chief Grants Management Officer within 60 days of Management's determination of the financial conflict of interest if HZI is the Main Awardee or to the university or institution with primary responsibility for the project (HZI as Subawardee).

Management instructs the investigator to manage, reduce or eliminate the financial conflict of interest and to report back within 60 days.

3) If Management comes to the conclusion that the financial conflict of interest has been adequately managed, reduced or eliminated, the DMC department shall report to the competent authorities pursuant to § 6 Paragraph 1.

4) If Management comes to the conclusion that the objectivity of the NSF or NIH project continues to be compromised due to the conflict of financial interests, or if investigators fail to comply with the duty to report, the DMC department shall inform the competent authorities pursuant to § 6 Paragraph 1. Management shall take the necessary steps. Possible measures could include the exclusion of individual project members or a premature termination of the project.

§ 7 Training on Financial Conflict of Interest

Before the start of the project, the investigators take the web-based NIH course on financial conflicts of interest ("FCOI Online Tutorial"). The investigators repeat the NIH course at least

every four years and confirm their participation in writing to the DMC department using the "Certificate of Completion" form. This will be issued at the end of the online tutorial.

§ 8 HZI as Main Awardee

1) If HZI manages an NSF or NIH project with primary responsibility (HZI as Main Awardee), it commits the participating universities (Subawardees) to comply with the U.S. requirements set out in the Grants Policy Statement, Section 510, or the 42 Code of Federal Regulation Part 50 Subpart F (NIH).

2) To this end, the participating universities or other institutions must have their own regulations on financial conflicts of interest which meet the requirements of § 2 Paragraph 2. Participating universities or institutions undertake to report existing financial conflicts of interest in connection with an NSF or NIH project to HZI within 30 days of becoming aware of them. HZI informs Management and the NSF's Office of the General Counsel or the Chief Grants Management Officer of NIH shall be informed accordingly.

3) If a participating university or institution does not have adequate regulatory guidelines, it can adopt the regulations of this HZI directive for the NSF or NIH project. Participating universities or institutions undertake to notify HZI of any financial interests in connection with an NSF or NIH project within 30 days of becoming aware of them. The subsequent procedure is carried out pursuant to these guidelines

4) The universities or institutions involved shall confirm in writing to the DMC department, on the basis of the Financial Conflicts of Interest Certification Form, which of the options described in § 8 Paragraphs 2 and 3 apply to them.

§ 9 Entry into Force

This Company Directive entered into force on 1 July 2019.

(This is a translated copy of the German original and is valid without a signature)

Annexes:

The documents mentioned in this Company Directive can be accessed via the following links:

- 1) *NSF Proposal and Award Policies and Procedures Guide*
https://www.nsf.gov/pubs/policydocs/pappg19_1/nsf19_1.pdf
- 2) *NIH Grants Policy Statement*
<https://grants.nih.gov/policy/nihgps/index.htm>
- 3) *42 Code of Federal Regulation Part 50 Subpart F*
https://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm
- 4) *Web-based training as per § 7 (FCOI Online Tutorial)*
https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

Or can be downloaded from the Intranet pages of DMC:

- 5) *disclosure form*
- 6) *Subrecipient Financial Conflicts of Interest Certification Form*

