

VETERINÄRMEDIZINISCHE UNIVERSITÄT WIEN (VETMEDUNI) POLICY ON FINANCIAL CONFLICTS OF INTEREST IN SPONSORED RESEARCH APPLICABLE TO ALL SPONSORED RESEARCH APPLICATIONS SUBMITTED TO AGENCIES WITHIN THE PUBLIC HEALTH SERVICE

1. Applicability

This PHS Conflict of Interest policy (**Policy**) must be met in cases of sponsored research submitted to the US Public Health Service (**PHS**) by Vetmeduni. **The PHS Conflict of Interest (COI) policies apply to Investigators involved in a Sponsored Research project that is part of PHS application for funding that has either been submitted by, or awarded to, Vetmeduni.**

2. Definitions

2.1. **Family** means any spouse or domestic partner, and dependent children.

2.2. **Financial Conflict of Interest (FCOI)** means a Significant Financial Interest (SFI) or Travel that could directly and significantly affect the design, conduct, or reporting of PHS-funded Research.

2.3. **Institutional Responsibilities** means an Investigator's professional responsibilities/work performed at and on behalf of Vetmeduni (e. teaching, research).

2.4. **Investigator** means the project director (PD) or the principal investigator (PI) and any other person who is responsible for the design, conduct, or reporting of PHS sponsored Research awarded to Vetmeduni.

2.5. **Relevant Officials** will be the **Vice Rector for Research** and the senior staff members in the **Büro für Forschungsförderung und Innovation, Vizerektorat für Forschung und Internationale Beziehungen**.

2.6. **Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g. a published article, book or book chapter) and product development (e.g. a diagnostic test or drug). As used in this policy, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, institutional infrastructure award, institutional training grant, program project, or research resources award.

2.7. **Reviewable Interest** means any Significant Financial Interest (SFI) belonging to an Investigator or an Investigator's Family, and any Travel, to the extent that it relates to the Investigators' Institutional Responsibilities.

2.8. **Senior/Key Personnel** means the PD or PI and any other person identified as senior/key personnel by Vetmeduni in the grant application, progress report, or any other report submitted to the PHS by Vetmeduni.

2.9. **Significant Financial Interest (SFI)** means a financial interest consisting of one or more of the following interests of the Investigator and Investigator's Family:

1. With regard to any publicly traded entity, when the value of any remuneration (salary and any payment for services that are not otherwise identified as salary, for example consulting fees, honoraria, paid authorship) received from the entity in the twelve (12) months preceding disclosure of the interest aggregated with the value of any equity in the entity (for example, stock, stock options, or other ownership interests as determined through reference

to public prices or other reasonable measure of fair market value) in the entity as of the date of the disclosure exceeds \$5,000.

2. With respect to any non-publicly traded entity (excluding Vetmeduni), when the aggregated value of any remuneration received from the entity in the twelve (12) months preceding disclosure of the interest exceeds \$5,000, or any equity in the entity; or

3. Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.

Exclusions: The term SFI does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Vetmeduni to the Investigator if the Investigator is currently employed or otherwise appointed by the Vetmeduni; 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; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution or 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 an institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an 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 an institution of higher education.

2.10. **Travel** means any travel that is reimbursed (i.e., the Investigator is made whole for the financial outlay required) or sponsored (i.e., the costs are paid on behalf of the Investigator such that the exact monetary value may not be readily available) other than by Vetmeduni, a Federal state or local government agency, an institution or 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 an institution of higher education.

3. Investigator Disclosure to Vetmeduni

All Investigators conducting Research for which a funding application has been made to PHS must disclose the information required herein on an annual basis to the **Büro für Forschungsförderung und Innovation, Vizerektorat für Forschung und Internationale Beziehungen**. Before an application for funding, Investigators planning to participate in PHS-funded Research are required to disclose all Reviewable Interests (namely, (i) any SFIs belonging to the Investigator or the Investigator's Family, and (ii) any Travel, to the extent the Investigator determines that the Reviewable Interest relates to the Investigators' Institutional Responsibilities). Investigators must update their disclosures annually during the period of the PHS award, as well as within 30 days of discovering or acquiring a new Reviewable Interest.

3.1. **Travel Disclosures [For PHS-funded Research Only]:** The following information must be provided in connection with any Travel disclosure in the context of PHS-funded Research: 1. The purpose of the trip; 2. The identity of the sponsor/organizer of the trip; 3. The destination of the trip; and 4. The duration of the trip.

3.2. **Additional Information Requested by Vetmeduni:** Investigators must provide in a timely manner any information related to their disclosed Reviewable Interests that Vetmeduni, in its discretion, deems relevant to its review and FCOI assessment.

4. Review by Vetmeduni

Prior to expenditure of any funds under a PHS sponsored Research award, the Relevant Official at Vetmeduni must reasonably determine whether any Reviewable Interest disclosed by any Investigator **is related to the PHS sponsored Research**; if so, whether it can reasonably be determined that the Reviewable Interest constitutes a Financial Conflict of Interest (FCOI); and if a FCOI is determined to exist, how the FCOI will be managed.

An Investigator's Reviewable Interest is related to PHS sponsored Research when Vetmeduni reasonably determines that the Reviewable Interest could be affected by the PHS sponsored Research; or is in an entity whose financial interest could be affected by the PHS sponsored Research. Vetmeduni will be informed by the relevant Investigator in the determination of whether a Reviewable Interest is related to the PHS sponsored Research.

An FCOI exists if Vetmeduni reasonably determines that the Reviewable Interest related to the PHS sponsored Research could directly and significantly affect the design, conduct or reporting of the PHS sponsored Research.

