

 Fondazione CENTRO SAN RAFFAELE	MANAGEMENT OF THE FINANCIAL CONFLICT OF INTEREST IN RESEARCH (U.S. PHS AND U.S. PHS-LIKE FUNDED PROJECTS)	PRO 008	
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Addressed to: General Directorate FCSR, OSR Research Area, FCOI Official, FCOI Committee, OSR Training Office.

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ATTACHMENTS

1. FCSR FCOI 001 Investigator Financial Interests Disclosure Form
2. FCSR FCOI 002 Investigator Project /Contract Form
3. FCSR FCOI 003 Sub-Recipient Financial Conflict of Interests Agreement

Rev.	History of Revision	Date
0	First Issue	31/08/2016

Drawing up	Development	Review	Approval
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1 SCOPE

The purposes of this procedure are:

- to clarify the responsibilities of Investigators and Project Teams with respect to conflicts of interest and
- to establish a set of standards and rules in order to provide a reasonable expectation that the design, conduct and reporting of any funded research project that takes place at Fondazione Centro San Raffaele or at any of its sub-recipient organizations is free from bias resulting from Investigator's financial conflicts of interest.

The term 'conflict of interest' refers to a situation where a conflict arises for an individual between two competing interests. This procedure helps to ensure that if an actual or reasonably perceived conflict exists between the interests of the Investigator and his/her family members and/or Project Team and the duties or responsibilities towards the Sponsor, the conflict of interest is managed in an appropriate manner.

The standards and rules established by this procedure have been determined in accordance with the requirements of the Financial Conflicts of Interest Regulation issued by the Department of Health and Human Services (42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94, as revised on August 2011) that obliges Fondazione Centro San Raffaele to maintain a written policy on conflict of interests disclosure as a condition for receiving PHS awards.

2 APPLICABILITY

This procedure applies to all research projects funded by the U.S. PHS or by other international, national, private or public Sponsor (for example Charity, Government etc), requiring the adoption of U.S. PHS regulation on Financial Conflicts of Interest.

2.1 LEGAL DISCLAIMER

FCSR has the exclusive property of this document. This procedure is published on the FCSR institutional website; any other copy has to be considered a non-controlled working copy. FCSR personnel are required to verify that the procedure in their possession corresponds to the official and most updated version of this document.

The management of FCSR has the responsibility to:

- comply with the requirements of this document;
- disseminate the procedure to the personnel under its supervision;
- ensure, through targeted inspections, the correct implementation of internal control procedures.

This document, which has to be considered a binding regulation for FCSR personnel, is an internal control procedure. It represents a regulating tool finalized to the adoption of provisions contained in the Organization, Management and Control Model ex. Legislative Decree N.231/01.

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Any intentional and significant violation of internal control procedures is subject to sanctions according to what is established by the Italian Collective Bargaining Agreement, the Italian Labor and Employment legislation, the Italian Workers' Statute and FCSR disciplinary code.

The proper implementation of this internal control procedure is periodically evaluated by Internal Audit Division and by FCSR Supervisory Body established pursuant to Legislative Decree N. 231/2001.

3 ABBREVIATIONS, TERMS AND DEFINITIONS

ABBREVIATIONS AND TERMS	DEFINITIONS
FCSR	Fondazione Centro San Raffaele
OSR	Ospedale San Raffaele srl
HHS	The United States Department of Health and Human Services and any components of the Department to which the authority involved may be delegated
PHS	The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH)
Sponsor	Any international Agency, Institution, Government, Charity requiring the adoption of PHS regulation on the Financial Conflicts of Interest
PHS-like Funded Project	Any project that requires the adoption of PHS regulation on the Financial Conflicts of Interests
PHS Awarding Component	The organizational unit of the PHS that funds the research
Financial Interest	Anything of monetary value, whether or not the value is readily ascertainable
Project Team	The Project Coordinator or Principal Investigator and any other person (e.g. collaborators or consultants), regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS or a Sponsor, or proposed for such funding
Investigator	Any person responsible for the design, conduct, or reporting of research funded by the PHS or a Sponsor or proposed for such funding
Project Coordinator or Principal Investigator (PI)	An Investigator or responsible person who has primary responsibility for the scientific and technical conduct, reporting and administration of a sponsored research project or sponsored service
Institutional responsibilities	Training, research, clinical service and any other Investigator's professional responsibility on behalf of FCSR

