



Instruction of April 28th, 2022, of the Presidency of the Spanish National Research Council establishing the procedure for the prevention of financial conflicts of interest regarding the participation in international projects funded by the Public Health Service (PHS) of the United States of America

The framework for action of the Spanish National Research Council (hereinafter CSIC) is defined by its nature as a public body of the General State Administration. Its staff, comprising scientific staff, technical staff and management staff, as public employees, must act in full compliance with the law and observe in its actions a series of principles defined by the Spanish regulatory framework. To this end, the fundamental legislation in this area is the Royal Legislative Decree 5/2015 of October 30, 2015, approving the consolidated text of the Law on the Basic Statute of Public Employees; the Royal Legislative Decree 2/2015 of October 23, 2015 approving the consolidated text of the Workers' Statute Act; the Law 53/1984 of December 26, 1984 on the incompatibilities of staff in the service of public administrations; the Royal Decree 33/1986 of January 10, 1986 approving the Disciplinary Regulations for Officials of the State Administration; the Criminal Code, approved by the Organic Law 10/1995, of November, 23.

Specifically, in the field of scientific research, the Law 14/2011 of June 1, 2011 on Science, Technology and Innovation establishes the creation of the Spanish Research Ethics Committee as a collegiate, independent and consultative body on matters related to professional ethics in scientific and technical research. This governance body of the Spanish System of Science, Technology and Innovation (SECTI) promotes the creation of codes of good practice among the implementing agents of the SECTI. Codes of conduct should include the treatment of conflicts of interest between public and private activities.

The National Declaration on Scientific Integrity, promoted and drafted by CSIC, underlines the importance of an honest and responsible conduct in research, as the primary foundation for the advancement of knowledge, and establishes the institution's commitment to promoting a culture of integrity, stimulating good scientific practice, promoting training actions to raise awareness, educating in this field and fostering an institutional culture of scientific integrity.

Article 17 of the Statute of the Spanish National Research Council, approved by the Royal Decree 1730/2007 of December 21, establishes the creation of an Ethics Committee, which prepared a Handbook on Conflicts of Interest, approved by resolution of the Presidency of CSIC of July 27, 2015. This manual is intended to provide guidance to facilitate the identification and prevention of conflicts of interest, as well as the strengthening of high ethical standards. Its objective is to identify, prevent, manage, monitor and control conflicts of interest that may affect CSIC staff.

In addition, the revised edition of the Code of Scientific Practice of CSIC, published in 2021, aims to guide the development of scientific activity in its various facets and dimensions, with the ultimate aim of ensuring the quality of CSIC research and preventing inappropriate conduct.

With regard to conflicts of interest, CSIC staff must comply with the above-mentioned regulations, the instructions issued by the governing bodies and the recommendations made by the Ethics Committee, contained in the CSIC Handbook on Conflicts of Interest.



The U.S. Public Health Service, hereinafter referred to as PHS, to promote objectivity in research requires all funding institutions to comply with 42 CFR Part 50 Subpart F. The National Institute of Health (NIH) is part of the PHS and is dedicated to conducting and promoting medical research. For the fulfilment of its mission, the NIH provides funding both inside and outside the United States of America. The PHS regulations apply to all entities that receive either local or foreign funds and whether they participate as principal recipients or in cooperation with a national entity in the country.

The Spanish legislation and regulations of CSIC, even for the same purpose, differ from the US legislation 42 CFR Part 50 Subpart F in the treatment of conflict of interest in the research, so it is necessary to establish a specific complementary procedure applicable to conflicts of economic interests regulating the participation of CSIC research groups in projects financed by the NIH.

FIRST.- Subject matter and scope.

1. The purpose of this Instruction is to establish a procedure complementary to the national and institutional regulations for the management of conflicts of economic interests of CSIC researchers regarding all projects applying for or receiving funds from U.S. PHS agencies, such as NIH, as well as other funding entities that specifically request similar controls to those required by the PHS rules on objectivity in the research.

2. This instruction applies to any principal investigator and to any other CSIC employee, regardless of their professional status or position, who is responsible for the design, conduct or reporting of PHS-funded research.

SECOND. Definitions.

Without prejudice to the definitions set out in the CSIC Conflicts of Interest Manual, projects receiving funding from the NIH shall take into account the following definitions in terms of financial interest and conflict of financial interests.

