

# Policy of the Medical Faculty of Heinrich Heine University on Financial Conflicts of Interest concerning Grants from the US Public Health Service (PHS) Agencies and the US National Science Foundation (NSF)

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## **1. First Part: General provisions**

### **Section 1 Scope of application**

- (1) The Policy of the Medical Faculty of Heinrich Heine University (HHU) on Financial Conflicts of Interest concerning Grants from the US Public Health Service (PHS) Agencies and the US National Science Foundation (NSF) (hereinafter referred to as the Policy) applies to all members and affiliates of the Medical Faculty of the HHU who are involved in projects funded by PHS Agencies (e.g. The National Institutes of Health - NIH) or the United States National Science Foundation (NSF) as funding agencies (hereinafter referred to as 'PHS or NSF Project'); they are hereinafter referred to as 'Researchers'.
- (2) Researchers are committed to adhere to the requirements of this Policy when working on PHS or NSF Projects.
- (3) The Medical Faculty of the HHU can either carry out a PHS or NSF Project (University Hospital of Düsseldorf as Main Awardee) as the party with primary responsibility or contribute to PHS or NSF Projects that are realized by another institution holding the with primary responsibility (University Hospital of Düsseldorf as Subawardee).

### **Section 2 Applicable legal provisions**

- (1) In addition to the provisions set out in this Policy, Researchers must also comply with the rules and regulations specified by the funding body for the respective project. This regularly includes the NIH Grants Policy Statement for PHS Projects and the NSF Proposal and Award Policies and Procedures Guide for NSF Projects.
- (2) For NSF projects, the requirements on financial conflicts of interest in the NSF Proposal and Award Policies and Procedures Guide, Part II. Award and Administration Guide, Chapter IX A (NSF Award and Administration Guide Chapter IV.A), and for PHS and NIH projects the US requirements on financial conflicts of interest in accordance with [42 Code of Federal Regulation \(CFR\) Part 50 Subpart F](#) must be complied with.

### **Section 3 Advance information on project applications**

It is imperative that Researchers inform the research management of the HHU Medical Faculty at an early stage if they wish to apply for project funding from the NSF, NIH or the PHS Agencies.

## **2. Second Part: Financial conflicts of interest**

### **Section 4 Definitions**

- (1) A financial conflict of interest (FCOI) is defined as a significant financial interest of the Researcher, spouse or partner within the meaning of the German Act on Registered Life Partnerships (LPartG), fiancé and/or dependent children and foster children (hereinafter collectively referred to as 'those close to the researcher') that could have the potential to influence the planning, conduct or reporting of PHS or NSF-funded research. Financial interest is used as a comprehensive term, regardless of the monetary value, and includes any financial value.
- (2) Indications of a significant financial interest may include the existence of assets, such as shares or intellectual property rights, compensation payments or sponsored travel that are related to the content of the PHS or NSF Project. Financial interests arising

from contractual relationships with the Medical Faculty of the HHU do not constitute a significant financial interest. Teaching activities or advisory activities in favor of public or non-profit institutions are also excluded.