Significant Financial Interest	<p>A Significant Financial Interest is defined as:</p> <ol style="list-style-type: none"> 1. A financial interest consisting of one or more of the following interests of the Investigator or the Investigator's spouse and dependent children that reasonably appears to be related to the Investigator's institutional responsibilities: <ul style="list-style-type: none"> - 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. Remuneration includes salary, consulting fees, honoraria, paid authorship and any other payment for services not otherwise identified as salary; 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 at the date of disclosure; - 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); - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income 2. Any reimbursed or sponsored travel related to the Investigator's institutional responsibilities. It is not considered a Significant Financial Interest any travel reimbursed or paid by a federal, state or local government agency, 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 <p>The term "Significant Financial Interest" does not include the following types of financial interests:</p> <ul style="list-style-type: none"> - salary, royalties, or other remuneration paid by FCSR to the Investigator who is currently employed or otherwise appointed by FCSR; - any ownership interest in FCSR held by the Investigator; - 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, teaching engagements or service on advisory committees
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	or review panels sponsored by a Federal, state, or local government agency, 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
Sub-recipients	Partners and subcontractors of FCSR
Disclosure of Financial Interests	An Investigator's disclosure of Financial Interests to FCSR
Financial Conflict Of Interest (FCOI)	A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research or in general an PHS-like funded project
FCOI report	FCSR report of a financial conflict of interest to a PHS Awarding Component or Sponsor Awarding Component
FCOI Official	The Official designated by OSR in accordance with FCSR General Director to solicit the Investigators' Disclosure of Financial Interests and ensure FCSR compliance with all the reporting requirements specified in the present procedure. By effect of the existing framework agreement between OSR and FCSR the OSR FCOI Official serves as FCSR FCOI Official as well
FCOI Committee	The Committee appointed by OSR in accordance with FCSR General Director to review Investigators' Significant Financial Interests Disclosure and determine whether any of the Significant Financial Interest constitutes a FCOI according to FCSR FCOI guidelines. By effect of the existing framework agreement between OSR and FCSR the OSR FCOI Committee serves as FCSR FCOI Committee as well
GAR	Research Administrative Office of OSR
GO	Grants Office of OSR
RACO	Research Agreements and Contracts Office of OSR
TO	Training Office of OSR

4 RESPONSIBILITIES

The table below represents a summary of the main responsibilities required by the present procedure. For each activity an indication of the deadline and of the person in charge of its completion is provided. An in-depth description of all the activities and responsibilities can be found in the following paragraphs.

ACTIVITIES	DEADLINE	PERSON IN CHARGE
Initial Disclosure of Financial Interests to FCOI Official	No later than the time of application In case of new Investigators who are planning to join an ongoing PHS-funded research project or a PHS-like funded project , the disclosure must be submitted before joining the project	Investigators who apply to a research project funded by PHS or in general by a Sponsor New Investigators joining an ongoing PHS-funded research project or a PHS-like funded project
Second Disclosure of Financial Interests to FCOI Official	Before the beginning of the project, no later than the time of the award notification In case of new Investigators who are planning to join an ongoing PHS-funded research project or a PHS-like funded project , the disclosure must be submitted before joining the project	Investigators with a grant awarded by PHS or in general by a Sponsor New Investigators joining an ongoing PHS-funded research project or a PHS-like funded project
Annual Update Disclosure of Financial Interests to FCOI Official	During the period of the award 45 days prior to the end of the fiscal year (January1 - December 31) as requested by the FCOI Official	Any Investigators participating to an ongoing PHS-funded research project or PHS-like funded project
Disclosure of new Financial Interests to FCOI Official	Within 30 days from the discovery/acquisition of the Financial Interest	Investigators participating to an ongoing PHS-funded research project or PHS-like funded project
Identification of Significant Financial Interest	Within 10 days from the Financial Interest disclosure	FCOI Official
Review of initial Financial Interests Disclosure and definition of a management plan, if needed	Prior to the expenditure of any funds provided under a PHS award or Sponsor award In case of new Investigators who are planning to join an ongoing project, the review must be done before the Investigator joins the project	FCOI Committee
Review of annual Financial Interests Disclosure and definition/modification of the management plan, if needed	Prior to the submission of the annual/multi-year progress report or prior to an extension	FCOI Committee
Review of new or newly discovered Financial Interest and definition of a management plan, if needed	Within 60 days of the disclosure	FCOI Committee
Submission of the initial FCOI report to PHS or to the Sponsor	Prior to the expenditure of any funds provided under a PHS or any Sponsor award	FCOI Official

