Managing conflict of Interest – specific process regarding applications to and award form NIH

To enable Inserm to identify the existence of conflicts of interest that could weaken the authority of its expertise and decisions, each person participating in the Institute's missions must declare his or her links of interest. A procedure has been put in place for this purpose since 2011 and digital reporting platform has been set up.
In accordance with the commitments set out in the French Charter of Expertise at Inserm and included in the French National Charter of Ethics for Research Professionals, Inserm has established a procedure for managing these links and conflicts of interest, approved by its Board of Directors on October 6, 2011.

- A form and an analysis grid that facilitate this process are is available (for information only) to Inserm agents on the Institute's intranet.
- A digital platform allows them to declare their possible links.

The typology of links proposed in the declaration formalizes the most common situations and is not exhaustive. It is therefore up to the persons requested to examine and report any present or past elements, whether foreseen or not provided for in the declaration, which are liable to bias their judgment or to give rise to a suspicion of conflicts of interest between its mission for the Institute and its external activities.

Inserm has implemented its own procedure to met the NIH's requirements regarding the Financial Conflict of Interest (FCOI) regulation at 42 CFR Part 50 Subpart F, applicable to Public Health Service (PHS) grants and cooperative agreements. This specific policy is supplementary to, and followed in conjunction with, the Inserm's existing policies, procedures and guidelines on related matters which are publicly available on Inserm website.
The NIH policy and extensive guidance is accessible here:
http://grants.nih.gov/grants/policy/coi/
and the FAQ section provides a guide through the requirements :
http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
The purpose of this Guide Notice is to remind the NIH extramural research community that the requirements of 42 CFR Part 50, Subpart F, Objectivity of Research, apply to each institution, domestic and foreign, that applies for or receives NIH research funding in the form of grants or cooperative agreements. The regulation, also known as the Financial Conflict of Interest (FCOI) regulation, applies to both prime and subrecipient institutions, domestic or foreign, and through implementation, to each Investigator who is planning to participate in, or is participating in, such research. These regulations do not, however, apply to Phase I Small

Business Innovative Research and Small Business Technology Transfer applications or awards.
The purpose of the NIH regulation is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of NIH-funded research is free from bias resulting from Investigator financial conflicts of interest. Therefore, it is critical that there is a clear understanding of the applicability of these regulatory requirements. Equally important is that the regulation is a term and condition of all NIH grant and cooperative agreement awards, which means that compliance with the requirements is a condition of funding.

One such area of the FCOI regulation requiring clarity is Investigator disclosures with respect to foreign financial interests. The regulation refers to exclusions of Institutions of higher education as defined in 20 U.S.C. 1001(a) or a federal, state or local government agency when disclosing financial interests. However, these references refer to a U.S. Institution of higher education or a federal, state, or local government agency within the U.S. Therefore, Investigators, including subrecipient Investigators, must disclose all financial interests received from a foreign Institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).
This specific policy implemented by Inserm applies to everyone (university researchers, honorary staff, students, consultants, external collaborators, etc) who is responsible for design, conduct and reporting of research funded by the NIH itself, by NIH Institutes and by the Public Health Service of the US Department of Health and Human Services (of which the NIH is a part).

What is a Conflict of interest ?
French law defines that any situation of interference between a public interest and public or private interests, likely to influence or appear to influence the independent, impartial and objective exercise of a function, constitutes a conflict of interest.
For its part, the concept of an interest link covers the professional and financial links between a natural person and a legal person or other natural person whose activity falls within the scope of Inserm. It also concerns institutional, family, intellectual or moral ties.
Furthemore, the French law states that the public servant shall ensure that any conflict of interest situation in which he or she finds himself or herself or may find himself or herself is or may be immediately eliminated or prevented.

What is a financial conflict of interest according to the NIH policy?
A Significant Financial Interest is a financial interest consisting of one or more of the following interests of an Investigator (and those of an Investigator’s spouse and dependent

children), that reasonably appears to be related to the Investigator's Inserm responsibilities (these may include activities such as research, research consultation, teaching, professional practice, committee memberships, and service on review board panels, etc.):-

- For any publicly traded Entity*, an SFI exists if the value of any remuneration (including salary and any payment for services not otherwise identified as salary, e.g. consulting fees, honoraria, paid authorship) received from the Entity in the 12 months preceding
- For any non-publicly traded Entity*, an SFI exists if the value of any remuneration received from the Entity in the 12 months the disclosure and the value of any equity interest (including any stock, stock option or other ownership interest as determined through reference to public prices) in the Entity as of the date of disclosure, when aggregated, exceeds US$ 5,000.
- preceding the disclosure, when aggregated, exceeds US$ 5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest.
- Intellectual property rights and interest (e.g. patents, copyrights) on receipt of income related to such rights and interest.