5. Management of Identified FCOIs

5.1. For any identified FCOI, Vetmeduni, through its Relevant Officials, will take appropriate action to manage the conflict in order to reduce the potential for it to compromise the safety or validity of the Research. Research in which an Investigator is found to have an FCOI will not be permitted to proceed until the Investigator has agreed to implement an acceptable management plan.

5.2. Investigators have an on-going obligation to adhere to an imposed management plan and failure to do so may be grounds for sanctions under this policy. Vetmeduni will monitor Investigator compliance with an imposed management plan on an ongoing basis until the completion of the PHS sponsored Research project.

6. Reporting FCOIs to PHS

6.1. For all PHS awards, prior to expenditure of any funds under the award, Vetmeduni is required to report to the PHS awarding agency the existence of an FCOI and submit an FCOI report.

6.2. Vetmeduni is responsible for submitting FCOI reports to PHS initially (prior to expenditure of funds), annually during the award period, and within 60 days of any subsequently identified FCOI.

7. Subrecipient or Subcontractor

When Research is to be funded by PHS and carried out through a subrecipient, Vetmeduni will establish in writing, at the time of proposal submission, whether this policy, or that of the subrecipient will apply to the subrecipient's Investigators, as well as the time frames within which the subrecipient must provide any information necessary to ensure that Vetmeduni is able to meet its reporting obligations to the PHS awarding agency.

8. Public Accessibility

For PHS-funded Research, Vetmeduni will ensure public accessibility of information concerning the FCOIs currently held by Senior/Key Personnel subject to this policy. Unless and until Vetmeduni determines otherwise, Vetmeduni will, upon receipt of a complete written request for information in accordance with the process and requirements outlined in section 14, provide a written response within five (5) business days regarding any SFI disclosed and still held by the Senior/Key Personnel

that has been determined to relate to the PHS funded research and constitute an FCOI pursuant to this policy.

9. New Interests that Arise During an On-Going Sponsored Research Project

To the extent a new Reviewable Interest is disclosed to Vetmeduni in the course of an on-going PHS sponsored Research project (i.e., an Investigator who is new to participating in the Research discloses a Reviewable Interest or an existing Investigator discloses a new Reviewable Interest), or Vetmeduni identifies a Reviewable Interest that was not previously reviewed in a timely manner by Vetmeduni in accordance with this policy, Vetmeduni will, within 60 days from the date of the disclosure: (i) determine if the Reviewable Interest relates to the Investigator's Research; (ii) if it relates, determine if it qualifies as an FCOI; and (iii) if it is an FCOI, implement on at least an interim basis a management plan in accordance with this policy. Vetmeduni may, depending on the circumstances of the SFI, conclude that additional interim measures are necessary with regard to the Investigator's participation in the Research between the date of disclosure or identification and the completion of DFCI review.

10. Retrospective Review, Identification of Bias and Mitigation Reporting of PHS-Funded Research

10.1. Retrospective Review: In the event of failure to meet PHS regulations, including failure by the Investigator to disclose timely a Reviewable Interest that is determined to constitute an FCOI; Vetmeduni's failure to review or manage such an FCOI; or Investigator failure to comply with an FCOI management plan, Vetmeduni will, within 120 days of its determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS - funded Research project to determine any bias in the design, conduct or reporting of Research during the time period of the noncompliance. Vetmeduni will document the retrospective review adequately.

10.2. Mitigation: If bias is found during the retrospective review, Vetmeduni will notify the PHS awarding agency promptly, if applicable, develop and implement a mitigation plan, and submit the PHS required mitigation report, which will include at least the elements documented in the retrospective review and a description of the impact of the bias on the Research project and Vetmeduni's plan of action or actions taken to eliminate or mitigate the effect of the bias. Any FCOI report submitted to the PHS awarding agency with respect to such Research will be updated as necessary in light of the results of the retrospective review.

10.3. Disclosure for PHS-Funded Drug/Device Research: In any case in which the Department of Health and Human Services (HHS) determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by Vetmeduni, the Investigator will be required to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

11. Training [For PHS-funded Research only]

For PHS-funded Research, Investigators must complete all required conflicts of interest training prior to engaging in Research at or under the auspices of Vetmeduni, and at least every four years following the initial training. Additionally, Investigators will be required to receive training immediately in any of the following circumstances:

- Vetmeduni revises its policy or procedures governing FCOI in PHS-funded Research that affects the requirements applicable to Investigators;

- An Investigator is new to Vetmeduni;
- Vetmeduni finds that an Investigator is not in compliance with this policy or an imposed management plan.

12. Record Retention

Vetmeduni will retain documentation related to its FCOI review and management process to the extent required by law and any other applicable Vetmeduni record retention policies, but in no case will records be maintained for less than three years due to relevant U.S. regulations. Records will be maintained in the **Büro für Forschungsförderung und Innovation, Vizerektorat für Forschung und Internationale Beziehungen**.

13. Noncompliance and Sanctions

In the event an Investigator fails to comply with this policy or an FCOI management plan imposed hereunder, a wide variety of sanctions, including but not limited to restricting or conditioning the Investigator's ability to apply for grants through Vetmeduni may be imposed. Additionally, if the failure of an Investigator to comply with this policy or an FCOI management plan appears to have biased the design, conduct or reporting of the PHS Research, Vetmeduni shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

14. Public Accessibility Process

PHS requires that Vetmeduni provide public access to certain information regarding financial conflicts of interest held by senior/ key personnel on research projects funded by PHS. Vetmeduni will make available the following information:

- Name of senior/key personnel with the financial conflict of interest;
- The individual's title and role in the research project;
- The name of the entity in which the financial interest is held;
- The nature of the financial interest;
- The approximate value of the financial interest (by ranges).