- (3) A Significant Financial Interest (SFI) and a Financial Conflict of Interest shall therefore exist pursuant to Article 42 Code of Federal Regulation (CFR) Part 50.603 if one or more of the following interests of Researchers and/or those close to them associated with the institutional tasks of the Researchers:
- a) Listed company: Value of any compensation (e.g., salary, consulting fees, remuneration, paid authorship) received from the company in the 12 months prior to disclosure as well as the value of any equity interest (e.g., shares, stock options, or other ownership interests) in the company at the time of disclosure that, in the aggregate, exceeds US\$ 5,000;
  - b) Non-listed company: Value of all compensation received in the twelve months prior to disclosure that, in the aggregate, exceeds US\$ 5,000, or any equity interest;
  - c) Intellectual property rights and interests (e.g. patents, copyrights) that exceed US\$ 5,000 upon receipt of income. IP rights assigned to the institution and agreements on participation in license fees associated with such rights are excluded from the definition of SFI;
  - d) All reimbursed or sponsored travel associated with the institutional duties of Researchers that exceeds US\$ 5,000 in value, with the exception of travel reimbursed or sponsored by the following entities:
    - a federal, state or local government agency in the United States
    - an institution of higher education in the United States
    - an academic teaching hospital
    - a medical center or
    - a research institute that is affiliated with a U.S. institution of higher education.
- (4) The definition of SFI excludes the following types of interests:
- a) In general, all payments received by Researchers from or via the Medical Faculty of the HHU are excluded if the Researcher is currently employed or otherwise appointed, including but not limited to:
    - Salaries, royalties or other remuneration, including reimbursement of travel expenses;
    - Intellectual property rights that have been assigned to the Medical Faculty of the HHU and agreements on participation in license fees in connection with these rights;
  - b) Income from capital investments such as investment funds and pension investments, provided that the Researcher does not directly control investment decisions;
  - c) Income from seminars, lectures, teaching assignments, or service on advisory committees or review panels funded by a federal, state or local government agency in the USA, an institution of higher education in the USA, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education in the USA

### **Section 5 Duty to disclose financial interests**

- (1) All Researchers must disclose whether and which financial interests exist in accordance with Section 4 by filling out the 'Disclosure Form: Self-disclosure of Financial Interests in the context of PHS/NSF Projects'.
- (2) Any (conflicts of) financial interests must be disclosed to the Research Management of the Medical Faculty of the HHU:

- a) prior to submitting the project application;
  - b) during the project period annually on June 1; and
  - c) within 30 calendar days if a financial conflict of interest arises during the project period.
- (3) The reports regarding financial interests (disclosure forms) are confidential documents. In the event that financial interests are reported, they may be disclosed to the Dean's Office of the Medical Faculty at HHU, the Management Board of Düsseldorf University Hospital and the relevant employees, whose involvement is essential for the clarification of the matter. If a conflict of interest is identified, the reports can be disclosed to the NSF's Office of the General Counsel, the Chief Grants Management Officer of the NIH or the responsible PHS Agency (University Hospital of Düsseldorf as Main Awardee) or to the institution that is primarily responsible for carrying out the project (University Hospital of Düsseldorf as Subawardee).
- (4) The research management of the HHU Faculty of Medicine shall retain the disclosure forms and all records of all disclosures of financial interests of Researchers as well as the review for publication by the HHU Faculty of Medicine together with the corresponding decision (regardless of whether a disclosure resulted in the identification of a financial conflict of interest by the HHU Faculty of Medicine or not) for at least three years from the date of submission of the final project report; this also applies to any related actions taken by the HHU Faculty of Medicine or any 'retrospective reviews', if applicable. If litigation or an investigation is initiated prior to the expiration of the three-year period, the records will be retained at least until all litigation or investigation findings related to the records have been resolved and final action has been taken.

### **Section 6 Procedure for reporting financial interests**

- (1) If financial interests are reported, the research management of the HHU Medical Faculty shall communicate this directly to the Dean's Office of the HHU Medical Faculty. If the Dean's Office of the HHU Medical Faculty determines that the planning, implementation or reporting of the NSF or PHS Project appears to be affected due to significant financial interests, a financial conflict of interest shall be deemed established. The research management of the HHU Medical Faculty, in collaboration with the Researcher(s), will report the financial conflict of interest to the NSF's Office of the General Counsel or the Chief Grants Management Officer of the NIH or the competent PHS Agency within 60 days of the identification of the financial conflict of interest by the Dean's Office of the HHU Medical Faculty in the event that the University Hospital of Düsseldorf is primarily responsible (University Hospital of Düsseldorf as Main Awardee) or to the institution that is primarily responsible for carrying out the project (University Hospital of Düsseldorf as Subawardee). This report follows the U.S. requirements of 42 Code of Federal Regulation (CFR) Part 50.605(b).
- (2) The Dean's Office of the HHU Medical Faculty shall instruct the Researcher concerned to manage, reduce or eliminate the financial conflict of interest and may impose appropriate actions (e.g. full public disclosure, appointment of an independent person to monitor the project, changes to the research plan, etc.). An implementation report must be submitted to the Medical Dean's Office of the HHU within 30 days.
- (3) If the Dean's Office of the HHU Medical Faculty comes to the conclusion that the financial conflict of interest has been sufficiently managed, reduced or eliminated, the research management of the Medical Faculty of the HHU shall report to the responsible bodies in accordance with Section 6 (1).
- (4) If the Dean's Office of the HHU Medical Faculty comes to the conclusion that the objectivity of the NSF, NIH or PHS Project is still impaired due to the financial conflict of interest or if Researchers do not comply with the reporting obligation, the research

