Policy on the handling of grants from US funding bodies in the context of research projects at Hannover Medical School from 25.09.2024

The Executive Board of Hannover Medical School issues the following directive:

1. General provisions

1.1 The primary goal of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from Investigator financial conflicts of interest.

1.2 In addition to this guideline, the relevant regulations of the aforementioned US PHS agencies (42 Code of Federal Regulation (CFR) Part 50 Subpart F) and the NSF (NSF Award and Administration Guide (AAG) Chapter IV.A) must be noted. To ensure the independence and objectivity of research, financial conflicts of interest must generally be avoided.

1.3 Scope of application

These regulations apply in connection with the application for and receipt of funding (grants) from the National Science Foundation (NSF), the US Public Health Service (PHS) agencies, such as the National Institutes of Health (NIH) or the Defense Advanced Research Project Agency (DARPA) of the US Department of Defense (DoD). The Hannover Medical School (defined here as “Institute”) can play a main coordinating role (main awardee) or the role of sub-recipient (sub-awardee).

Acceptance of this funding obliges both MHH and the project staff concerned to comply with specific requirements of the funding body.

This guideline implements these requirements and regulates the associated duties, processes and responsibilities.

2. Financial processing / reporting / audit

2.1 Financial settlement

A separate third-party funded project is opened for each grant. This is done in

accordance with the current version of the "External Funding Guidelines for Research" and the general regulations of the MHH and always requires a legally effective contract with the funding institution or the coordinating institution (main awardee).

The principle investigator assigns all costs directly attributable to the respective project as direct costs to this third-party funded project. The principle investigator is obliged to adhere to the allocation of the approved budget in the respective cost categories; in the event of ambiguities or intentions to change or possible deviations, the Grants and Contracts Administration must be contacted.

F&A costs (facilities and administrative costs, indirect costs) are collected as overhead income on the externally funded project and overhead expenses are charged in the same amount. The F&A costs are a transitory item for the externally funded project and are allocated to cover the MHH's overhead costs.

2.2 Reporting

Reporting to the funding body is carried out in close coordination between principle investigator and the Grants and Contracts Administration. Factual reports are sent directly to the funder by the principle investigator. If payments from the funder are dependent on the recognition of the factual reports, the Grants and Contracts Administration must be informed of the result immediately. The Grants and Contracts Administration is responsible for preparing the financial reports. All relevant information and documents provided by the principle investigator are made available in a suitable form to the responsible processing department of the third-party funds department in a timely manner. Questionnaires from funding bodies on MHH's accounting, bookkeeping and auditing standards must be addressed to the External Funding Department immediately and will be completed there. In this context, it should be noted that neither the principle investigator nor the project staff are authorized to sign documents in a legally binding manner on behalf of MHH; only the Executive Board of MHH (or representatives or authorized agents) are authorized to represent MHH externally.

2.3 Audit

If MHH's total expenditures through US Federal Grants exceed $750,000 in the current fiscal year, an audit must be conducted in accordance with 45 Code of Federal Regulation (CFR) Part 75 Subpart F, which is coordinated by the external funding department. The requirements of the NIH Grants Policy Statement (NIHGPS) and other specifications of the respective HHS National External Audit Review Center

apply. The cost of the project audit will be charged pro rata to each affected U.S. Federal grant.

The need for an audit in connection with US federal grants is assessed by the External Funding Department. If, in addition to the documents already regularly provided for reporting purposes, further documents are required to assess the scope of the audit, these must be made available to the External Funding Department immediately upon request.

3. Financial conflicts of interest

3.1 Definitions

“Affected Parties” in the above sense according to 42 CFR Part 50 Subpart F, §50.603 means:

a. all Investigators,

b. their spouses and partners within the meaning of the German Civil Partnership Act (LPartG),

c. their children who are under their parental care.

“*Conflicts of interest (COI)*” means a conflict of interest is a situation in which a person is caught up in mutually exclusive obligations, commitments or objectives for personal gain.

