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1. Scope:

This document defines the FCSR policy on dealing with and reporting allegations of possible Research Misconduct involving United States Public Health Service (USPHS). The present policy is available on the FCSR web site <http://www.fondazionesanraffaele.it/>.

2. Applicability:

All members of the FCSR research community involved in research activities funded by USPHS.

3. Definition and abbreviation:

Allegation	Any communication received by OdV concerning potential research misconduct
Research misconduct	<p>Research misconduct is defined as fabrication, falsification, plagiarism, or other serious deviation from commonly accepted practices in the relevant scientific community for proposing, performing or reviewing research, or in reporting research results.</p> <ul style="list-style-type: none"> • Fabrication is making up data or results and recording or reporting them. • Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. • Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit. • Serious deviation from accepted practices includes but is not limited to: <ul style="list-style-type: none"> - Abusing confidentiality (i.e. peer review process) - Stealing, destroying, or damaging the research property of others with the intent to alter the research record; and - Directing, encouraging, or knowingly allowing others to engage in fabrication, falsification, or plagiarism. <p>Research misconduct <u>does not include</u> honest error or differences in opinion.</p>
FCSR	Fondazione Centro San Raffaele (San Raffaele Foundation)
HR Department	Human Resources Department (provided by San Raffaele Hospital)
OdV	Organismo di Vigilanza (Supervisory Body pursuant to legislative decree 231/2001) of FCSR
ORI	Office of Research Integrity (United States)
OSR	Ospedale San Raffaele (San Raffaele Hospital)
USPHS	United States Public Health Service

4. Description:

As a Foreign Institution receiving US federal research funds, FCSR must sign and submit to ORI the “Statement on Dealing with Allegations of Research Misconduct Under Public Health Service Research-related Activities for Foreign Institutions”, a legally binding statement regarding managing and reporting possible research misconduct when USPHS funds are involved (the Statement submitted to ORI is available on the FCSR web site <http://www.fondazionesanraffaele.it/>).

For this purpose, FCSR has incorporated into its policies and procedures the ORI approach for dealing with and reporting possible research misconduct when USPHS funds are involved, as follows:

- a. FCSR has designated its OdV for receiving and managing any allegation concerning potential research misconduct and develop procedures for use by research staff or

others who wish to report potential research misconduct involving USPHS funds;

- b. Research staff or others who wish to report a potential research misconduct involving USPHS funds must send an email to the OdV at the following email account: organismodivigilanza@fondazioneosanraffaele.it or send a letter to: Organismo di Vigilanza di FCSR, Via Olgettina 60, 20123 – Milan (Italy);
- c. OdV will notify the U.S. Office of Research Integrity (ORI) when an allegation of potential research misconduct involving USPHS funds is received;
- d. OdV will then work with ORI or other appropriate offices of the U.S. Department of Health and Human Services (HHS) to develop and implement a process for responding to the research misconduct allegation that is consistent with U.S. Federal regulation, 42 CFR Parts 50 and 93; OdV will investigate the potential research misconduct with the support of the HR Department, Scientific Directorate, and internal or external independent researchers;
- e. HR Department will submit appropriate reports (in English) to ORI, previously validated by OdV and Scientific Directorate, that describe the process followed in conducting the investigation, the evidence on which the conclusions of the investigation are based, and if a finding of research misconduct is made, the administrative actions that are taken against the respondent or any other action to be undertaken in compliance with applicable regulation;
- f. HR Department will submit the “Annual Report on Possible Research Misconduct” to ORI by April 30th of each year, previously validated by OdV and Scientific Directorate.

5. References:

- U.S. Federal regulation 42 CFR Parts 50 and 93 (available on the ORI web site at <http://ori.hhs.gov>)
- ORI “Statement on Dealing with Allegations of Research Misconduct Under Public Health Service Research-related Activities for Foreign Institutions” (the template is available on the ORI web site at <http://ori.hhs.gov>)
- FCSR Code of Ethics
- FCSR Organization, Management and Control Model