



**ISTITUTO DI RICERCHE
FARMACOLOGICHE
MARIO NEGRI · IRCCS**

**Financial Conflict of Interest (FCOI) Policy
for U.S. Public Health Service (PHS) Funding**

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1. Purpose.

This Financial Conflict of Interest on U.S. Federal Grants Policy (hereinafter referred to as the "**policy**") was adopted by Istituto di Ricerche Farmacologiche Mario Negri ("**Mario Negri**" or the "**Institute**") in application of Title 42 of the U.S. Code of Federal Regulations, Part 50, Subpart F (the "**Regulation on Promoting Objectivity in Research**" or the "**Regulation**"), in order to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by U.S. federal grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest. It applies to all researcher and other staff involved in research funded by U.S. federal entities. This policy is adopted in light of possible awards of U.S. federal grants to the Institute and in compliance with U.S. federal regulations that require that all investigators disclose any potential financial conflict of interest to the Institute prior to undertaking U.S. federally funded research. This policy is applicable to U.S. federally funded sponsored project activity at Mario Negri including projects funded with U.S. federal flow-through when the sponsoring agency policy requires a financial conflict of interest disclosure.

2. Scope – Conflict of provisions.

This policy covers all projects conducted with U.S. government funds in Mario Negri and applies to all employees, sub recipients, consultants, or any other covered organizations or persons involved in U.S. governmental awards.

In the event of any conflict between the provisions of this policy and the provisions of the Regulation, the latter shall prevail at all times. The provisions of this policy are in no case intended as a limitation of the provisions of the Regulation; if a mandatory provision of

the Regulation is not replicated herein, it does not mean that the policy intended to derogate from that mandatory provision of the Regulation.

3. Definitions.

Terms and expressions used herein with capital initials have the same meaning as in the Regulation, as from time to time amended. For information only, as of the date hereof, terms and expressions used herein with capital initials have the meaning ascribed to them hereafter.

Public Health Service (PHS): a division of the Department of Health and Human Services in the United States, and any components of the PHS to which the authority involved may be delegated, including the U.S. National Institute of Health.

Disclosure of significant financial interests: means an investigator's disclosure of significant financial interests (SFI) to Mario Negri.

Financial Conflict of Interest (FCOI): means financial conflict of interest or more fully described as a significant financial interest (SFI), real or perceived, that could directly and significantly affect the design, conduct, or reporting of U.S. federally funded research.

Financial interest: means anything of monetary value, whether the value is readily ascertainable.

Institutional responsibilities: has the same meaning as in § 50.603 of the Regulation.

Investigator: means the project director (PD) or principal investigator (PI), co-principal investigator, and any other senior/key personnel, regardless of title or position, who is responsible for the design, conduct, or reporting of U.S. federally funded research, 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, including behavioral and social-sciences research. The term encompasses any basic and applied research, be it bench work, creative activity (e.g., a published article, book, or book chapter), or product development (e.g., clinical trials, diagnostic test, or drug). As used in this policy, the term refers to any such activity for which research funding is available from a U.S. federal agency through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, training grant, program project, or research resources award.

Senior/key personnel: means the PD/PI and any other person identified as senior/key personnel by Mario Negri in the grant application, progress report, or any other report submitted on the research to the U.S. federal funding agency by Mario Negri under the scope of this policy.

