

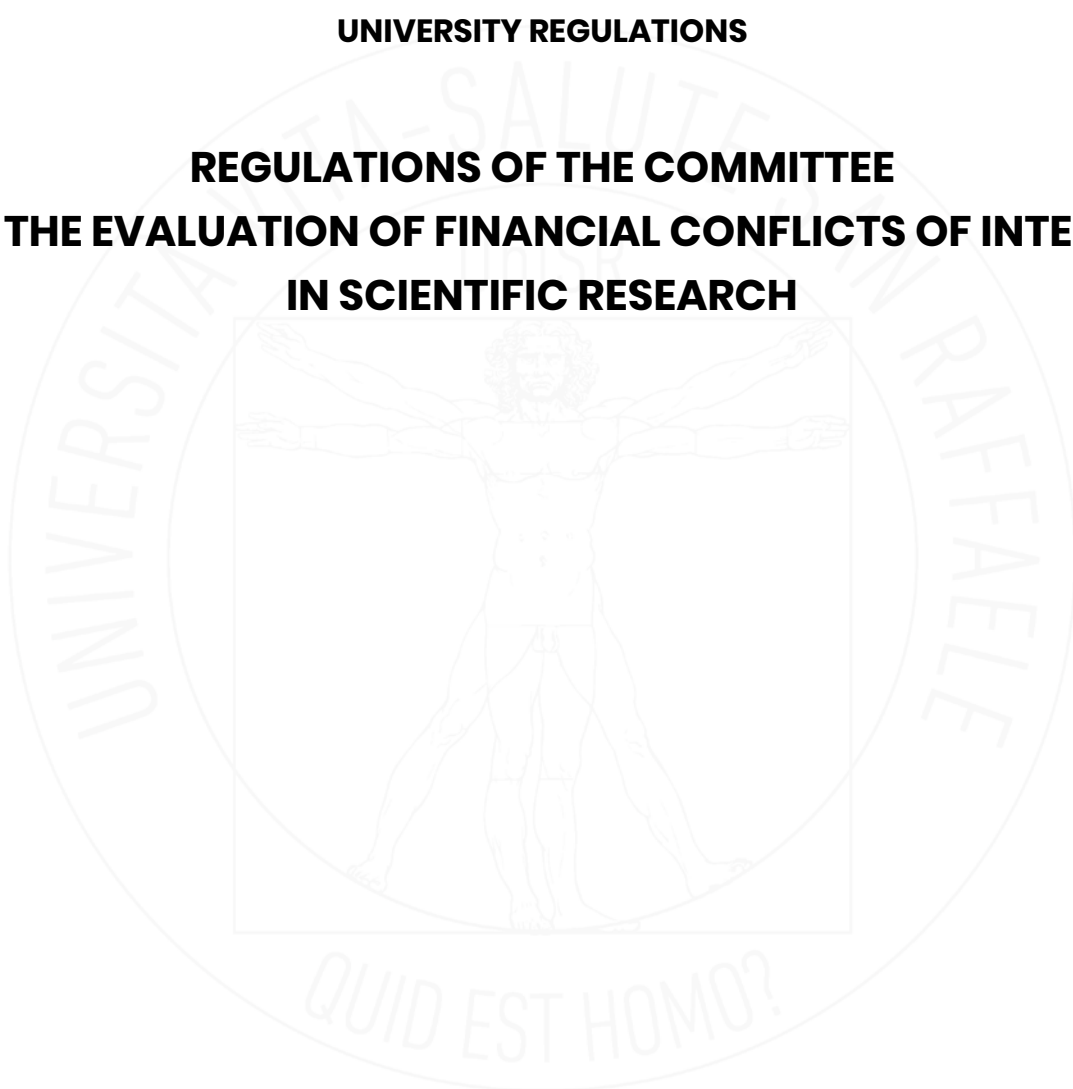


UniSR

Università Vita-Salute
San Raffaele

UNIVERSITY REGULATIONS

REGULATIONS OF THE COMMITTEE FOR THE EVALUATION OF FINANCIAL CONFLICTS OF INTEREST IN SCIENTIFIC RESEARCH



ISSUED WITH RECTOR'S DECREE NO. 7560 OF 31/03/2022

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1 Purpose and Scope

ART.1 Purpose and application

1.1 These Regulations govern the composition and operation of the Committee for the Evaluation of Financial Conflicts of Interest in Scientific Research established by Vita-Salute San Raffaele University and, in particular, identify its powers and functions in the field of research projects funded by international or national, private or public, profit or non-profit sponsors, requiring the application of rules and procedures concerning financial conflicts of interest.