1. Conflict of financial interests (FCOI): It is understood that any researcher is involved in a Financial Conflict of Interest when he/she has a significant personal financial interest that could directly and significantly affect the design, conduct or reporting of PHS-funded research.

1.1 Personal interests: Personal financial interests are considered as:

- a) the researcher's own financial interests.
- b) his/her family's financial interests, including those of spouses or persons with whom the researcher lives in a similar relationship of affection, and relatives within the fourth degree of consanguinity or second degree of affinity.
- c) those of the persons with whom he/she has a pending dispute.
- d) those of persons with whom the researcher holds an intimate friendship or manifest enmity.



1.2 Financial interests: Financial interest means any resource of monetary value, e.g. payment for services, equity interests in companies (such as shares, stock options or other proprietary interests), or intellectual property rights (e.g. patents, copyrights and royalties of such rights).

1.3 Significant financial interest: a financial interest is considered to be significant where it is reasonably related to the researcher's institutional responsibilities and is in one of the following:

a) in respect of any listed entity, there is a significant financial interest if the value of any remuneration received from the entity in the twelve months preceding the statement and the value of any equity interest in the entity at the date of the statement, when added, exceeds the equivalent amount in euros of \$5,000. For the purposes of this definition, remuneration includes salary and any payment for services not identified as wages (e.g. consultancy fees, fees, paid authorship); the equity participation includes any share, equity option or other ownership interest, as determined by reference to government prices or other reasonable fair market value measures;

b) regarding any non-listed entity, there is a significant financial interest if the value of any remuneration received from the entity in the 12 months preceding the statement as a whole exceeds the amount equivalent in euros to \$5,000, or where the researcher has any equity interest (e.g. shares, stock options or other ownership interest); or

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

2. Researcher: The lead researcher of the project and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of the PHS-funded research, or proposal for such funding, which may include, for example, collaborators or consultants, is understood as such.

3. Declaration of Financial Interests (SFI): This is the statement in the form in Annex I of the financial interests of the researcher that might conflict with the development of his project.

4. Sub-recipients: These are non-CSIC researchers who receive funding from CSIC from the PHS.

5. External partner (Sub-awardee): This is the indirect recipient of a grant awarded by the PHS to carry out part of the project and receives the funds through the principal recipient (coordinator/awardee) of the grant.

6. FCOI Report: This is the report issued by the CSIC on a financial conflict of interest in relation to the award of a PHS grant.



THIRD.- Type of participation.

1. Applications for PHS grants may be submitted on an individual basis by a CSIC researcher as principal recipient or representative of a group of legal persons, the procedure described in this instruction being mandatory in any event.
2. If CSIC participation is performed as Subawardee, CSIC researchers must follow the procedure described in this instruction or rely on the conflict of economic interest policy applicable to the principal recipient entity of the funds, thus setting it out in the written agreement with that entity.

FOURTH.- Presentation and revision of the forms for the declaration of financial interests.

1. All researchers interested in participating in the PHS-funded research shall declare their financial interests to the CSIC as defined in this instruction, by submitting the declaration form (hereinafter SFI) set out in Annex I, in the following situations:

- At the time of application for PHS funding.
- Once a year during the period of implementation of the PHS grant.
- On the expiry date of a progress report/proposed non-compliant continuation, an extension without cost or a request for extension.
- Within thirty (30) days of the emergence of any significant new financial interest.

Researchers must also declare on this form any trip reimbursed or sponsored (i.e. paid on behalf of the researcher and not reimbursed, so the exact monetary value may not be available) related to their institutional responsibilities. Such declaration shall include at least the purpose of the trip, the identity of the sponsor/organiser, the destination and duration.

Principal Investigators (PIs) are responsible for identifying personnel involved in the design, drafting or preparation of research reports and for ensuring that they complete the Declaration Form (SFI).

2. The Management of the Centers and Institutes is responsible for the receipt, processing and archiving of the declaration forms.

The Legal Counsel (hereinafter AJUR), under the General Secretariat of CSIC, will be responsible for reviewing and evaluating the declaration forms. They will count for the performance of all their functions on the support of other CSIC departments that may be involved, including the guidance and recommendations of the Vice President of International Relations (hereinafter referred to as VRI).

3. Researchers shall provide the Declaration of Financial Interest forms to the Management of their Centers or Institutes at the time of the PHS funding application. Management will review the SFIs and request the researcher to provide additional information, if necessary.