Significant financial interest (SFI): means one of the following:

- a significant financial interest exists if the following situations apply to the investigator and/or the investigator's spouse or domestic partner as evidenced by registration or certification as a same-sex partner, children, and immediate relatives (siblings and parents) involving companies that reasonably appear to be related to the proposed research:
 - for publicly traded companies, if income in excess of US dollars 5.000 (in the aggregate) is received during the twelve months preceding the disclosure. Examples of income include salary, consulting fees, honoraria,

- paid authorship, stock, stock options, or other ownership interests (based on public prices or other reasonable measures of fair market value);
- for non-public traded companies, if income more than US dollars 5.000 (in the aggregate) is received during the twelve months preceding the disclosure, or when any equity interest is held (e.g., stocks, stock options, or other ownership interests);
- if any income is received from intellectual property rights and interests (e.g., patents, copyrights).
- any travel paid for by any entity other than a U.S. Federal, state or local government, an institution of higher education, an academic teaching hospital, a medical center or a research institute associated with an institution of higher education must be disclosed. This disclosure will include, at a minimum, the purpose of the trip, identity of the sponsor/organizer, destination, and duration. In accordance with Mario Negri's FCOI policy, the Director of OSPA or their designee will determine if further information is needed, including a determination or disclosure of monetary value, to determine whether the travel constitutes an FCOI with the U.S. federally funded research.

Significant financial interest does not include the following types of financial interests:

- salary, royalties, or other remuneration paid by Mario Negri to the investigator if the investigator is currently employed or otherwise appointed by Mario Negri, including intellectual property rights assigned to Mario Negri and agreements to share in royalties related to such rights;

- income from investment vehicles, such as mutual funds and retirement accounts, if the Investigator does not directly control the investment decisions made in these vehicles;
- income from seminars, lectures, or other teaching engagements, or from service on advisory panels or review panels from a U.S. Federal, state, or local government agency, as well as an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education in the United States of America.

4. Financial Conflict of Interest Committee.

- 4.1. *Membership* – This committee (the “**Committee**”) consists of 3 to 5 members appointed by the board of directors of Mario Negri. All members of the committee are expected to have demonstrated grantsmanship. The chair of the Committee will be appointed by the board of directors of Mario Negri.
- 4.2. *Duties* – The Committee will (i) review the FCOI forms and the associated management/monitoring; (ii) either accept or suggest modifications to manage or eliminate the potential conflicts; (iii) promote any amendment to this policy needed to adequate it to any modifications brought to the Regulation and/or deemed appropriate to better serve the purpose and the scope of the Regulation; (iv) appoint, for each research project for which research funding is available from a U.S. federal agency, a “**FCOI Official**”; (v) reasonably evaluate if any disclosed significant financial interest: (1) could be affected by the research, or (2) is in an entity whose financial interest could be affected by the research; (vi) carry out

any other activities provided for in this policy or in the Committee's rules of operation.

- 4.3. *Rules of operation* – The rules of operation of the Committee are approved (and, if necessary, amended) by the Board of Directors of Mario Negri.
- 4.4. *FCOI Official* – The FCOI Official may be a member of the Committee or a person outside the Committee. The FCOI Official may be appointed for several research projects. The FCOI Official will hold office for the duration of the research project, unless the Committee deems it appropriate to remove him/her from the role (with respect to one or more research projects). The FCOI shall be: (i) totally free of interests directly or indirectly related to the research; (ii) of good moral character; (iii) adequately trained with respect to the content of the Rules in force at the time.

5. Institutional Responsibilities and Procedures.

- 5.1. *Investigator Training* – In order to facilitate compliance with the U.S. federal policy, Mario Negri is responsible for investigator training, collection, and evaluation of FCOI forms, and enforcement of this policy. In addition to making this policy and associated forms available on its web site, training will be provided by duly formed professionals appointed by the Committee for all investigators prior to engaging in U.S. federally funded research. Training must be repeated at least every 4 (four) years, and in any case immediately when (i) changes are brought to the Regulation; (ii) the Institute revises its FCOI policies or procedures in any manner that affects the requirements of Investigators; (iii) an investigator is new to Mario Negri; (iv) an investigator is found to be in non-compliance with the Institute's FCOI policy or management plan.

- 5.2. *Disclosure requirements* – At the time of submission of a grant to a U.S. federal agency – not later than the time of application for PHS-funded research – all participating investigators are required to fill out and submit a FCOI form to the FCOI Official; the FCOI forms will be reviewed by the Committee.