In the policy, 'Entity' means any domestic or foreign, public or private organisation (excluding a US Federal/government agency) from which an Investigator (and spouse and dependent children), receives remuneration or in which any person has an ownership or equity interest. As SFIs, Investigators must also disclose the existence of any travel related to their Inserm responsibilities that is reimbursed or sponsored by commercial funders. This includes travel paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available. This does not include travel which an Investigator claims through the Inserm's system for claiming expenses and is charged to a research project

Investigators are not required to disclose salary, royalties, or other remuneration (includes travel reimbursement) paid by the applicant or recipient institution (Inserm) nor any equity interest held in the for-profit company that is applying for or that receives PHS/National Institutes of Health (NIH) research funding (e.g., SBIR/STTR applicants/recipients). Such financial interests are excluded from disclosure per the definition of "Significant Financial Interest"

A financial conflict of interest exists when, after investigation carried out by Inserm, Inserm reasonably determines that Significant Financial Interest ('SFI') that is related to an NIH-funded research project and that could directly and significantly affect the design, conduct or reporting of the NIH-funded research. SFIs that do not directly and significantly affect the design, conduct or reporting of the NIH-funded research are not FCOIs.

Who is concerned by this specific process ?

This specific process applies to the Investigator, defined as the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by NIH, or proposed for such funding, which may include, for example, collaborators or consultants.

This specific process applies to the subrecipients. Therefore, Inserm will incorporate, as part of a written agreement with a subrecipient, terms that establish this specific process will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements. Subrecipient Institutions who rely on their FCOI policy must report identified Financial Conflicts of Interest to Inserm in sufficient time to Inserm to report the FCOI to the NIH to meet its reporting obligations.

Disclosure, review and management

Disclosure of any link of interests and conflit of interest situation by the Investigator is mandatory. As previsoulsy mentionned, this disclosure applies to the subrecipients.

Such disclosure shall be made:

- when submitting applications for funding by the NIH,
- when a new investigator is involved in the funded research
- then, after expenditure of funds, once a year in order to, as necessary, update the intial declaration,
- Each time as necessary in ordre to provide an updated version of the declaration (within 30 days of discovering/acquiring a new SFI)
- When requested by Inserm

The purpose of the declaration of links of interest is to identify these links and to enable them to be assessed on the basis of objective and concrete criteria.

Furthermore, Investigator and Subrecipiens shall disclose any bias due to a FCOI found in the design, conduct or reporting of the project to the ROI/DI.

The regional office of Inserm (ROI) or the Inserm' department (ID) in charge of the financial management of the NIH grant shall put in place the ad hoc procedures, notably in accordance with the principles adopted by the Board of Directors in 2011 with regard to the management of links and conflicts of interest and the National Institute of Health Grants Policy Statement (NIH GPS).The regional office of Inserm or the Inserm' departments shall :

- review all disclosures of link of interests
- determine whether any significant financial interests relate to NIH funded research

- determine whether a financial conflict of interest exists (an SFI declaration constitutes an FCOI due to (i) the impact on the NIH-funded project or (ii) the outcome the NIH-funded project may have on the SFI); and, if so,
- develop and implement a management plan, to be submitted to the NIH, that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.

When

DOI/DI will be responsible for monitoring Investigator compliance with Management Plans until completion of the funded project.

In the event that a bias is identified in the design, conduct or reporting of a project, the DOI/DI will promptly notify the NIH, complete a Mitigation Report and take such other necessary corrective actions.

In the event that an Investigator fails to comply with his/her obligations to the NIH and Inserm with regards to any FCOI, including following an agreed management plan, DOI/DI will promptly notify the NIH and take such other necessary corrective actions.

In the case of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment, corrective actions will include Investigators being required to disclose FCOIs in public presentations of the results of the project.

In case of non-compliance with the French laws or the current specific procedure, Inserm is entitled to provide for employee sanctions or other administrative or financial actions to ensure compliance or punish any failings.

Maintenance of records

In accordance with the REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation GDPR), each validated declarations of interest containing personal data are kept by Inserm in a confidential manner for ten (10) years after the declaration is filed (validated version), before being destroyed. Draft declarations are kept for two (2) months and then automatically destroyed.