2 Aim and objectives

ART.2 Background

- With a view to ensuring the utmost transparency in the conduct of its institutional activities, Vita-Salute San Raffaele University has adopted an Organisation, Management and Control System pursuant to Italian Legislative Decree no. 231 of 8 June 2001, as well as a Code of Ethics, which can be consulted at <https://www.unisr.it/ateneo/statuto-regolamenti>;
- again with a view to ensuring the utmost transparency, with specific reference to scientific research, Vita-Salute San Raffaele University has also decided to establish a “Committee for the Evaluation of Financial Conflicts of Interest in Scientific Research”, which is called upon to intervene and assess all funded research projects requiring an in-depth review and assessment of the existence of a financial conflict of interest as governed by these Regulations.

3 Abbreviations Acronyms Definitions

Abbreviation and definition	Description
FCOI Committee	Committee for the Evaluation of Financial Conflicts of Interest in Scientific Research.
FCOI	Financial Conflict of Interest, i.e. an actual and significant financial interest that directly and significantly influences the planning, conduct or reporting of a specific research project.
FCOI Official	A person appointed by the UniSR Board of Directors to manage all administrative and procedural requirements under these Regulations (in particular, gathering information on the financial interest of the members of the team involved in the research project and assessing the significance of any financial interests).
FCOI Assistant	A person appointed by the FCOI Official to carry out operational activities in financial conflict of interest management processes, to assist the FCOI Official and/or the FCOI Committee.

Management Plan	Financial Conflict of Interest Management Programme developed by the FCOI Official and submitted to the FCOI Committee for review and approval.
Retrospective Review	FCOI assessment report regarding the impact on a research project, prepared by independent researchers, appointed by the FCOI Committee for this purpose.
SFI	Significant Financial Interest, i.e. a potential financial interest that could influence the planning, conduct or reporting of a specific research project.
UniSR	Vita-Salute San Raffaele University.

4 Provisions of the Regulations

ART.3 Composition

3.1 The FCOI Committee consists of 3 (three) full members, appointed by the UniSR Board of Directors, with proven experience and professional expertise in the field of scientific research and/or company organisation.

3.2 Three (3) alternate members must also be appointed, again by the UniSR Board of Directors, from among the persons meeting the requirements set forth in the preceding subsection.

ART.4 Chair of the FCOI Committee

4.1 During its first meeting, the FCOI Committee appoints from among its members, a Chair, who is entrusted with the management and coordination of the FCOI Committee, such as convening meetings, setting agendas, and ascertaining that the meetings of the FCOI Committee are duly constituted and properly conducted and the minutes are properly drafted.

ART.5 Loss of FCOI Committee membership

5.1. The members of the FCOI Committee cease office three (3) years after their appointment.

5.2. In the event of the resignation or early removal from office of a member of the FCOI Committee, he/she shall be replaced by an alternate member in order of appointment; the latter shall remain in office until the UniSR Board of Directors appoints the full and alternate members necessary to re-establish the composition of the FCOI Committee in accordance with the provisions of Article 3.

5.3. In the event of a serious impediment to participation in one or more meetings of the FCOI Committee or of incompatibility with the items on the agenda, the alternate member in order of appointment shall take over, for the meetings for which there is an impediment or incompatibility only.

5.4. If replacement by alternate members does not allow for the integration of the FCOI Committee, the Board of Directors shall replenish the FCOI Committee without delay.

ART.6 Functions of the FCOI Committee

6.1 The FCOI Committee ensures compliance with the provisions on financial conflicts of interest in funded research projects.

In particular, the FCOI Committee has the task of reviewing and assessing the disclosures required by the Procedure for the management of financial conflicts of interest in research activities, adopted by UniSR and provided by the parties responsible for the research project in order to determine whether, with regard to a given project, there is a financial conflict of interest that could affect the proper planning and conduct of the research project.

The FCOI Committee, therefore:

- deliberates on significant financial conflicts of interest;
- approves the Management Plan;
- approves corrective plans to eliminate or mitigate the effects of a significant financial conflict of interest.

6.2 In the case of SFIs, the FCOI Official submits the disclosures to the FCOI Committee for evaluation under the terms of the Procedure adopted at UniSR and more precisely:

- a) where possible, before the researcher submits a grant application for a research project;
- b) in any case, before the researcher commits the funds allocated to the research project;
- c) in the case of research projects that have already started, within 60 days after notification by the FCOI Official for new interests disclosed by the researchers and, in any case, before submitting the periodic Research Project progress report to the funding agency/funding body;
- d) within 45 days of the completion of the Retrospective Review, as defined by the Procedure adopted by UniSR.

