

**REGULATION  
on Prevention of Financial Conflict of Interest (FCOI)  
in Externally-Funded Research  
(for projects funded by the National Institutes of Health  
and other FCOI-controlled international funding)**

**Responsible Office:** NaUKMA Office of Vice-President for Research & IT.

**Monitoring and Reviewing Bodies:** NaUKMA Institutional Review Board – IRB (NaUKMA Research Ethics Committee); Finance, Fundraising & Grants Committee of the NaUKMA Academic Council.

**Related Laws & Policy:** 42 CFR Part 50, Subpart F.

## **1. Purpose**

1.1. US Federal Regulations for promoting objectivity in research (42 CFR Part 50, Subpart F) establish special FCOI standards requiring investigators or any other persons conducting research, who are the recipients of federal funding or other FCOI-controlled international funding, to disclose financial interests that may present an actual or potential conflict of interest in relationship to such projects prior to the submission of a proposal for funding and over the course of research award. Therefore, institutions that receive federal or other FCOI-controlled external funding for research to be undertaken within their structural units develop specific mechanisms by which financial conflicts of interest will be satisfactorily managed, reduced or eliminated prior to the expenditure of any funds on an award.

1.2. To promote objectivity in research and ensure there is no reasonable expectation that the design, conduct, or reporting of the aforesaid externally-funded research will be biased by any conflicting financial interest of an investigator, the National University of Kyiv-Mohyla Academy (NaUKMA) has adopted this Policy on Prevention of Financial Conflict of Interest (FCOI) in Externally-Funded Research to apply to the university research projects funded by the National Institutes of Health and other FCOI-controlled international funding, and to abide by the requirements of the US Federal Regulations and other FCOI-controlled sponsorships in relation to such projects.

## **2. Definition of Terms Used in the Regulation**

2.1. **“Investigator” Definition:** An Investigator is the Principal Investigator or any other member of the research team, who is responsible for the design, conduct, or reporting of research, including subcontractors, or collaborators. Graduates of the

Doctoral School (postdocs), doctoral candidates, graduate students or consultants, who meet the Investigator's definition, are also subject to this Policy.

## 2.2. "Significant Financial Interest" Definition<sup>1</sup>:

A **financial interest**, consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

2.2.1. With regard to any publicly traded entity, a significant financial interest 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;

2.2.2. With regard to any non-publicly traded entity, a significant financial interest 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 Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);

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

2.2.4. Investigators also must disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities (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); provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by 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. The disclosure of the occurrence of any reimbursed or sponsored travel, at a minimum, should include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip.

2.2.5. The term "significant financial interest" does not include the following types of financial interests: salary, royalties, or other remuneration paid to the Investigator by NaUKMA if the Investigator is currently employed or otherwise appointed by the university, including intellectual property rights assigned to the university and agreements to share in royalties related to such rights; 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

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<sup>1</sup> For a complete description of Significant Financial Interests, eligible exclusions and Frequently Asked Questions in relation to FCOI, please see: <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=question52857>.

from seminars, lectures, or teaching engagements sponsored by 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; 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.

### **3. Policy**

3.1. The NaUKMA Policy on Prevention of Financial Conflict of Interest (FCOI) that basis itself on US Federal Regulations 42 CFR Part 50, Subpart F requires that investigators of the university international research projects funded by the National Institutes of Health and other FCOI-controlled international funding disclose any significant financial interests held by themselves, their spouse and/or dependent children that would reasonably appear to be affected by the research for which funding is sought.

3.2. The principal investigator, project director, co-principal investigator, or any other person conducting research at the National University of Kyiv-Mohyla Academy, and who is responsible for the design, conduct, or reporting of research that is being funded or proposed for funding by the National Institutes of Health or other FCOI-controlled international funding, must disclose whether they (including their spouse and dependent children) have significant financial interests related to the work being conducted under the sponsored project at the time of grant application and at award's milestones indicated in Section "Procedure" below. Should a new reportable significant conflict of interest arise at any time, the Investigator must immediately disclose this interest.

3.3. Each Investigator is responsible for disclosing his or her own financial interests. In addition, the Lead Principal Investigator identifies all investigators on his or her research project, who need to submit disclosures, and ensures their timely submission.

### **4. Procedures**

4.1. All investigators involved in the research projects funded by the National Institutes of Health or other FCOI-controlled international funding, whether or not they have significant related financial interest(s), are required to complete a "**Significant Financial Interest Disclosure Form**" (see attached template in Attachment 2) and upon completion submit it to the NaUKMA Office of Vice-President for Research & IT (8/5, Voloska St., building 5, room 309). Forms may also be scanned and e-mailed directly to the Vice-President for Research & IT [science@ukma.edu.ua](mailto:science@ukma.edu.ua) and [yaroshenko@ukma.edu.ua](mailto:yaroshenko@ukma.edu.ua) with a copy sent to the Chair of NaUKMA Institutional Review Board (IRB), Tetiana Yurochko [t.yurochko@ukma.edu.ua](mailto:t.yurochko@ukma.edu.ua).

4.2. If the Investigator has no conflict, he or she simply states that in the disclosure form.

4.3. A disclosure form should be submitted in the following cases:

- Before a proposal for a grant is submitted;
- Over the course of an annual disclosure update;
- As new disclosure submitted within 30 days after new or significant financial interest(s) are acquired.

4.4. At the time a grant application is planned and communicated to the Vice-President for Research & IT, the Principal Investigator responsible for the implementation of the research project funded by the National Institutes of Health or other FCOI-controlled international funding is required to fill out the “Significant Financial Interest Disclosure Form”.

4.5. The Principal Investigator is also responsible for ensuring that all appropriate project staff complete the document and return it to the Vice-President for Research & IT. If a significant conflict of interest should arise during the course of the project, the Investigator must immediately disclose such interest to the Office of Vice-President for Research & IT.

4.6. All investigators outside of NaUKMA, involved in its research projects funded by the National Institutes of Health or any other FCOI-controlled international funding, whether through subcontracts, consulting agreements, etc., are also required to submit financial disclosures to the university on an annual basis as required by this Policy.

4.7. If the Investigator indicates that a significant financial interest exists, the Vice-President for Research & IT notifies the NaUKMA Institutional Review Board (IRB00012330) as primary research monitoring and reviewing body for further review. At this stage, Investigator may also be asked to submit additional information that will be reviewed by the Board.

4.8. If the NaUKMA Institutional Review Board determines that there is a potential conflict of interest, the Vice-President for Research & IT together with NaUKMA Finance, Fundraising & Grants Committee conduct additional evaluation of the information.

4.9. If it is determined there is a significant financial conflict of interest, the NaUKMA Institutional Review Board will work with the Investigator to develop a resolution to manage, reduce or eliminate the conflict. The resolution will be recorded in a protocol and communicated to the Investigator. This document will be executed prior to the expenditure of funds or during the award phase in case of new disclosure and kept on file in the Office of Vice-President for Research & IT.

4.10. Upon request, National University of Kyiv-Mohyla Academy agrees to make information available to the sponsoring agency regarding all conflicting interests and how these conflicts have been managed, reduced, or eliminated.

4.11. Records of financial disclosures and any resulting actions are maintained at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified as exclusions for different situations by the donor.

## **5. Public Accessibility**

5.1. The NaUKMA Policy on Prevention of Financial Conflict of Interest (FCOI) in Externally-Funded Research is available to the general public and posted on the official webpage of the NaUKMA Office of Vice-President for Research & IT for detailed requirements and definitions: <https://www.ukma.edu.ua/eng/index.php/research/129-research/832-research-ethics-policy>.

## **6. Informing and Orientation**

6.1. Each investigator engaged in the NaUKMA research projects funded by the National Institutes of Health or other FCOI-controlled international funding will complete either in-person or online the **Financial Conflict of Interest Disclosure Orientation** with FCOI Administrator at the NaUKMA Institutional Review Board (IRB) to get sufficient guidelines on participation in research in the framework of any federal or FCOI-controlled international grants requiring FCOI disclosure. Financial Conflict of Interest Disclosure requirements and procedures are also widely shared among the NaUKMA research network through available internal channels of communication and enforced by the Office of Vice-President for Research and IT.

## **7. Policy Update**

7.1. The Policy is subject to regular updates at least every four years, and immediate update under the designated circumstances:

- Institutional FCOI policies change in a manner that affects requirements for investigators;
- Donor regulations, policies or relevant laws in relation to FCOI change impacting current university disclosure policies and procedures.

**Significant Financial Interest  
Disclosure Form**

This Disclosure Form is to be completed by each Principal Investigator/ Investigator conducting an externally-funded research funded by the National Institutes of Health or other FCOI-controlled international funding and pursuant to the **NaUKMA Policy on Prevention of Financial Conflict of Interest in Externally-Funded Research (FCOI)**. Please refer to the Policy provided on the official webpage of the NaUKMA Office of Vice-President for Research & IT for detailed requirements and definitions: <https://www.ukma.edu.ua/eng/index.php/research/129-research/832-research-ethics-policy>.

Complete this form and submit it to *Vice-President for Research and IT* (at the address: Kyiv, 8/5, Voloska St., building 5, room 309 ). Forms may also be scanned and e-mailed directly to the Vice-President for Research & IT [science@ukma.edu.ua](mailto:science@ukma.edu.ua) and [yaroshenko@ukma.edu.ua](mailto:yaroshenko@ukma.edu.ua) with a copy sent to the *Chair of NaUKMA Institutional Review Board (IRB), Tetiana Yurochko* [t.yurochko@ukma.edu.ua](mailto:t.yurochko@ukma.edu.ua).

1. Research Project title and number of the grant agreement: \_\_\_\_\_  
\_\_\_\_\_
2. Project Director/Principal Investigator or Contact PD/ PI, if a multiple PD/PI model is used:  
\_\_\_\_\_
3. Surname, name and title of the Investigator making this report about his/her financial interest(s):  
\_\_\_\_\_
4. Please check, which of the forms provided below you are submitting:
  - Initial Disclosure Form*: before the time of application for externally-funded research award;
  - Update Disclosure Form*: within 30 days upon discovering or acquiring a new significant financial interest during the externally-funded research award;
  - Update Disclosure Form*: in the framework of the regular Annual Update, in accordance with the grant agreement requirements, during the externally-funded research award.

5. Indicate whether you, as Investigator, have any Significant Financial Interests related to the work to be conducted under the research project(s):
- I have no Significant Financial Interest as that term is defined in the Policy (stop completing this Disclosure Form at this point and submit it as described above);
  - I do have Significant Financial Interest(s) to report (**continue completing the rest of this Disclosure Form further**).
6. Please provide information listed below for each Significant Financial Interest (use additional pages, if necessary):
- Provide the name of each legal entity, in which you have a Significant Financial Interest: \_\_\_\_\_  
\_\_\_\_\_
  - Provide information on the nature of financial interest (for example, equity, consulting fee, travel reimbursement, or honorarium): \_\_\_\_\_  
\_\_\_\_\_
  - Indicate the value of the Significant Financial Interest (in dollar equivalent): \_\_\_\_\_
  - For Reimbursed or Sponsored Travel required to be reported by the Policy, indicate all of the following:
    - The purpose of the trip: \_\_\_\_\_
    - The identity of the sponsor/organizer: \_\_\_\_\_
    - The destination: \_\_\_\_\_
    - The duration: \_\_\_\_\_
7. Describe how the Significant Financial Interest relates to the given externally-funded research:
8. Do you believe that the externally-funded research project(s), which you implement could directly and significantly affect the Significant Financial Interest(s) you are reporting?

Date: \_\_\_\_\_

Signature: \_\_\_\_\_