Training requirements

Each PHS-supported Investigator, including new investigators involved in the NIH funded project, shall complete, and confim such completion to the ROI/DI, the NIH online tutorial regarding FCOI training according to the following timetable:

- Prior to engaging in research related to any PHS-funded grant
- At least every 4 years
- Immediately, if:

- Institution revises its FCOI policy that affects requirements of Investigators
- An Investigator is new to an Institution
- An Investigator is not in compliance with the policy or management plan set up by the ROI/DI

This tutorial is available here:

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

Furhtermore, Inserm shall implement by all ways at its disposal any process in order to comply with the training requirements of the NIH GPS 4.1.10 according to the Title 42 CFR 50.604 (b).

Information

This specific process shall be publicly available on the Inserm website
Furthermore, INSERM shall undertake to in a timely manner complying with the NIH policy requirements :

- inform each Investigator of the:
  - Inserm's policy regarding conflict of interest
  - Specific process regardig NIH grants
  - Investigatore training responsibilities
  - Investigator's disclosure responsibilities
  - US regulation regarding NIH grants

- Establish a process to require each PHS-supported Investigator to attend one of the Inserm-supported research contract trainings in which FCOI requirements are addressed

Reports provided to NIH

ROI/DI shall send initial, annual (i.e., ongoing) and revised FCOI reports, including all reporting elements required by the NIH policy, to the NIH for Inserm and its subrecipients, if applicable, as required by the NIH policy.
The previsionnal timetable for the report is the following :

- Report any FCOIs prior to expenditure of funds
- Report any FCOIs within 30 days of an Investigator discovering or acquiring a new SFI
- Report any FCOIs within 60 days of identification for an Investigator who is newly participating in a project

- Report any FCOIs following a retrospective review to update a previous report, if appropriate
- Report any FCOIs following a retrospective review within 120 days of Inserm determining non-compliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner.
- Report any FCOIs within 60 days for new, or newly identified SFIs for existing Investigators
- Report annually on FCOIs throughout the full duration of the funded project and any changes to management plans
- Implement a management plan within sixty days whenever Inserm identifies identifies an SFI that was not disclosed timely by the Investigator or not previously reviewed by Inserm

Data Processing

For the avoidance of doubt, definitions mentionned in article 4 of the GDPR apply to the current specific process.

Processing carried out by Inserm

Inserm is the Controller of the Processing carried out by Inserm as mentionned on the digital plateform.

Processing carried out by the NIH

In accordance with the NIH policy, Inserm shall provide NIH with Personnal data concerning the Investigator. Due to the applicable laws and regulation in force in the USA, and in the absence of an adequacy decision pursuant to Article 45(3) of the GDPR or of appropriate safeguards pursuant to Article 46 of the GDPR a transfer or a set of transfers of personal data to a third country or an international organisation shall take place only when the data subject has explicitly consented to the proposed transfer, after having been informed of the possible risks of such transfers for the data subject due to the absence of an adequacy decision and appropriate safeguards;

NIH is the Controller of the Processing carried out by NIH in order to assess the management of the financial conflicts of interest by Inserm and to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan,

The Processing carrried out by NIH is lawfulness because :

- the data subject has given consent to the processing of his or her personal data for one or more specific purposes;
- and is necessary for compliance with a legal obligation to which the Controller is subject.

The following data and Personnal data shall notably, but are not necessarily limited to the following, be provided by Inserm to NIH in the framework of the FCOI report required by NIH:

(i) Project number;
(ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
(iii) Name of the Investigator with the financial conflict of interest;
(iv) Name of the entity with which the Investigator has a financial conflict of interest;
(v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
(vi) Value of the financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
(vii) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
(viii) A description of the key elements of the Institution's management plan, including:

(A) Role and principal duties of the conflicted Investigator in the research project;

(B) Conditions of the management plan;

(C) How the management plan is designed to safeguard objectivity in the research project;

(D) Confirmation of the Investigator's agreement to the management plan;

(E) How the management plan will be monitored to ensure Investigator compliance; and

(F) Other information as needed.

In addition to the information referred to hereinabove, the NIH as Controller shall provide the Data subject with the following further information necessary to ensure fair and transparent processing:

(a) the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period;

(b) the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability;

(c) because the processing is based on the consent, the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal;

(d) the right to lodge a complaint with a supervisory authority;

(e) because the provision of personal data is a statutory requirement, the consequences of failure to provide such data shall be the withdrawal of funding.