Submission of the annual FCOI report to PHS or to the Sponsor	Only in case of FCOI, if possible at the same time as when FCSR is required to submit annual/multi-year progress report (i.e. 60 days prior to the start date or 45 days prior to the start date of the noncompeting continuation award or at the time of the project extension)	FCOI Official
Submission of a revised FCOI report to PHS or to Sponsor	Within 60 days of any subsequently identified FCOI	FCOI Official
Monitoring of the management plan implementation	On an ongoing basis until completion of the PHS-funded research project or PHS-like funded project	FCOI Official
Retrospective Review	Within 120 days of the determination of non-compliance	One or more neutral researchers identified by the FCOI Committee
Definition of a mitigation plan	Immediately when bias is found as a result of a retrospective review	FCOI Committee
Submission of the mitigation report to PHS or to the Sponsor	Promptly when bias is found as a result of a retrospective review	FCOI Official
Training	Prior to the Investigator's engagement in any PHS-funded research project or PHS-like funded project	TO/FCOI Official

The FCOI Official is assisted by GO in all tasks/activities indicated in the current procedure.

5 MATERIALS AND EQUIPMENT

FCSR institutional website

6 DESCRIPTION OF ACTIVITIES

6.1 DISCLOSURE OF FINANCIAL INTERESTS

6.1.1 Pre-award financial interest disclosure

Before submission of a grant application/contract draft to the PHS or to other Sponsors requiring the adoption of PHS regulation on the Financial Conflicts of Interest the PI/Project Coordinator must:

1. inform via email the GO (in case of grants) or the RACO (in case of contracts) and always the FCOI Official;

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2. communicate via email to the FCOI Official (fcoi-fcsr@fondazioneanraffaele.it) and the GO/RACO the names of the Project Team members, if known, and the names of the sub-recipient organizations, if any;
3. submit his/her Investigator Financial Interests Disclosure Form (Attachment n° 001) via email to the FCOI Official (fcoi-fcsr@fondazioneanraffaele.it). FCOI Official will inform GO/RACO of the submission and receipt of the form.

The Financial Interests Disclosure Form must be also submitted by all the other Project Team members prior to the submission of the application/contract draft.

On the basis of the information received by the PI/Project Coordinator, the FCOI Official checks whether all Project Team members have duly submitted the Financial Interests Disclosure Form and solicits those who failed to do so.

Before submission of the application/contract the GO/RACO are required to send via email to the FCOI Official (fcoi-fcsr@fondazioneanraffaele.it) the Investigator Project/Contract Form (Attachment n° 002) containing basic information regarding the project/contract. If FCSR carries out a PHS-funded research or PHS-like funded project through one or more sub-recipients, the FCOI Official asks each sub-recipient to sign and send via email (fcoi-fcsr@fondazioneanraffaele.it) the Sub-Recipient Financial Conflict of Interests Agreement (Attachment n° 003) before the submission of the project.

The sub-recipient's collaborators, who share the responsibility for the design, conduct or reporting of research results are expected to comply with the HHS Regulation on FCOI according to the policies and procedures of their employer institution. By signing the Sub-Recipient Financial Conflict of Interests Agreement (Attachment n° 003), the sub-recipient institution certifies that its policy is in compliance with HHS Conflict of Interest Regulation and it is responsible for reviewing the disclosures submitted by its Investigators. If a FCOI is identified, the sub-recipient institution has to send FCSR a notification of the conflict and of the plan to manage, reduce or eliminate it for the whole duration of the project according to the deadlines specified in the Sub-Recipient Financial Conflict of Interests Agreement.

As defined in the agreement, if the sub-recipient institution does not have a Conflict of Interest Policy that complies with the HHS regulations, its Investigators must comply with FCSR policies and procedures for disclosure and review of Financial Interests for the whole duration of the PHS-sponsored research project or of the PHS-like funded project. In this case the FCOI Official sends the FCSR Investigator Financial Interests Disclosure Form (Attachment n°001) to each sub-recipient. In case the sub-recipient institution does not accept to comply with FCSR procedures, it does not qualify to receive funding from FCSR.