6.3 Following the review and assessment of the disclosures, if an FCOI is identified, the FCOI Committee approves the dedicated Management Plan prepared by the FCOI Official to manage the financial conflict of interest.

6.4 Whenever an FCOI has not been identified or managed in a timely manner for any reason (e.g., the FCOI disclosure was delayed or the researcher failed to disclose a significant financial interest that was later identified as an FCOI), or if the Management Plan approved by the FCOI Committee has not been complied with, a Retrospective Review shall be undertaken to determine whether and how the research activity (in its planning, conduct and/or reporting phases, for example) has been influenced and/or affected by a significant financial interest. The retrospective review must be delegated to one or more independent researchers appointed by the FCOI Committee. If an FCOI is identified as a result of the Retrospective Review, the FCOI Committee will approve corrective actions identified by the FCOI Official to eliminate or mitigate the effect of the distortion.

6.5. In order to perform its functions, the FCOI Committee may avail itself of the cooperation of UniSR staff with the necessary professional requirements.

6.6. In the event of the untimely detection of an FCOI and if necessary, the FCOI Committee will report non-compliant conduct in research activities to the competent body for the relevant assessments and the imposition of any sanctions.

ART.7 Meetings and deliberations

7.1 The FCOI Committee meets whenever there are disclosures in which significant financial interests (SFI) are identified for evaluation, in accordance with Article 6.2 and the relevant Operational Procedure on the Management of Financial Conflicts of Interest in Research Activities.

7.2 The FCOI Committee may also be convened if at least two of its members so request.

7.3 Meetings of the FCOI Committee are convened by its Chair by notice sent by e-mail to the other members at least 5 days before the date set for the meeting. In cases of proven urgency, the convocation period is reduced to 3 days. The notice shall identify the date, place and time of the meeting, the agenda as well as any alternative means of intervention using ICT. Any documentation (by way of a non-limiting example, the disclosures made by the researchers concerned and/or other evidence on which the assessment of the significance of the interest was based) may be sent to the members of the FCOI Committee by the FCOI Official and/or the FCOI Assistant prior to the meetings.

7.4 Meetings of the FCOI Committee may be held using ICT or by video conference provided that:

- the Chair is able to ascertain the identity of the participants, moderate the proceedings of the meeting, and ascertain and proclaim the results of voting;
- those present are allowed to participate in the discussion and simultaneous voting on the items on the agenda, as well as to peruse, receive or transmit documents.

Compliance with these procedures must be recorded in the relevant minutes.

7.5 Meetings of the FCOI Committee shall be attended by the FCOI Official.

7.6 The FCOI Committee is duly constituted when the majority of its members are present. Any absences by members must be justified and promptly disclosed in writing to the Chair.

7.7 Meetings of the FCOI Committee and its resolutions are valid, even if not formally convened, when all full members in office attend.

7.8 Resolutions of the FCOI Committee are adopted by an absolute majority of those present; in the event of a tie, the Chair has the casting vote. This is without prejudice to the right of any dissenting member to have the reasons for his/her dissent recorded in the minutes.

7.9 The members of the FCOI Committee are obliged to abstain from voting in cases where they have a conflict of interest with the subject matter of the deliberation, giving appropriate justification. In this case,

the Chair shall adjourn the meeting to another date, to be attended by the alternate members in order of appointment, replacing the full members with a conflict of interest.

7.10 At the opening of each meeting, the Committee appoints a Secretary as proposed by the Chair. The Secretary is responsible for drawing up minutes of the meetings and deliberations, which must be signed by the Chair and the Secretary, and filed by the Chair.

ART.8 Confidentiality

8.1 Each member of the FCOI Committee and all persons it involves in the management of financial conflicts of interest in research activities shall keep confidential any information they become aware of in the course of their relevant activities. The members of the FCOI Committee and all the aforesaid persons shall refrain from using confidential information for purposes other than those set forth in the Procedure on the Management of Financial Conflicts of Interest in Research Activities. All information, material, documents and reports shall be stored by the FCOI Official and/or the FCOI Assistant in a dedicated computer and/or paper database with restricted access and the storage of the data contained therein shall be carried out in compliance with the requirements of Legislative Decree No. 196 of 30 June 2003 and the GDPR, Regulation (EU) 2016/679. The data and information stored in the database shall be made available to entities outside the FCOI Committee upon request to the FCOI Official and subject to verification of the requirements for access thereto.

ART.9 Amendment of the Regulations

9.1 Any amendments to these Regulations, where consistent with the provisions of the Procedure on the Management of Financial Conflicts of Interest in Research Activities, may only be made by the same procedure by which the Regulations were adopted.

The Italian version of this Regulations is the only legal means of communication of the relative contents and in case of dispute, the Italian version shall prevail.