“*Designated Official(s)*” means individual(s) at the Institution who is(are) responsible for reviewing SFI disclosures and making determinations of FCOI per the regulatory criteria in 42 CFR 50.604(f). At the time of Research application this means the respective personnel at the MHH staff unit FWT2. From the time point of acceptance of a Research proposal this means the respective personnel at the MHH Grants and Contracts Administration.

“*Financial Conflict of Interest (FCOI)*” means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research. Note: A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator’s Significant Financial Interest is related to a research project (i.e., the Significant Financial Interest could be affected by the research or the Significant Financial Interest is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of the research.

“*Institute Responsibilities*” means an Investigator’s professional responsibilities on behalf of the Institute, and as defined by the Institute in its policy on financial conflicts

of interest, which may include for example: activities such as research, research consultation, training, professional practice, and service on panels such as Institutional Review Boards, Data Safety and Monitoring Boards or Ethics Boards.

"*Investigator*" means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NSF, PHS/NIH, Defense Advanced Research Project Agency or proposed for such funding, which may include, for example, collaborators or consultants.

"*Research*" means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development. As used in this subpart, the term includes any such activity for which research funding is available from the National Science Foundation (NSF), the US Public Health Service (PHS) agencies, such as the National Institutes of Health (NIH) or the Defense Advanced Research Project Agency (DARPA) of the US Department of Defense (DoD) through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, Institute training grant, program project, or research resources award.

"Senior/Key Personnel" means the Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under the regulation.

"*Significant Financial Interest (SFI)*" means:

A Financial Interest consisting of one or more of the following interests of the Affected Parties that reasonably appears to be related to the Investigator's Institute responsibilities:

- with regard to any publicly traded entity, a exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- with regard to any non-publicly traded entity, a S F It exists if the value of any remuneration received from the entity in the twelve months preceding

the disclosure, when aggregated, exceeds $5,000, or when the Affected Parties hold any equity interest (e.g., stock, stock option, or other ownership interest), or a management or governance position; or

- intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income in excess of $5,000 related to such rights and interests.

Significant Financial Interests do not include:

- salary, royalties, or other remuneration paid by the Institute to the Investigator if the Investigator is currently employed or otherwise appointed by the Institute, including intellectual property rights assigned to the Institute and agreements to share in royalties related to such rights.
- Any ownership interest in the Institute held by the Investigator since the Institute is a for-profit organization.
- income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency located in the United States, a United States Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.
- Income from service on advisory committees or review panels for a Federal, state, or local government agency located in the United States, a United States Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

Note: Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received any foreign entity, including foreign Institution of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000).

Reimbursed or Sponsored Travel:

- Investigators also must disclose the occurrence of any foreign or domestic reimbursed or sponsored travel that exceeds $5,000 (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their

Institute responsibilities;

- Provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency located in the United States, a United States Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education. Reimbursed or sponsored travel received from a foreign government, or a foreign institution of higher education is required to be disclosed if such income exceeds $5,000.
- Disclosure for travel shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institute will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
- The initial disclosure must include reimbursed or sponsored travel received over the previous twelve-months. Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

Note: the Foreign Disclosure Requirements Related to the Exclusions: Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received any foreign entity, including foreign Institution of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000).

3.2 Obligations

3.2.1 Training of Investigators

Training will inform about the Institute's policy, Investigator's SFI disclosure responsibilities and requirements per the policy, and the Federal regulation. Investigators will be required to complete the NIH FCOI training modules and provide a certificate of completion to the Designated Officials. The Designated Officials will retain a copy of the certification of completion of FCOI training for audit purposes. Immediate training will be required if the Institute revises this policy in a manner that affects the Investigator, when an Investigator is new to the Institute, or as a result of a finding of noncompliance with this policy or a management plan, or other related

misconduct.