- management of the Medical Faculty of the HHU will inform the responsible bodies in accordance with Section 6 (1). The Dean's Office of the HHU Medical Faculty will then take the necessary actions to remedy the conflict of interest. Possible actions include the exclusion of individual Researchers from the project or premature termination of the project or, in the case of clinical trials, to commit the Researcher to include a reference to the financial conflict of interest in all publications.
- (5) A retrospective review is mandatory whenever a financial conflict of interest is not identified or managed in a timely manner, including
- a) the failure of the Researcher to disclose a material financial interest that is classified as a financial conflict of interest by the Dean's Office of the HHU Medical Faculty;
  - b) the failure of the Medical Faculty of the HHU to review or manage such a financial conflict of interest; or
  - c) the failure of the Researcher to adhere to a prescribed plan for dealing with financial conflicts of interest.
- (6) The Dean's Office of the Medical Faculty of the HHU will conduct (within 120 days of identifying the violation) a 'retrospective review' of the Researcher's activities and the PHS-, NSF- or NIH-funded research project to determine whether any PHS-, NSF- or NIH-funded research, or any part thereof, conducted during the period of the violation was influenced within the scope of the planning, conduct or reporting of that research. This retrospective review complies with the requirements of U.S. Title 42 Code of Federal Regulation (CFR) Part 50.605(a). Based on the results of the retrospective review, the Dean's Office of the Medical Faculty will update the previously submitted financial conflict of interest report, as appropriate, and determine the future actions to be taken to deal with the financial conflict of interest. If a case of bias is identified, the Dean's Office of the Medical Faculty of the HHU will notify the PHS, NSF, or NIH Awarding Component and submit a Remedial Action Report without delay. The corrective action report will comply with the requirements of Title 42 Code of Federal Regulation (CFR) Part 50.605(a) and NIH FAQs I. Parts 1-4.1

### **Section 7 Public announcement**

- (1) After funding has been approved by the PHS, NIH or NSF, but prior to the use of funds in a research project funded by the PHS, NIH or NSF, the Faculty of Medicine of HHU shall - with regard to all significant financial interests that meet the following criteria - disclose on a publicly accessible website the information listed below under Section 7 (2):
- a) The significant financial interest on the part of a Researcher has been disclosed by the Researcher concerned and continues to apply;
  - b) It has been determined by the HHU Medical Faculty that the relevant financial interest is related to research funded by PHS, NIH or NSF;
  - c) The HHU Medical Faculty has determined that the financial interest results in a financial conflict of interest.
- (2) The Medical Faculty of the HHU must provide information on the publicly accessible website and in response to written inquiries within five (5) working days at least with regard to the following points:
- a) Name of the Researcher concerned;
  - b) Function of the Researcher within the research project;
  - c) Type of financial interest;
  - d) Approximate value of the financial interest (in USD); (i) 0 - 4,999 USD; (ii) 5,000 - 9,999 USD; (iii) 10,000 - 19,999 USD; (iv) values between 20,000 and 100,000