6.1.2 Post-award financial interest disclosure

If the grant is awarded or the contract is signed, the GO/RACO timely informs the FCOI Official and communicates the annual progress reports deadlines, thus allowing the FCOI Official to plan the disclosure and reporting activity for the whole duration of the project. The FCOI Official immediately and formally asks the PI/Project Coordinator to confirm the list of all Project Team members/sub-recipient organizations. In case of modifications to the list of team members/sub-recipient organizations, the FCOI Official solicits the Investigator Financial Interest Disclosure Form from all the new members/organizations (**CTR_ PRO_008_001**).

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At this time, the PI/Project Coordinator submits his/her new Investigator Financial Interests Disclosure Form (Attachment n° 001) via email to the FCOI Official (fcoi-fcsr@fondazioneanraffaele.it). , and also in this case FCOI Official will inform GO/RACO of the new submission and receipt of the Form.

Whenever a new Investigator/sub-recipient organization joins an ongoing PHS-funded research project or PHS-like funded project/contract, the PI/Project Coordinator has the duty to immediately inform via email the FCOI Official (fcoi-fcsr@fondazioneanraffaele.it) and the GO/RACO and to remind the new Investigator to submit his or her initial Investigator Financial Interests Disclosure Form before joining the project.

In order to prevent any late disclosure of a Financial Interest, **at the end of every month** the FCOI Official sends to the PI/Project Coordinator a reminder asking to confirm/update the full list of the Project Team members/sub-recipient organizations.

In addition to the initial disclosure responsibility, **each Investigator has the ongoing duty through the period of a PHS research award or PHS-like funded project /contract to disclose, at least annually, his/her Financial Interest. A new submission of the Investigator Financial Interests Disclosure Form to the FCOI Official is therefore required each year.** The annual submission must be done 45 days before the end of FCSR fiscal year (January1-December 31). The new Investigator Financial Interests Disclosure Form must include the updated information regarding any previously disclosed Financial Interest and any other information that was not previously disclosed to FCSR. A reminder to each Investigator is sent annually by the FCOI Official, who has the responsibility to collect the updated Investigator Financial Interests Disclosure Forms (**CTR_ PRO_008_002**).

In all those cases where a new Financial Interest is discovered or acquired, the Investigator must submit to the FCOI Official a new Investigator Financial Interests Disclosure Form with the most updated information within 30 days from the discovery/acquisition. An automatic reminder is sent to all the Investigators by the FCOI Official each month in order to prevent any late disclosure. The FCOI Official also in this situation will inform GO/RACO of the new submission and receipt of the Form.

A new submission of the Investigator Financial Interests Disclosure Form to the FCOI Official is also required whenever a new release of this procedure is issued during the year. The Form must be submitted by all the Investigators within 30 days from the new release.

6.2 REVIEW OF DISCLOSURES

Within 10 days from the submission of the Investigator Financial Interests Disclosure Form, the FCOI Official determines whether the disclosed financial interests are Significant Financial Interests on the basis of the applicable regulation and according to the FCOI guidelines issued by FCSR (FCSR-LG FCOIC 001). If so, the relevant Investigator Financial Interests Disclosure Form must be reviewed by the FCOI Committee in order to determine whether a FCOI exists.

The FCOI Official calls the FCOI Committee meetings as needed in order to meet the deadlines defined by this procedure and in order to review:

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- the initial Investigator Financial Interests Disclosure Forms of the Investigators who apply for a new PHS-sponsored research project or PHS-like funded project ;
- the initial Investigator Financial Interests Disclosure Forms of new Investigators who plan to join an ongoing PHS-funded research project or PHS-like funded project ;
- the Investigator Financial Interests Disclosure Forms of existing Investigators who disclose a new Financial Interest or update any previously disclosed Financial Interest;
- the annual Investigator Financial Interests Disclosure Forms of all involved Investigators.

The presence of any Financial Interest disclosed by the Investigators and determined to be a Significant Financial Interest by the FCOI Official does not necessarily imply the existence of a FCOI. The FCOI Committee has the duty to review each of the above-mentioned disclosure forms and to determine whether the disclosed Financial Interest can generate a FCOI (i.e. the Financial Interest is a Significant Financial Interest, it is related to the PHS-funded research or PHS-like funded project and can directly and significantly affect its design, conduct or reporting). The above evaluation is conducted accordingly to the FCOI guidelines issued by FCSR and its result is communicated to the PI/Project Coordinator by the FCOI Official.