3.2.2 Disclosure

The Investigators in the relevant (planned and/or approved) research project are obliged to disclose the SFI of all Affected Parties to the Designated Officials at defined times (see below) in accordance with the regulations of the US PHS agencies (42 CFR Part 50 Subpart F) and the NSF (NSF AAG Chapter IV.A). Research should not be undertaken on pending applications where a Significant Financial Interest is present until a determination has been made and is managed pursuant to this policy.

If the research project was influenced by a previously undisclosed SFI, the Presidential Board of MHH expects the Investigator concerned to eliminate the FCOI and to report this in writing to the Grants and Contracts Administration within 30 days.

Disclosure is made via the form "MHH: CONFLICT OF INTEREST DISCLOSURE FORM" (Annex 1), which must be completed and signed internally at MHH at defined times (see below) and sent via the principle investigator to the Designated Officials (responsibilities and deadlines are summarized and explained below).

Phase	Tasks & duties (of the investigator)	Time	Reference
Application	First-time disclosure of SFIs by the Investigators already named at this time	Before submitting the funding application, but no later than 14 days before the deadline	I.
	Participation in training on Financial Conflicts of Interest (see 3.2.1)	Before the start of the project, but no later than 14 days before the deadline	I.
Project duration	Disclosure of SFIs by all Investigators of the Research	Annually	II.

	Participation in training on financial conflicts of interest (see 3.2.1)	every 4 years or if necessary	II. a)-d)
	Disclosure of newly acquired SFIs	In case of need	III.

I. At least 14 days before the application deadline, the Disclosure Form must be completed by all Investigators at that time and submitted by the Principle Investigator to the Designated Officials (respective personnel at FTW2 staff unit). At the same time, these persons confirm their binding participation in the training (see 3.2.1).

Existing conflicts can be resolved by the respective persons until the contract is signed. They therefore do not prevent the application or possible project participation at this time.

The Principle Investigator informs the FWT2 staff unit of the evaluation result of the application. If funding is awarded, the Disclosure Forms and any other available documents are handed over to the Grants and Contracts Administration, which stores them accordingly. If no funding is awarded, the documents are immediately destroyed by FWT2.

II. During the project period, the Disclosure Form must be completed regularly once a year by all Investigators and submitted collectively by the Principle Investigator to the Designated Officials (respective personnel at the Grants and Contracts Administration). The date of the last training (see 3.2.1) is also recorded in this form. Participation in the training must be repeated at least every 4 years. In addition, in accordance with 4.1.10 of the NIH Grants Policy Statement, the training must be conducted immediately at the direction of the External Funding Division if a) a change in this policy affects the duties of Investigators; b) a new Investigator is involved; c) an Investigator fails to comply with the reporting requirement or submission of the Disclosure Form in a timely manner; or d) a FCOI is suspected.

III. If a new SFI arises during the course of the project, the person concerned must report this immediately, but at the latest within 30 days, by completing a disclosure form and forwarding it to Designated Officials. In addition, any proposed solutions to eliminate the conflict of interest in the project must be reported.

3.3 Viewing/checking the submitted disclosure forms

The Designated Official(s) shall solicit and review SFI Disclosures within fourteen days, unless otherwise agreed and determine if they are a FCOI. A Financial Conflict of Interest exists when the Institute, through its Designated Official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a Research project and constitutes FCOI. The SFI is related to the Research when:

- the SFI could be affected by the research or
- the SFI in an entity whose financial interest could be affected by the research.

If the SFI is determined to be related to the Research, an FCOI exists when the designated Official(s) determine the SFI could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

If there is a FCOI and the Investigator concerned cannot eliminate the FCOI independently, the Compliance department in the Legal department is involved to clarify the matter. This unit examines the facts within14 days and - if necessary - discusses the next steps and measures to be taken (FCOI management plan). The result of the review is communicated to the Principle Investigator, who informs the Investigator concerned. The Principle Investigator is generally the first point of contact for queries from project staff. The Principle Investigator informs the Designated Official(s) about the status.