- (4) USD in steps of 20,000; (v) values above 100,000 USD in steps of 50,000 or a note that the corresponding value cannot be readily quantified;
- e) Name of the institution where the Researcher has a financial conflict of interest to improve transparency and accountability.
- (3) The HHU Medical Faculty will update the above information within 60 days of any change to this information, but at least once a year.
- (4) In all cases in which it is established that a PHS-funded clinical research project dealing with the evaluation of the safety or effectiveness of a drug, medical device or medical treatment was developed, planned, conducted or reported by a Researcher with a financial conflict of interest that was not managed or reported in accordance with the requirements, the HHU Medical Faculty will require the Researcher to disclose this financial conflict of interest at each public presentation of the research results and to publish an addendum to previously published presentations and publications.

### **Section 8 Further training on financial conflicts of interest**

- (1) Before starting to work on a PHS, NIH or NSF Project, all Researchers must complete the web-based training on financial conflicts of interest ('FCOI Online Tutorial') of the PHS Agency or NSF and repeat this training at least every four years.
- (2) In addition, all Researchers shall take part in further training within the meaning of Section 8 (1) without delay, provided that
- a. the duties of a Researcher change due to an amendment to this Policy;
  - b. Researchers are newly employed at the Medical Faculty of the HHU, or
  - c. in the case set out in Section 6 (4) Sentence 1.
- (3) Without requiring further request, all Researchers shall provide the research management of the HHU Medical Faculty with a written confirmation of their participation in a further training session in accordance with paragraphs 1 and 2 using the 'Disclosure Form: Self-disclosure of financial interests in the context of PHS/NIH/NSF Projects'. This will be provided at the end of the online tutorial.

### **Section 9 University Hospital of Düsseldorf as Main Awardee/ Subawardee**

- (1) If the University Hospital Düsseldorf carries out an NSF or PHS Project as the party with primary responsibility (University Hospital Düsseldorf as Main Awardee), it shall commit the participating institutions (Subawardees) in writing to comply with the US requirements in the NSF Grant Policy Manual, Part 510, or the 42 Code of Federal Regulation Part 50 Subpart F (PHS & NIH).
- (2) For this, the participating institutions must have their own regulations on financial conflicts of interest that fulfill the requirements of Section 2. Participating institutions undertake to report any arising financial conflicts of interest in connection with an NSF or PHS Project to the research management of the HHU Medical Faculty within 30 days of becoming aware of them. The latter will inform the Dean's Office of the HHU Medical Faculty and will notify the NSF's Office of the General Counsel or the Chief Grants Management Officer of the NIH or the competent PHS Agency.
- (3) If a participating institution does not have adequate regulations in force, it may adopt the regulations of this HHU Medical Faculty Policy for the NSF or PHS Project. Participating institutions undertake to notify the HHU Medical Faculty of any arising financial interests in connection with an NSF, NIH or PHS Project within 30 days of becoming aware of them. The further procedure is then carried out in accordance with this Policy.

- (4) Using the Subrecipient Financial Conflicts of Interest Certification Form, the participating institutions shall confirm in writing to the research management of the Medical Faculty of the HHU which of the options as set out in Section 9 (2) and (3) apply to them.
- (5) If the University Hospital of Düsseldorf is involved as a contributor to PHS or NSF Projects for which another institution has primary responsibility (University Hospital of Düsseldorf as Subawardee) and this other institution declares its own regulations on financial conflicts of interest to be applicable, all Researchers declare that they additionally accept and comply with the obligations arising from those regulations on financial conflicts of interest. In the event of a conflict between this Policy and the financial conflict of interest regulations of another institution, the provisions of this Policy shall apply. An exception shall however be made where this Policy explicitly violates rules and regulations stipulated by the funding provider.

**3. Third Part:  
Entry into force**

**Section 10 Entry into force**

This Policy comes into force retroactively with effect from February 15, 2024.

Adopted by the Dean's Office of the HHU Medical Faculty on February 26, 2024:

Prof. Dr. med. Nikolaj Klöcker, Dean of the Medical Faculty