The initial review of the Financial Interest disclosed by the Investigators must be conducted prior to the expenditure of any funds or, in case of new Investigators participating to an on-going project, before the new Investigator joins the project. If a FCOI is identified, the FCOI Committee has the duty to develop a management plan that specifies the actions required to manage the FCOI. The management plan shall include the following information:

- the role and principal duties of the Investigator with the financial conflict of interest;
- how the plan will safeguard objectivity in the research activity;
- how the plan will be monitored;
- the conditions or restrictions imposed to manage the FCOI.

If a FCOI is identified before the expenditure of funds and it is unmanageable the FCOI Committee may decide to cancel or postpone the project.

The management plan is put into writing by the FCOI Official, signed by each member of the FCOI Committee and sent to the interested Investigator to obtain his/her agreement to the plan and to the Principal Investigator/Project Coordinator if applicable. The plan must be implemented prior to the expenditure of PHS-funds or Sponsor funds awarded for the research project. The FCOI Official has the duty to monitor its implementation on an ongoing basis until completion of the PHS-funded research project or PHS-like funded project and must promptly inform the FCOI Committee, the PI/Project Coordinator and GO/RACO, in case of non-compliance (**CTR_PRO_008_003**).

It is understood that in any case if a FCOI is identified during the course of an ongoing PHS-funded research project or other PHS-like funded project, the FCOI Official immediately informs the GAR office that stops any expenditure of the PHS or PHS-like funds until the FCOI Official issues a formal clearance.

Whenever, during the course of an ongoing PHS-funded research project or other PHS-like funded project, an Investigator discloses a new Financial Interest or FCSR identifies a Financial Interest that was not disclosed in a timely manner by an Investigator or which

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was not previously reviewed for whatever reason, the FCOI Official determines if the Financial Interest is significant and, if so, asks the FCOI Committee to review the disclosure within 60 days. In case the FCOI Committee determines that a FCOI exists it defines a management plan.

In addition, whenever a FCOI is not identified or managed in a timely manner for whatever reason (i.e. the Investigator did not disclose a Financial Interest that was later determined to be a FCOI or FCSR did not manage the FCOI or the Investigator failed to comply to a management plan) FCSR must complete a Retrospective Review of the Investigator's activities and of the PHS-funded research project or PHS-like funded project within 120 days of the determination of non-compliance. The purpose of the Retrospective Review is to determine if the ongoing PHS-funded research or PHS-like funded project was biased in its design, conduct or reporting. The review is conducted and coordinated by one or more neutral researchers identified by the FCOI Committee. At the end of the review these researchers submit a report to the FCOI Committee containing the following information:

- project number;
- project title;
- PI/Project Coordinator;
- name of the Investigator with the FCOI;
- name of the entity with which the investigator has a financial conflict of interest;
- reasons for the Retrospective Review;
- detailed methodology used for the Retrospective Review;
- findings of the review and conclusions.

If bias is found, the FCOI Official must promptly notify the PHS Awarding Component or Sponsor awarding component and the FCOI Committee has to immediately determine the actions to be taken in order to eliminate or mitigate the effect of the bias. These actions are put into writing in a mitigation report drafted by the FCOI Official. The report must include also the key elements documented in the Retrospective Review and the description of the impact of the bias on the research project and must be signed by each member of the FCOI Committee. Once ready, the report is sent by the FCOI Official to the Investigator with a FCOI in order to obtain his/her agreement and to the PI/Project Coordinator. FCOI Official will inform GO/RACO of the compilation and approval of the report.

The FCOI Committee is also required to review the updated all Investigator Financial Interest Disclosure Forms submitted annually by each Investigator. This review must be conducted prior to the submission of the annual/multi-year progress report or at a time of extension of the project.

Each resolution of the FCOI Committee is reported in the meeting minutes register. The register must be signed by each member of the FCOI Committee and it is kept by the FCOI Official to support any internal or external control.

It is understood that in case of FCOI, the Investigator submits all necessary disclosure forms and related information requested by the FCOI Official.