The FCOI management plan shall provide for its periodic review and update at least annually. If there is no reasonable way to manage a FCOI, then the Investigator may be prohibited from participating in the related Research until such a time as the FCOI is eliminated or it can lead to a prematurely termination of the Research.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to staff members working on the project; to the Institution's Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc.;
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;

- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g. sale of an equity interest); or
- Severance of relationships that create financial conflicts

If the objectivity of a corresponding project funded by an American funding body remains impaired due to financial interests and a FCOI thus exists, this must be reported to the funding body within 60 days of being identified by the Designated Offical(s):

- If MHH is the main awardee, this notification is made to the Office of the General Counsel (NSF), the Chief Grants Management Officer (NIH), or other individuals/institutions designated by the funding agency,
- If the MHH is sub-awardee, the coordinating institution will be informed.

As a recipient of funds, MHH is obliged to make all reports relating to SFIs (Disclosure Forms) and relevant documents available to the funding body or coordinating institution on request. This is done via the Grants and Contracts Administration, which stores all reports relating to SFIs (disclosure forms) in the electronic third-party funding file (EDMA) for at least three years after completion of a respective project.

3.4 Actions related to non-compliance with the policy

3.4.1 Whenever a FCOI is not identified or managed in a timely manner, including:

- failure by the Investigator to disclose a SFI that is determined by the Institute to constitute a FCOI;
- failure by the Institute to review or manage such a FCOI; or
- failure by the Investigator to comply with a FCOI management plan;

the Institute shall, within 120 days of the Institute's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the Research project to determine whether any Research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such Research.

The Institute shall document the retrospective review which must include at least the following key elements:

- project number;
- project title;
- principle investigator contact;
- name of the Investigator with the FCOI;
- name of the entity with which the Investigator has a FCOI
- reason(s) for the retrospective review;
- detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- findings of the review; and
- conclusions of the review.

3.4.2 The Institute shall notify the Office of the General Counsel (NSF), the Chief Grants Management Officer (NIH), or other individuals/institutions designated by the funding agency of bias found in the design, conduct, or reporting of Research including whether Investigator´s failure to comply with this FCOI policy or management plan appears to have caused such bias. In the event bias is found, Institute will submit a mitigation report in accordance with the regulation. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the Research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the Research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). If the FCOI was previously reported the mitigation report will be submitted as a "Revised FCOI Report." Thereafter, the Institution will submit FCOI reports annually as prescribed by the regulation.

3.5 Sub-recipients

Institute shall require sub-recipient compliance with the FCOI requirements as mandated by PHS regulation:

3.5.1. If applicable, obtain a certification from the sub-recipient that its FCOI policy complies with the regulation.-

3.5.2. If applicable, include in the written sub-recipient agreement a requirement for the sub-recipient to report identified FCOIs for its Investigators in a time frame that allows the Institute to report identified FCOIs as required by the regulation (i.e., prior to the expenditure of sub-recipient funds and within 50-55 days of identifying an FCOI during the period of an award) to allow the Institute to report the FCOI as required by the regulation (i.e., prior to the expenditure of funds and within 60 days of identifying an FCOI during the period of an award).

3.5.3. Alternatively, if the sub-recipient does not have a compliant policy, include in the written agreement a requirement to solicit and review sub-recipient Investigator disclosures of SFIs. The sub-recipient Investigator must disclose SFIs to the Institute that are directly related to the sub-recipient's work for the Institute to enable the Institute to identify, manage, and report identified FCOIs. The Institute will monitor sub-recipient Investigator compliance with any FCO implemented management plan.

3.6 Public accessibility requirement

3.6.1. Institute shall post this FCOI policy on the Institute public website, as required by the NIH Grants Policy Statement Section 4.1.10 Financial Conflict of Interest at 1.10 Financial Conflict of Interest (nih.gov)

3.6.2. FCOI Informational requests by the public concerning identified FCOIs held by Senior/Key Personnel should be made to the requestor within five (5) business days with minimum reporting elements as provided for under applicable regulation 42 CFR 50.605(a)(5)(ii).

4. Entry into force

These regulations enter into force on 04.12.2024.