Public disclosure

Personnal data shall be disclosed :

(i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

The Investigator shall disclose FCOIs in each public presentation of the results of a project (and as an addendum to previously published presentations) for any FCOI not properly managed or reported by the Investigator for a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment.

Effective Date

The specific procedure is effective from 20 May 2021

NIH FCOI Management Plan

Information required	Information / Comments
Name of the Investigator with the FCOI	
Investigator's title and role on the NIH-funded project	
Principal Investigator/s on Grant	
NIH grant reference	
Aptos account code	
Name of the entity with which the Investigator has an FCOI	
Nature of the financial interest (e.g. equity, consulting fee, travel reimbursement, honorarium)	
Value of the financial interest (dollar ranges are permissible) $0 - $4,999; $5K - $9,999; $10K - $19,999 Amounts between $20K and $100K by increments of $20K Amounts above $100K by increments of $50K If the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value, a statement is required	
How does the financial interest relate to the NIH-funded project and why has Inserm determined that the financial interest conflicts with such research?	

NIH FCOI Management Plan

What are the role and principal duties of the conflicted Investigator in the NIH-funded research project?	
What are the conditions of this management plan?	
Which individuals have been involved in drawing up this Management Plan (names and roles)?	
How is the management plan designed to safeguard objectivity in the research project?	
How will the management plan be monitored to ensure Investigator compliance?	
Updated Management Plan to any previously submitted to the NIH: **What is the status of the management plan** (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists)**?** **Include a description of any changes to the management plan since the last FCOI report was submitted to the NIH.**	

Other relevant information	
Investigator's signature and Date of Signature (confirmation of the Investigator's understanding of and agreement to the management plan)	
official (Signature, Name, and Date of Signature)	

NIH Pre-Submission Declaration Form

Declaration by Investigators when submitting applications for funding by US Department of Health & Human Services organisations, such as the NIH, the National Cancer Institute and the National Institute of Allergy & Infectious Diseases. This declaration is required for all applications, including those that are routed via other organisations, e.g. universities in the USA.

All investigators applying for funding from any US Department of Health & Human Services organisation have to comply with a Financial Conflicts of Interest ('FCOI') Policy by making declarations regarding FCOIs, Significant Financial Interests ('SFIs') and undertaking training before the submission of an application.

In this context, 'Investigators' means anyone who is or would be responsible for the design, conduct, or reporting of the application/project e.g. Principal Investigators (PIs) and Co-Investigators (Co-Is), as well as any other similarly responsible individuals, including honorary staff, students, technicians, external collaborators or consultants. It is the role of the individual and the degree of independence with which that individual works, rather than their title, that determines whether they fall within the definition of an 'Investigator'.

All Investigators must familiarise themselves with the specific procedure, make the declarations below and sign and register this form (as pdf) in https://glci.inserm.fr before an application may be submitted. Where an application has more than one Investigator, they may make their declarations collectively on one form or on separate forms. Inserm will not authorise any application until all Investigators have completed a declaration and taken any necessary action.

Information required	Project Details
Title of project	
Funding organisation (e.g. NIH)	
Name of lead organisation, where applicable	
Details of any external collaborators, including subcontractors, consultants, non-College staff, including KHP staff	

Declaration by Investigator/s

I/we have read and understood the responsibilities and requirements for Investigators regarding FCOIs and SFIs and agree to abide by them should the application be successful.

I/we have (each) completed the NIH on line tutorial.

I/we have (each) completed an SFI disclosure form and submitted it in line.

Where completion of the SFI disclosure form has revealed an FCOI, the details are details below. I/we will follow Inserm requirements with regard to any such FCOI.

Declaration made by ..... (Print Name) Date .....

Signature.....

Declaration made by ..... (Print Name) Date .....

Signature.....

KCL NIH Retrospective Disclosure of form

Information required	Information / Comments
Name of the Investigator with the SFI / FCOI	
Investigator's title and role within the NIH-funded project	
Principal Investigator's Name	
NIH grant reference	
Aptos account code	
Project title	
Name of the entity with which the Investigator has an 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	
Impact of any bias found on the project (e.g. extent of harm done, including any qualitative or quantitative data to support any actual or future harm; analysis of whether the research project is salvageable)	

KCL NIH Retrospective Disclosure of form

Plan of action or actions taken to eliminate or mitigate the effect of any bias found	
Conclusions of the review, including whether the SFI constitutes an FCOI and reasons for the decision, and next steps with regard to reporting to NIH	
Which individuals have been involved in drawing up this compiling the data on this form (names and roles)	
Signature (Name and Date of Signature)	
Date of completion	