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6.3 REPORTING TO PHS

When a PHS or a Sponsor funded grant/contract is officially awarded to FCSR, the GO/RACO informs the FCOI Official. Prior to the expenditure of any funds under a PHS or a Sponsor award/contract, the FCOI Official must provide to the PHS Awarding Component or Sponsor component (or to the coordinating institution in case FCSR is not the coordinator of the project), in case of FCOI, an initial report regarding the identified FCOI of FCSR Investigators and ensure that a management plan has been developed and implemented. In case FCSR carries out the research through one or more sub-recipients, the FCOI Official must also submit the FCOI report of all its sub-recipient Investigators. If the FCOI is eliminated before expenditure of funds, FCSR is not required to submit a report to the PHS or to the Sponsor.

The FCOI report shall include sufficient information to enable the PHS Awarding Component or Sponsor component to understand the nature and the extent of the FCOI and to assess the appropriateness of the management plan. The report shall include at least the following information:

- project number;
- PI/Project Coordinator;
- name of the Investigator with a FCOI;
- name of the entity with which the Investigator has a financial conflict of interest;
- nature of the financial interest (equity, consulting fee, travel, etc);
- value of the financial interest 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;
- a description of how the Financial Interest relates to the PHS-funded research or to the PHS-like funded project and the basis for the determination that a FCOI exists;
- description of the key elements of the management plan.

The GAR office can authorize the expenditure of the PHS or of the PHS-like funds or the transfer of such funds to sub-recipient organizations only after a formal clearance of the FCOI Official has been received. The GAR Office informs of any decision concerning the expenditure the GO.

For any FCOI reported to a PHS Awarding Component or Sponsor component, FCSR shall provide an annual FCOI report for the duration of the project period, including extensions with or without funds. GO and RACO must inform the FCOI Official in case of any project extension and project termination. The annual report must address the status of the previously reported conflicts and any changes to the management plan. The annual report shall specify whether the financial conflict is still being managed or explain why it no longer exists. It is due at the same time of the annual progress report, multi-year progress report or at the end of extension period. The annual report covers the period of time from the identification of FCOI to the end of current award year.

In case, during the period of the award, a new or newly-discovered FCOI is identified (included any FCOI of new Investigators who join an ongoing PHS-funded research or PHS-like funded project activity), the FCOI Official must submit a new FCOI report to the PHS or to the Sponsor within 60 days of determining that a FCOI exists. Where such FCOI report involves a Financial Interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed, FCSR is required to complete a Retrospective Review. When bias is found as a result of a Retrospective Review, a

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mitigation report must be promptly submitted by the FCOI Official to the PHS Awarding Component or Sponsor awarding component.

It is understood that if the failure of an investigator to comply with the current procedure or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS research or of the PHS-like funded project, FCSR promptly notifies the PHS Awarding Component or Sponsor of the corrective action to be taken. The PHS Awarding Component or Sponsor consider the situation and, as necessary, take appropriate action, or refer the matter to the FCSR for further action, which may include directions to the FCSR on how to maintain appropriate objectivity in the PHS research or of the PHS-like funded project. PHS or Sponsor may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS or Sponsor award or when the transfer of a PHS or Sponsor grant(s) involves such an Investigator.

In any case in which the HHS or equivalent Sponsor's office determines that a PHS-funded research project or an PHS-like funded project has been designated, conducted or reported by an Investigator with a FCOI that was not managed or reported by FCSR as required by this procedure and by the HHS Regulation imposed by PHS or Sponsor, FCSR shall require the Investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

6.4 TRAINING

FCSR research personnel, including collaborators, consultants or sub-recipients that do not have their own policy, must complete a training about this FCOI procedure prior to engaging in any PHS-funded research or PHS-like funded project . For Investigators who are new to FCSR the training shall be completed prior to the start of the PHS-funded research or of the PHS-like funded project activity.

All research personnel affected by the present procedure must receive a new training at least every four (4) years or immediately when any of the following circumstances apply:

- FCSR revises its Financial Conflict Of Interest policies or procedures in any manner that affects the requirements of Investigators;
- FCSR finds that an Investigator is not in compliance with FCSR FCOI management plan;
- For any new Investigator in FCSR.

The FCOI Official has to communicate on an ongoing basis an updated list of the Investigators to the TO. The TO is required to inform each Investigator about the need to complete the online FCOI training and to provide the needed instructions. Each Investigator has the responsibility to complete the training within the deadline specified by the TO. The FCOI Official and the GO are informed whenever the training is completed or if the Investigator fails to complete it and has to write this information down on a training register (**CTR_ PRO_008_004**).