4. The management will send the documentation to the AJUR, which will analyse the SFIs and, after consulting the necessary CSIC departments, will inform if there is a significant conflict of financial interests. It shall take into account factors such as the nature of the researcher's relationship with an entity, the financial interests at stake and the undue influence they may have on the conduct of the researcher's work.

5. If AJUR reports that an SFI may constitute a significant financial conflict of interest, the Management, together with the relevant CSIC departments, shall draw up and implement a management plan specifying the measures that have been taken and will be taken to manage that conflict of financial interest.

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

(I) Follow-up of research by independent researchers able to take action to protect the design, development and reporting of research against biases arising from the financial conflict of interests;

(II) Modification of the research plan;

(III) Change of staff or modification of staff responsibilities, or disqualification of staff from participating in all or part of the research;

(IV) Reduction or elimination of financial interest (e.g. sale of a shareholding); or

(V) The breakdown of relations that create financial conflicts.

6. Provided that AJUR is informed of the existence of a potential significant financial interest that has not been declared on time by a researcher or, for any reason, has not been previously reviewed during an ongoing PHS-funded research project, AJUR, with the assistance of the relevant CSIC departments, shall, within sixty (60) days of knowledge of it, undertake the following actions:

— Review the material financial interest;

— Determine whether it is related to PHS-funded research;

— It shall determine whether there is a financial conflict of interest and, if so, all legal and regulatory mechanisms shall be activated through the Management on a provisional basis to reduce, eliminate or manage the effects of the conflict of interest until the end of the research.

7. All revisions of the potential financial conflict of interest must be completed before any research commences or research costs are incurred under the grant awarded by the PHS, as well as before submitting a progress report, a supplementary funding proposal or an extension request at no cost.

8. Management may request the researcher to provide additional information, if not previously declared, and to arrange a meeting to design appropriate measures to address a specific situation.

9. No researcher for whom a conflict of interest has been found may participate in PHS-funded research activities without AJUR's prior favorable opinion.



FITH — Reporting to the PHS.

1. CSIC shall, through VRI, inform the PHS granting entity of the existence of any significant financial interest that is considered conflicting and shall ensure the implementation of the relevant management plan.

Specifically, VRI, with the assistance of the relevant CSIC departments, will present a FCOI report in the following situations:

— At the beginning of the aid, before the start of the implementation of the funds, both in relation to the declaration of financial interests of the researcher who has been identified as a conflict of interest, and the implementation of the measures taken to reduce, eliminate or manage the effects of the conflict of interest. An annual report will be submitted during the duration of the project.

— In certain situations requiring additional declarations, such as in the case of the extension of the grant (e.g. by notification of extension or request for prior approval).

— Within sixty (60) days of the determination of the existence of a significant conflict of financial interests based on the declaration of financial interests of a researcher, or due to an unsubmitted or unreviewed declaration of financial interests, during the course of a research financed by the PHS.

— Within sixty (60) days of the determination of the existence of a financial conflict of interest for a researcher joining an ongoing NIH research activity.

There is no obligation to submit a FCOI report if AJUR does not identify a significant conflict of financial interest in the SFIs, or if it is eliminated before the implementation of the budget awarded by the PHS commences.

2. In addition to the FCOI report, provided that a conflict of economic interest is not identified or managed in a timely manner, the CSIC through the VRI shall complete a retrospective review of the researcher's work to determine whether all or part of the research carried out during the non-compliance period is biased in the design, development or notification of the research. The review must take place within a period not exceeding 120 days since the determination of existence of the conflict of interest, and shall be carried out in consultation with all appropriate CSIC departments.

Based on the results of the retrospective review, VRI shall update the previously submitted FCOI reports, specifying the actions to be taken to reduce or eliminate the FCOI, and submit a mitigation report.

3. All FCOI reports shall include sufficient information to enable the PHS contracting agency to understand the nature and scope of the FCOI and to assess the adequacy of the management plan.