The Committee will assess the potential for a conflict and initiate the review and response procedures outlined below. In addition, all investigators must submit an updated FCOI form annually during the period of the award (by deadlines established by Mario Negri) to include any information that was not disclosed previously to Mario Negri, and to include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest). Any newly discovered or acquired significant financial interest (e.g., through purchase, marriage, or inheritance) must be disclosed within 30 (thirty) days. New Investigators added to a project after the start date of the project must also complete a disclosure form. This includes situations where a non-Investigator employee's status is changed to that of Investigator. New or changed Investigators must also complete the training, as described above.

- 5.3. *Subcontracts* – If the U.S. federally funded research involves a subrecipient (e.g., subcontractors or consortium members), Mario Negri (as the awardee institution) will take reasonable steps to ensure that any subrecipient investigator complies with the U.S. federal policies by:

- establishing in writing with the subrecipient whether the financial conflicts of interest policy of Mario Negri or that of the subrecipient will apply to the subrecipient's investigators.
 - If the subrecipient's investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify that its policy is compliant with U.S. federal policies. In the absence of this certification, the agreement will state that subrecipient investigators are subject to the financial conflicts of interest policy of Mario Negri for disclosing significant financial interests that are directly related to the subrecipient's work for the Institute.
 - Additionally, if the subrecipient's investigators must comply with the subrecipient's financial conflicts of interest policy, the written agreement will specify a deadline for the subrecipient to report all identified financial conflicts of interest to Mario Negri so that the Institute can provide timely FCOI reports, as necessary, to the relevant federal agency.
 - Alternatively, if the subrecipient's Investigators must comply with Mario Negri's financial conflicts of interest policy, the written agreement will specify a deadline for the subrecipient to submit all Investigator disclosures of significant financial interests to Mario Negri so that the Institute can provide timely FCOI reports, as necessary, to the relevant federal agency.

- providing FCOI reports to the U.S. federal agency regarding all financial conflicts of interest of all subrecipient investigators consistent with this policy, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

5.4. *Review of FCOI and management of conflicts* – An investigator's significant financial interest is related to U.S. federally funded research when the Committee reasonably determines that the significant financial interest: (1) could be affected by the research, or (2) is in an entity whose financial interest could be affected by the research.

A FCOI exists when the Committee reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the U.S. federally funded research. At the time of submission of a grant to a federal agency, all participating investigators are required to fill out and submit a FCOI form. Signed FCOI forms will be reviewed by the FCOI Official; outcomes may include:

- if a FCOI form indicates no significant financial interest, the forms will be filed at the Committee for informational purposes;
- if a FCOI form indicates a potential financial conflict of interest, the proposal will be submitted by FCOI Official to meet agency deadlines and the Committee will contact the investigator for additional information. If the Committee then determines that a conflict of interest does exist, the Committee will forward the FCOI form, along with his/her assessment, to

the appropriate investigator. Financial conflicts of interest will be addressed by one of the following approaches:

- the FCOI Official will work with the investigator to develop a management plan to eliminate the conflict of interest. If any plan is defined, the FCOI Official will report the plan to the Committee. The Committee will timely notify appropriate institutional and funding agency administrators, as required by the agency's guidelines;
 - if it is not possible to eliminate the conflict of interest, a plan to reduce or manage the conflict must be developed by the investigator in consultation with FCOI Official. This plan will then be forwarded by the FCOI Official to the Committee for review and input. The Committee will notify appropriate institutional and funding agency administrators of the conflict, as required by the agency's guidelines as discussed below;
 - all conflicts of interest must be resolved, and management plans approved by the appropriate institutional administrators before the research project can begin. Grant awards will not be released to the researcher until the conflict is appropriately addressed. In rare cases, the Institute may be required to decline the award if the conflict cannot be resolved or managed as discussed below.
- if a disclosure of a new conflict arises or the discovery of an undisclosed conflict is uncovered, the Committee will review and make

recommendations within 60 (sixty) days of the new conflict disclosure or unreported disclosure discovery.

