

## **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)**

**Leibniz Institute of Virology (LIV), Hamburg**

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### **1. General provisions**

#### **Section 1: Scope**

- (1) This policy applies to all LIV members (incl. guests, scholarship recipients, and students) working on research projects funded by US Public Health Service (PHS) agencies or the US National Science Foundation (NSF), and they are referred to as "investigators". All investigators must follow this policy.
- (2) This policy applies to all PHS- or NSF-funded research that the LIV carries out as the prime awardee or subrecipient.

#### **Section 2: Compliance with PHS and NSF regulations**

- (1) Investigators must comply with the regulations set by the funding body for the research project in addition to this policy. For PHS-funded projects, this usually includes the NIH Grants Policy Statement, and for NSF-funded projects, this includes the NSF Proposal and Award Policies and Procedures Guide.
- (2) Compliance with 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 is required for NSF-funded projects. For PHS-funded projects, 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**

- (1) LIV staff planning to submit a proposal for funding to NSF or a PHS agency must inform the Designated Institute Official (the Administrative Director & Member of the Board of Directors), who is responsible to enforce the FCOI policy at the LIV and deals with complaints or inquiries and Third Party Funding Management in a timely manner.

### **2. Financial conflicts of interest**

#### **Section 4: Definitions**

- (1) The term "financial conflict of interest" (FCOI) refers to a noteworthy financial interest held by an investigator, their spouse, registered civil partner within the meaning of the German *Lebenspartnerschaftsgesetz* (Registered Civil Partnership Act, LPartG) or their children that the LIV 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) The definition of “significant financial interest” (SFI) encompasses equity interests such as shares or intellectual property rights, remunerations, and sponsored travel related to PHS- or NSF-funded projects.

However, SFI does not cover financial interests that arise from an investigator's contractual relationship with the LIV. It also does not include income received from teaching activities or consultancy services offered to public or non-profit organizations.

#### **Section 5: Procedure for the disclosure and verification of financial interests**

(1) All investigators must disclose their financial interests as defined in Section 4 using the Disclosure Form of Financial Interests (Disclosure Form).

(2) Disclosures must be sent to the LIV Third Party Funding Management:

- (a) before a proposal for funding is submitted;
- (b) annually during the period of the project award (usually prior to renewal of an award by NSF or the Agency of the PHS); and
- (c) within 30 calendar days if an FCOI occurs during the project's award period.

(3) The LIV Third Party Funding Management shall retain the investigator's Disclosure Form of Financial Interests (Disclosure Form) for at least three years after completion of the NSF- or PHS- funded project. If litigation or an audit is initiated before the end of the three-year period, the records will be retained at least until any litigation or audit findings affecting the records are resolved and final action is taken.

(4) The LIV Third Party Funding Management shall immediately report any financial interest disclosed to it to the Board of Directors. If the latter determines that the financial interest appears to affect NSF- or PHS-funded research, an FCOI shall be presumed to exist, and the Third Party Funding Management at the LIV shall report the FCOI to the NSF Office of the General Counsel or the NIH Chief Grants Management Officer within 60 days of the Board of Directors' discovery of the FCOI; or the appropriate PHS agency (if the LIV is the primary beneficiary) or the primary recipient (if the LIV is a subrecipient). For these purposes, the Disclosure Form of Financial Interests (Disclosure Forms) may be made available to the above-mentioned entities as well as to LIV employees whose input is essential for the examination of the matter.

(5) The Board of Directors shall require the investigator to manage, reduce or eliminate the FCOI and report to it within 60 days on the actions taken to eliminate the FCOI.

(6) If the Board of Directors determines that the FCOI has been appropriately managed, reduced or eliminated, the LIV Third Party Funding Management shall report to the relevant bodies referred to in Section 5 (4).

(7) If the Board of Directors determines that the FCOI continues to affect NSF- or PHS-funded research, or if the investigator fails to comply with his or her reporting obligation, the LIV Third-Party Funding Management shall notify the competent bodies specified in Section 5 (4). The Board of Directors will then take appropriate measures to remedy the FCOI.

The following measures may be taken: Exclusion of certain scientists from participation in the project or discontinuation of the project.

#### **Section 6: FCOI training**

(1) Each investigator must complete FCOI training:

- (a) prior to engaging in research related to NFS- or PHS-funded research.
- (b) at least every four years;



- (c) if the LIV revises its FCOI policy;
- (d) when an investigator is new to the LIV;
- (e) when an investigator is found to be noncompliant with the LIV FCOI policy.

To complete training:

1. Go to <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm> to reach the NIH FCOI tutorial;
2. View tutorial and answer the review questions;
3. At the end of the tutorial, click the "Certificate" button;
4. When the certificate appears, type your name in the "Participant's Name" text box.

(2) Upon completion of the FCOI online tutorial, investigators must provide a copy of the "Certificate of Completion" to the Third Party Funding Management at the LIV as proof that they have fulfilled the training requirements outlined in Section 6 (1).

### **Section 7: The LIV as the prime awardee institution**

(1) If the LIV is awarded funds by NSF or PHS as the primary recipient, it will request written agreements from any subrecipients to comply with the rules stated in Section 510 of the NSF Grant Policy Manual or CFR Title 42, Part 50 Subpart F (PHS), as applicable.

(2) To comply with the requirements of Section 510 of the NSF Grant Policy Manual or CFR Title 42, Part 50 Subpart F (PHS), the LIV, as the prime awardee of NSF or PHS funds, will require subrecipients to have their own FCOI policy that aligns with NSF or PHS guidelines. The subrecipients must report any existing FCOI related to NSF- or PHS-funded research to the Third Party Funding Management at the LIV within 30 days of becoming aware of its existence. Upon receiving the report, The Third Party Funding Management will notify the Board of Directors and report the FCOI to the appropriate agency, either the NSF Office of the General Counsel or the NIH Chief Grants Management Officer, or the relevant Agency of the PHS.

(3) If a subrecipient lacks an appropriate FCOI policy, they can use the LIV policy for the NSF- or PHS-funded project. In this case, subrecipients must report any existing Financial Interest related to the research funding to the LIV within 30 days of becoming aware of it. The LIV will then take further action as per its FCOI policy.

(4) The subrecipients must give a written statement, known as the "Subrecipient Financial Conflicts of Interest Certification Form," to the Third Party Funding Management at the LIV. This form will confirm which of the options described in Section 7 (2) and (3) applies to them.

### **Section 8: Entry into force**

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