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6.5 SANCTIONS

Failure of an Investigator to file a complete and truthful Financial Interests Disclosure Form or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with the FCOI Official, the FCOI Committee and any other appointed award monitoring body, will be sanctioned according to FCSR disciplinary code for employees and collaborators (PRO 005).

With regard to external sub-recipient organizations, a termination clause must be inserted in the agreement. The clause should specify that any breach in the FCOI disclosure obligations of the Sub-recipient institution may cause the termination of the contract.

6.6 PUBLIC ACCESS TO INFORMATION

This policy is published on FCSR institutional website in a publicly accessible area. In case of future modifications, the revised version will be available on the website within 30 days from its release.

The FCOI Official email address and office address are identified as the recipient addresses for public request for information under the PHS regulation and under this policy. The addresses are published on FCSR institutional website.

The FCOI Official must respond to any request for information about FCOI within 5 business days from the date the request for information is received. The FCOI Official notes in its written response that the information provided is current as of the date of the correspondence and is subject to updates which should be requested subsequently by the requestor.

Information related to any Investigator's disclosure of Financial Interests and FCSR's review of and response to such disclosure is available to HHS or equivalent Sponsor's office, promptly upon request, whether or not the disclosure resulted in the determination of a FCOI.

It is understood that the access to any information related to any Investigator's disclosure of Financial Interests and FCSR review of and response to such disclosure is possible exclusively in the manner allowed by current applicable Italian law.

6.7 CONTROL MATRIX

Process	Sub-process	Control ID	Aim	Control activity	Person in charge	Frequency of control	Documents
Disclosure, management and reporting of the FCOI in research	Disclosure of Financial Interests	CTR PRO_008_001	Ensure the initial and second disclosure of all the Financial Interests and that all the Sub-recipients have their own FCOI policy or agreed to comply to FCSR procedure	Check whether all the project team members disclosed their Financial Interests and all the Sub-recipients submitted the Sub-recipient FCOI agreement	FCOI Official	As soon as the names of the team members and of the Sub-recipients are known and in any case before the expenditure of any funds	Sub-recipient FCOI Agreement and Financial Interests Disclosure Form
Disclosure, management and reporting of the FCOI in research	Disclosure of Financial Interests	CTR PRO_008_001	Ensure any updated list of Project team members/sub-recipient organizations or updated disclosure of all the Financial Interests		FCOI Official	As soon as the names of the team members and of the sub-recipients are known	Sub-recipient FCOI Agreement and Financial Interests Disclosure Form
Disclosure, management and reporting of the FCOI in research	Disclosure of Financial Interests	CTR PRO_008_002	Ensure the annual disclosure of all the Financial Interests	Check whether all the project team members submitted their annual disclosure	FCOI Official	Annually prior to the submission of the annual/multi-year progress report or prior to an extension or in any case before the end of FCSR fiscal year (December 31)	Financial Interests Disclosure Forms
Disclosure, management and reporting of the FCOI in research	Review of Disclosure	CTR PRO_008_003	Ensure the respect of the management plan	Check whether the management plan is applied	FCOI Official	On an ongoing basis until the completion of the project	Management plan
Disclosure, management and reporting of the FCOI in research	Training	CTR PRO_008_004	Ensure that all the Investigators are informed about this procedure	Check whether all Investigators have been trained according to the training plan specified in this procedure	TO and FCOI Official	On an ongoing basis	Training Register and Certificates

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7 RECORDING AND ARCHIVING

The Financial Interest Disclosures Forms submitted by the Investigators and any other documentation related to the review and management of the FCOI is retained for at least three (3) years from the date the final expenditures report is submitted to the PHS or to the Sponsor. The only exceptions are the following, if applicable:

- if any litigation, claim, financial management review, or audit is started before the expiration of three (3) year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken;
- when records are transferred to or maintained by the HHS awarding agency or equivalent Sponsor agency, three (3) year retention requirement is not applicable to the recipient.

8 REFERENCES

- HHS Financial Conflict of Interest Regulation (42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94, as revised on August 2011);
- PRO 005 “Sistema Sanzionatorio del personale dipendente e dei collaboratori” (Disciplinary System/Code);
- FCSR Code of Ethics;
- FCSR Organization, Management and Control Model;
- FCSR-LG FCOIC 001 – Financial Conflict of Interests Guidelines;
- D.Lgs. 196/2003 “Code on the protection of personal data” and subsequent amendments or integrations.