5.5. The Committee will review all the submitted material and either accept or suggest modifications to further eliminate the conflict. This could involve, at either the Committee's request or at the investigator's request, a meeting with the Committee. Expert opinions may also be sought by the Committee. Investigators may appeal any final decision in writing within 14 days. Examples of approaches that could be used to manage a FCOI include, but are not limited to:

- public disclosure of FCOI (e.g., when presenting or publishing the research);
- appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- modification of the research plan;
- change in 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).

5.6. *Severance of relationships that create financial conflicts* – Whenever Mario Negri implements a management plan, the Committee will monitor investigator compliance with the management plan on an ongoing basis until completion of the affected U.S. federally funded research project. In the event of any significant

conflicting financial interest that is discovered subsequent to initial reports to U.S. federal agencies, the Institute will implement a management plan within 60 (sixty) days and the Committee will complete a retrospective review to determine whether the research was biased and, if so provide a mitigation report if required by the relevant U.S. federal agency.

- 5.7. *Reporting of conflicts* – The Institute must certify in each application for funding to which this policy applies, that Mario Negri has a written and enforced administrative process to identify and manage financial conflicts of interests and that they will ensure compliance with all such related federal policies regarding FCOI. The Institute must provide initial and ongoing FCOI reports to the U.S. federal agency, as required. Therefore, Mario Negri is required to maintain records relating to all investigator disclosures of financial interests and the Institute's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institute's determination of a FCOI) and all actions under the Institute's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the U.S. federal agency, or as required by the specific agency. Mario Negri must also monitor investigator compliance with approved management plans throughout the duration of the funded project.
- 5.8. *Public accessibility to FCOI information* – Prior to the Institute's expenditure of any funds under a U.S. federally funded research project, Mario Negri shall ensure public accessibility via its web site of information concerning any significant financial interest disclosed to the Institute that meets the following three criteria:

- the significant financial interest was disclosed and is still held by the Investigator as defined by this policy.
- Mario Negri determines that the significant financial interest is related to the U.S. federally funded research; and
- Mario Negri determines that the significant financial interest is a FCOI.

The information that the Institute must make available via its web site will include the following: the investigator's name; the investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest or a statement that the interest is one whose value cannot be readily determined by normal assessments of fair market value. This posted information will be maintained and updated at least annually by the Committee and will remain accessible for at least 3 (three) years from the date that the information was most recently updated.

- 5.9. *Enforcement* – Investigators will not be able to access U.S. federal funds prior to disclosure of a FCOI and approval of a management plan. Noncompliance must also be reported to the appropriate U.S. federal funding agency. Certain agencies (e.g., NIH grants for clinical research) require public disclosure of FCOI on all public presentations and publications (including addendums for previously published items) for any relevant funded research that did not comply with U.S. federal disclosure regulations. Failure of investigators to comply with this policy, including restrictions emplaced by the management plans, will be grounds for

discipline and sanctions under the appropriate Institute policy or provisions of any applicable Collective Bargaining Agreement.

- 5.10. *Failure to Comply* – If an Investigator fails to comply with the policy or a management plan subsequently put in place, the Institute must, within 120 (one-hundred and twenty) days, undertake a retrospective review of the research project to determine if any bias in the design, conduct or reporting of the research. If a bias is found, the PHS funder must be notified and provided with a mitigation plan and thereafter report annually as normal, unless the University decides further interim measures are necessary. The funder is entitled to suspend or terminate the award.

6. Policy's updates – Public accessibility of the policy.

- 6.1. This policy shall be updated from time to time to reflect any changes in the Regulation and/or to improve its suitability to fulfil its purpose as set out in the Regulation
- 6.2. This policy shall at all times be publicly available on the Web Site of Mario Negri.