The FCOI report shall include at least the following points:



- I) Grant number/project;
- II) Name of the principal researcher (or PD/IP contact in case of a multiple IP project);
- III) Name of the researcher in conflict;
- IV) Management method, reduction or disposal used to protect from bias research financed by the PHS;
- V) Name of the entity with which the researcher has a FCOI;
- VI) Nature of financial interests (e.g. equity, intellectual property, consultancy fees, sponsored or reimbursed trips, fees);
- VII) Value of economic interest, or a statement that a value cannot be easily determined by reference to public prices or reasonable measures of fair market value.
- VIII) Description of how the FCOI relates to PHS-funded research and the basis for CSIC's determination that an SFI is in conflict with such research;
- IX) Description of the legal and regulatory elements used to reduce, eliminate or manage the effects of the conflict of interest until the end of the research.

CSIC through the VRI shall notify the PHS as soon as possible if a FCOI-based bias affecting PHS-funded research is determined and will take corrective action if a person does not comply with this Policy.

SIXTH — Non-compliances/Disciplinary actions

In case of non-compliance with this Instruction by a researcher, the Management of the Centers and Institutes shall inform VRI, so that all relevant scientific activities are suspended. AJUR shall also be informed, so that it can take further disciplinary action until the matter is resolved, or to take any other action deemed appropriate by the governing bodies of CSIC.

The penalties imposed and the processing of the prescriptive file will be managed by AJUR, and will be in accordance with the provisions of the consolidated text of the Law on the Basic Statute of Public Employees, approved by the Royal Legislative Decree 5/2015, of October 30, as well as with the provisions of the labor legislation.

SEVENTH — Training

Public employees of CSIC are obliged to know the national legislation and regulations of CSIC on the integrity of research and good scientific practices, specifically the National Declaration on Research Integrity, the CSIC Code of Good Scientific Practice and the CSIC Handbook on Conflicts of Interest.

In addition, each researcher interested in participating in PHS-funded research must know and be able to meet the requirements of this Instruction, the researcher's responsibilities with respect to PHS statements and regulations before applying for PHS funding, and for at least the following four years.



They must also complete the training within a reasonable period of time in case this policy is substantially modified, when the researcher is new to the institution or if it is determined that the researcher has not complied with this Instruction or with a management plan related to his/her activities.

EIGHTH — Advertising, record keeping and accessibility

1. This Instruction will be published on CSIC's website and on BO.CSIC.
2. CSIC ensures that records relating to all declarations of financial interests by researchers submitted under this Instruction (whether or not a declaration has resulted in the determination of a financial conflict of interest) are maintained for at least three years from the date of submission of the final grant expenditure report to the PHS.
3. CSIC undertakes to make available to PHS, without delay and upon request, information relating to the declaration of financial interests by the researcher and the review and response adopted, irrespective of whether the declaration has led to the determination of a conflict of financial interests by CSIC.
4. Requests for public accessibility and any queries relating to this Instruction shall be addressed by e-mail to the management of the CSIC Centers or Institutes and to the Legal Counsel, which shall be answered in writing within a period not exceeding five working days.

The written reply shall include the name of the entity with which there is a significant economic interest (FCOI), the nature of that economic interest and its approximate value, provided that it is determinable, in which case it shall also be indicated that the information is subject to updates, at least annually and within sixty (60) days of the identification by the CSIC of a new conflict of interest, and that such updates shall be subsequently requested by the applicant.

NINTH — Entry into force

This Instruction shall enter into force on the day following its signature.

Rosa Menéndez

President of CSIC



ANNEX I

DECLARATION OF INTEREST FORM (SFI)

I. Identification of the declarant

Full name	
Financial Identification Number	
CSIC Institute or Center	
Email	

<input type="radio"/> Official staff	
<input type="radio"/> Career civil servant	Body or Scale:
<input type="radio"/> Interim official	<input type="radio"/> Group A: Subgroup A1 <input type="radio"/> Subgroup A2
	<input type="radio"/> Group B
	<input type="radio"/> Group C: Subgroup C1 <input type="radio"/> Subgroup C2

<input type="radio"/> Labor staff	
Professional group: 01 02 03 04 05	Functional Area: <input type="radio"/> Management and common services <input type="radio"/> Technical and professional <input type="radio"/> Specific activities
<input type="radio"/> Training staff	

2. Classification of the type of declaration

<input type="radio"/> First declaration <input type="radio"/> Regular update <input type="radio"/> Update by occurrence (not foreseen in previous declarations)



I declare that the information contained in this document is true and correct, and I assume the obligation to update this statement every two (2) years or whenever circumstances may alter the responses to it.

Signature:

Date: