Addressed to: General Directorate FCSR, OSR Research Area

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Drawing up	Development	Review	Approval
OSR RIO: R. Buccione	OSR RIO: R. Buccione OSR Scientific Director: G. Martino OSR Human Resources Director: A. Limardi	OSR Organization & Quality Office: V. Parezanovic OSR Quality, Accreditation & RM: M.P. Garancini OSR Internal Audit Division: A. Locane	General Director: *G. Banfi*

1. SCOPE

Fondazione Centro San Raffaele (FCSR) values the honesty and integrity of its research community in accordance with its mission of conducting innovative fundamental and clinical research. FCSR is committed to ensuring the quality, trustworthiness and reproducibility of the research conducted by its investigators, by upholding high standards of integrity. FCSR also works to foster an environment in which the responsible conduct of research is explicitly discussed and encouraged

Research misconduct (RM) is a breach of FCSR standards and of those expected by FCSR funders and sponsors, a betrayal of the trust placed in FCSR by the public, and the failure to comply with the high expectations of the scholarly community for research integrity (RI) and accurate and experimentally-supported communication. FCSR commits to vigorously investigating, and if warranted, taking action on any credible allegation of RM, as outlined in this document.

The procedure described herein explains the handling of allegations of RM; its purpose is remedial with respect to the scientific record, the reputation of FCSR and its investigators, and the trust placed in them by funders and the public.

2. APPLICABILITY

This procedure is intended for all Investigators actively and directly participating in scientific research activities on FCSR premises. The term "Investigator" used herein therefore refers to all individuals involved in FCSR research projects and activities, regardless of their contractual profile, job title or affiliation.

Any disciplinary action(s) consequent to findings of Research Misconduct (RM) are the responsibility of the Human Resources Office and shall be commensurate with the seriousness of the RM, including, without limitation, the degree to which the RM was knowing, intentional or reckless; was an isolated event or part of a pattern; or had significant impact on the research record, research subjects, other researchers, the FCSR, other institutions or the public.

The guiding principle for this procedure is to apply maximal transparency, which includes acting in a timely fashion in case of alleged RM with fair, thorough and nimble procedures, including if the case, taking appropriate action.

2.1 Legal Disclaimer

FCSR retains the exclusive property of this document, which is published on the FCSR institutional website; any other version is to be considered as an unverified working copy. FCSR personnel are required to verify that the copy of the procedure in their possession matches the official and most updated version.

FCSR management is required to:

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

This document is an internal control procedure, therefore binding for FCSR personnel, and it is an operational regulation tool, also finalized to the adoption of the provisions set forth in the Organization, Management and Control Model ex. Legislative Decree N.231/01.

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

The correct implementation of this internal control procedure is periodically evaluated by the Ospedale San Raffaele (OSR) Internal Audit Division and by the OSR Supervisory Body established pursuant to Legislative Decree N. 231/2001.

3. ABBREVIATIONS, TERMS AND DEFINITIONS

ABBREVIATIONS AND TERMS	DEFINITIONS
GD	General Director
DRP	Detrimental Research Practice
IACUC	OSR, Institutional Animal Care and Use Committee
HRD	OSR, Human Recourses Department
HRIO	OSR, Head of the Research Integrity Office
OdV	OSR Organismo di Vigilanza (OSR Supervisory Body)
O&Q	OSR Organisation and Quality Office
RI	Research Integrity
RICE	Research Integrity committee of experts
RIO	OSR Research Integrity Office
RM	Research Misconduct

4. RESPONSIBILITIES

As specified in §6

4.1 Research Integrity Committee of Experts

In consultation with the General Director and the OSR Scientific Director, the RIO will have in place a RI committee of experts (RICE) formed by a number of OSR/FCSR scientists and officials who have clear expertise in a number of disciplines (e.g. imaging, IT, biochemistry, animal studies, clinical studies, statistics, normative, financial etc.). Specific RICE members, depending on the type of allegation, may therefore be called upon to participate in preliminary assessments (§6.2), preliminary enquiries (§6.3) and/or investigations (§6.4).

The Head of the RIO (HRIO), in consultation with the General Director and the OSR Scientific Director, nominates RICE members and establishes their turnover depending on specific needs. By definition, there is no limit on the number of RICE members at any given time, nor a time limit for serving on the RICE.

5. MATERIALS AND EQUIPMENT

Not applicable.

6. DESCRIPTION OF ACTIVITIES

6.1 Making an allegation of possible RM

1. Anyone who has witnessed an occurrence of possible has an unambiguous obligation to report it as outlined below.

2. If the alleged RM has occurred within the research group/clinical unit of the complainant, s/he is encouraged to confidentially contact their immediate superior[1]. If for any reason, the complainant is not comfortable in reporting the occurrence to their immediate superior[2], the HRIO should be contacted instead by email, telephone or in person. If the alleged RM has occurred outside the research group/clinical unit of the complainant, it should be reported directly to the HRIO. All allegations of RM received directly by other individuals, are directed to the HRIO.

3. While confidentiality will be assured, it must be understood that if the allegation is further pursued, it may become later necessary to disclose the identity of the complainant to a limited number of relevant parties, including eventually to the accused (respondent), if essential to exercise their right to defend themselves. This provision is also valid for

[1] For instance, a group leader in case of a post-doc or PhD student complainant, a division director for a group leader complainant or a head physician for a medical specialty student.
[2] It is not appropriate, for instance, for a complainant to report an allegation of RM to his/her immediate superior if the latter is also allegedly party to the occurrence.

complainants who choose the full anonymity option guaranteed by Italian law[3]. Should the complainant discuss the allegation at any time, including before filing it with FCSR, with additional parties beyond their immediate superior or HRIO, FCSR cannot ensure confidentiality.

4. To ensure fairness, avoid conflict escalation, and to protect the research environment, FCSR strongly discourages personal initiatives such as directly challenging a respondent with allegations of detrimental research practice or RM. Again, if undertaken, such initiatives may compromise the FCSR's ability to ensure confidentiality and possibly, to guarantee an effective investigation.

5. Allegations must be raised in good faith and must be supported by sufficient and direct knowledge of the facts. A reckless accusation of RM, especially by deliberately making false statements, is in itself a form of misconduct and may be acted upon.

   Complainants who in good faith give specifiable information regarding suspected RM will be protected from any prejudice or retaliation concerning their own academic and career advancement; the FCSR pledges to take appropriate measures to ensure this protection as is also is required by law (§7)[3]

6. Anonymous reports will be considered and the anonymity of the person reporting it (complainant) will be protected and remain unknown to all parties, as allowed by current Italian whistleblowing law[3] as soon as the appropriate procedures come into effect. However, knowing the identity of the complainant allows a more efficient process.

7. The FCSR Research Integrity office (RIO) is duty-bound to follow-up on anonymous whistleblowing on social media and internet forums (e.g. pubpeer.com) in the interest of transparency and the reputation of the FCSR and its investigators. FCSR investigators have the responsibility to bring anonymous whistleblowing cases they may learn of, whether or not concerning themselves, to the attention of the HRIO. FCSR investigators are strongly advised not to engage in discussions, rebuttals, denials, etc. on online forums of social media without prior discussion with the HRIO.

8. The RIO may also initiate an unsolicited assessment of possible RM by any current or former FCSR investigator or related to any research activity carried out by any current or former FCSR investigator, including in collaborative studies, based on well-grounded suspicions and after consultation with the General Director and the OSR Scientific Director. In this case, there is no obligation to disclose such internal initiative until step 6.2.1 of this procedure is completed.

9. Any individual who has questions/doubts on RCR practices and/or what might entail a possible RM or detrimental research practice (DRP) is advised to contact the HRIO for counsel and advice. Such requests for clarification remain confidential, are not reported to other officers, and are not construed as allegations.

6.2 Preliminary assessment of alleged RM

1. The HRIO, in consultation with the General Director and OSR Scientific Director, shall carry out a preliminary assessment of the technical merits of the allegation and, depending on the circumstances, endeavour to reach an informal resolution within 10 workdays. This informal process is not subject to the procedures set forth below, other than the listed

[3] Italian "whistleblowing" law 30/11/2017 n° 179, G.U. 14/12/2017. See also §7 "Safeguards" further below.

safeguards (§7), and will not entail contacts with the respondent. The HRIO may draw, however, on the expertise of RICE members under commitment to confidentiality.

2. If the allegation is found to have merit or should the informal resolution fail to provide a clear indication, the complainant shall be invited to file a formal allegation of RM to the RIO or if s/he so prefers, to the FCSR Supervisory Body (Organismo di Vigilanza; OdV)[4]. The latter will immediately transmit the case to the RIO for further action.

3. The HRIO upon receipt of the formal complaint, will initiate a preliminary inquiry (§6.3) to establish the merits of the allegation. The HRIO shall inform the OdV of all directly received formal allegations of RM.

4. Should the allegation be found instead to not have merit as RM, but nevertheless entail a possible non-conformity, O&Q will activate pertinent corrective actions.

6.3 Preliminary inquiry on alleged RM

1. Upon receiving a formal allegation of RM (§6.2.2), and should therefore the preliminary assessment (§5) have established that it has merit and should the attempt at informal resolution have failed, the HRIO, upon consultation with the COO for Research and the Scientific Director, will inform the following of the initiation of a preliminary inquiry (this section):

    a. Director of HRD
    b. Director of OSR Internal Audit
    c. Director of the complainant's Division/Research Centre/Research Institute.

2. The HRIO, in consultation with the General Director and the OSR Scientific Director will call upon a minimum of three appropriate RICE members to establish the technical merits of the allegation received and to determine whether it meets FCSR's definition of RM[5].

3. The preliminary inquiry, on a case-dependent basis, might require appropriate measures to secure the relevant primary data to avoid tampering with any evidence and/or secure the proceedings. Such measures may include, and are at not limited to computers, email accounts and data sharing services. The procedures and technical means to exercise this right, including the assistance of legally authorised digital forensics, are already in place and will be undertaken in consultation with the OSR IT, HRD and Legal Offices and may include unlimited access to and /or physical sequestration of computers, lab books and other FCSR property.

4. The preliminary inquiry phase might also require direct interviews with the complainant(s), respondent(s), material witness(es) and other relevant parties identified as having information regarding aspects of the allegation but should not require disclosure of the identity of the complainant to the respondent at this early stage. Appropriate safeguards (see below) apply to all interested parties, who in turn are bound to confidentiality on the proceedings. As in §6.1.3, in case of breach of confidentiality by the complainant, FCSR cannot guarantee the protection of anonymity.

5. The preliminary inquiry must be concluded by providing an indication for 1) dismissal of the

[4] As set forth in the FCSR internal procedure
[5] LG RIO 001 FCSR Research Integrity Guidelines

allegation or whether 2) a full investigation is warranted, within 40 working days of the receipt of the allegation, unless otherwise established by law or the applicable national collective employment contracts.

6. The conclusions of the preliminary inquiry do not constitute a finding and therefore do not establish culpability or assign remedial or disciplinary actions. As such they are not subject to appeal.

6.4 Investigation of alleged RM

Should the preliminary inquiry (§6.3) indicate that the allegation has merit, the RIO will escalate by initiating an investigation. If other scientific institutions are involved, they will be asked for their cooperation in investigating the allegations.

The HRIO, upon consultation with the General Director and the Scientific Director, shall immediately and confidentially inform the following parties, all duty-bound to confidentiality, of a pending investigation:

1. Director of OSR Internal Audit
2. Director of OSR HRD
3. The complainant
4. The respondent
5. The immediate superiors of both the complainant and the respondent, including their Research Directors

The HRIO, shall also confidentially inform the following parties of a pending investigation:

1. In case of collaborative work, the Institution(s) where the collaborators work.
2. If the specific policies and contract requirements so prescribe, the funding agency or other third party supporting the work

The General Director shall consequently appoint an investigation panel composed as follows, within 10 working days of the conclusion of the preliminary inquiry:

1. General Director (ex officio; Chair)
2. Director of OSR HRD (ex officio)
3. OSR Scientific Director (ex officio)
4. At least three experts in technical aspects of import to the investigation from the OSR/FCSR scientific staff; ideally members of the RICE, including those that might have already participated in the preliminary inquiry.

The first 3 individuals may nominate a high-ranking officer (with appropriate expertise), for instance their deputies, to represent them in the hearings and are not obligated to participate in all hearings. **The HRIO is to be kept informed on the proceedings but will NOT directly participate in the investigation** unless specifically invited to do so by the Chair. A non-FCSR/OSR expert may be included if s/he has the requisite expertise not otherwise available at OSR/FCSR, provided s/he signs an appropriate non-disclosure agreement.

If the RM allegations pertain to animal use, and/or treatment of human materials or patients, the investigation panel will be integrated with the participation of the Chair of the OSR IACUC and/or Ethics Committee, respectively.

The investigation panel shall:

1. Take reasonable steps to ensure impartial and unbiased investigation
2. Interview the complainant(s), respondent(s), material witness(es) and other relevant parties identified as having information regarding aspects of the allegation.
3. Analyse all research materials and evidence presented by the complainant(s) and the respondent(s).
4. Further pursue all significant leads and issues discovered that relate to the investigation.

Appropriate safeguards (§6.6) apply to all interested parties, who in turn are bound to confidentiality on the proceedings.

6.5 Remedial actions

The findings of the investigation panel are to be reported in a detailed investigation report within 60 working days of the establishment of the investigation panel and shared with the OdV. The complainant and the respondent have the right to file a circumstantiated appeal within 20 working days, to which the investigation panel must respond within 30 working days with a final non-appealable decision.

In case of a finding of culpable RM, the following remedial actions pertaining to the scientific domain shall be taken care of the RIO:

1. **Scholarly communications**. For findings of culpable scientific misconduct, and depending on the type of RM, a recommendation will be issued to the scholarly journal(s) that the submitted manuscripts and/or publications in question be corrected (e.g. in case of authorship disputes or compromised data which however do not impact on the conclusions of the paper), withdrawn if submitted but not yet published, or retracted if published. In case of published work, final decisions regarding the possibility of correcting and re-submitting the work lie solely with the publisher and are beyond the responsibility and influence of FCSR.

2. **Academic dissertations and theses**. For findings of culpable scientific misconduct, and depending on the type of RM, a recommendation will be issued to the appropriate University officials that the academic dissertations in question be corrected if possible, withdrawn or retracted. Final decisions regarding the possibility of correcting and re-submitting the dissertation lie solely with the University and are beyond the responsibility and influence of FCSR. Also, revocation of any academic titles gained through RM lies with the University (see below).

3. **Research Funding.** For findings of culpable scientific misconduct, and depending on the type of RM, a recommendation will be issued to the funder that the grant application in question be corrected or withdrawn if submitted but not yet approved or retracted if already approved for funding. In the latter case, should the funder request a partial or full return of the disbursed funds, the FCSR shall reserve the right to claim appropriate compensation from the investigator at fault.

4. If the scientific data are found to be significantly compromised but the investigation fails to lead to retrieval of the original data, it might not be possible to ascertain deliberate falsification. However, as a precautionary measure and in the interest of the scientific community, the findings will be fully disclosed to the scholarly journal/funding agency/University, who shall make a final decision regarding the withdrawal/retraction of the manuscript/paper.

5. Notwithstanding all the above, all parties directly affected by findings of RM, e.g., scientific journals, funding agencies and/or other Institutions, must be promptly informed of the outcome of the investigation. If the publication(s) had gained relevant significant popular media coverage, and in general, in case of publications focused on human disease and health, the FCSR Marketing and Communications Director may have to consider informing the general public via appropriate channels.

The outcome of the investigation may inform FCSR and the University to take further action. In fact, the above remedial actions do not exclude further criminal and/or employment-related and/or labour law-related disciplinary actions in accordance with disciplinary, labour, criminal, civil, administrative, budgetary, or academic examination laws. These however, extend beyond the remit and scope of this policy are disciplined by PRO 005 (applicable to FCSR employees and collaborator)s or otherwise specifically regulated by the type of contract, and may include:

1. Official reprimand
2. Removal from a research project
3. Direct supervision
4. Temporary or indefinite suspension from research activities
5. Temporary or indefinite suspension from work
6. Termination of employment or contract

After the finding of misconduct, the General Manager and the OSR Scientific Director, with the support of the RIO and O&Q, may consider further preventive actions such as for instance, verify the validity, and eventually block the publication of, further manuscripts which might have been based on the incorrect data. Furthermore, and if the case, the pertinent corrective and/or preventive actions will be activated to ensure ameliorative actions.

6.6 Safeguards

1. **Confidentiality:** To the extent possible consistent with a fair and thorough investigation and as allowed by law, knowledge about the identity of a complainant(s), a respondent(s) and any witness(es) shall be limited to those persons identified in this policy and others who need to know and all written materials and information with respect to any proceedings shall be kept confidential.

2. **Conflicts of Interest:** Reasonable steps will be taken to ensure that all individuals responsible for carrying out any part of the procedures described in this policy do not have unresolved financial or non-financial conflicts of interest (Appendix 1) with the complainant(s), the respondent(s) and any witness(es).

3. **Safeguards for complainants:** In addition to any other safeguards provided for in this policy and by law[3], the following safeguards shall be provided to a complainant:
   a. If an allegation has been made by a complainant in good faith, the University shall ensure that:
      i. the complainant is treated fairly and reasonably;
      ii. all reasonable and practical efforts are made to protect the complainant from potential or actual retaliation;
      iii. the procedures described in this Policy are fair and objective; and
      iv. diligent efforts are made to protect or restore the position and reputation of the complainant.
   b. During an Investigation, the Complainant shall have the right to identify persons who have information regarding any relevant aspects of investigation to be interviewed by the *investigation panel.*

However, should the investigation panel determine that a complainant has made an allegation for malicious reasons, or was otherwise not acting in good faith in making such allegation, a recommendation will be made that appropriate action be taken against such complainant for research misconduct.

4. **Safeguards for respondents:** In addition to any other safeguards provided for in this policy, the following safeguards shall be provided to a respondent:

   a) The respondent is assumed not to have committed Research Misconduct unless and until a finding of such has been made in accordance with this policy and should be protected from penalty and public knowledge of any accusation until judged responsible. The respondent in turn shall cooperate with the administrative procedures described in this policy, including by providing information, research records and evidence to the institutional representatives referred to herein when so requested.
   b) The FCSR shall not impede the ability of a respondent to continue to do his/her work and shall ensure that other disciplinary or adverse action not be taken, during the period of any Inquiry or Investigation, unless the investigation panel determines that there are compelling reasons to temporarily suspend the respondent's work and/or take other action such as a precautionary seizure of research records during all or a portion of such period.
   c) During a preliminary inquiry, the respondent shall have the right:
      i. to have reasonable access to the data and other evidence supporting the allegation; and
      ii. to respond to the allegation orally and in writing.
   d) During an Investigation, the respondent shall have the right:
      i. to appear before the *investigation panel* to present testimony on his/her behalf;
      ii. to identify persons who have any information regarding any relevant aspects of the Investigation;
      iii. to be interviewed by the *investigation panel*;
   e) After an investigation, the respondent shall have the right to review the final investigation report.
   f) The FCSR shall take all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of any respondent when no finding of RM is made.

5. **Safeguards for witnesses.** If a witness has cooperated with a RM proceeding in good faith, the FCSR shall ensure that:
   a. all reasonable and practical efforts are made to protect such witness from potential or actual retaliation; and
   b. diligent efforts are made to protect or restore the position and reputation of such Witness.

6. **Safeguards for RICE and investigation panel members**. The FCSR shall ensure that:
   a) all reasonable and practical efforts are made to protect RICE or investigation panel members from potential or actual retaliation; and
   b) diligent efforts are made to uphold the position and reputation of such members.

7. RECORDING AND ARCHIVING

The RIO, for the General Manager, will preserve and store full copies of all documentation involving each allegation, up to step 6.3 included, for at least 10 years. The documentation pertaining to steps from 6.4 on, if occurring, will be preserved and stored care of HR, for at least 10 years.

8. REFERENCES

LG RIO 001 OSR Research Integrity Guidelines
PRO 005 - Sistema Sanzionatorio del Personale Dipendente e dei Collaboratori FCSR (FCSR Disciplinary Code)
PRO 004 - Gestione delle segnalazioni all'OdV e alla Direzione del Personale (Informing and reporting to the Supervisory Body and OSR HR Department)
Policy 001 - Policy on Dealing with Allegations of Research Misconduct involving USPHS funds
Leggi in materia giuslavoristica (Italian Labor and Employment legislation)
CCNL - contratto collettivo nazionale di lavoro applicato / in vigore (Italian Collective Bargaining Agreement)
Codice Etico FCSR (FCSR Code of Ethics)
Modello di Organizzazione, Gestione e Controllo di FCSR (FCSR Organization, Management and Control Model)
2005/251/CE - Raccomandazione della Commissione dell'11 marzo 2005 riguardante la Carta europea dei ricercatori e un codice di condotta per l'assunzione dei Ricercatori (Commission Recommendation of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers)

8.1 Sources

The following sources are acknowledged in the compilation of the FCSR procedure for the handling of alleged RM.

1. European Code of conduct for Research Integrity http://www.allea.org/wp-content/uploads/2017/03/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017-1.pdf
2. Charité-Universitätsmedizin Berlin, Germany. Statute "Ensuring Good Scientific Practice" *from 20 June 2012 (AMB. Charité No. 092, p. 658) in the version of 31 May 2014*
3. Northwestern University, USA Policy for Reviewing Alleged Research Misconduct https://sites.northwestern.edu/orintegrity/files/2017/06/ORI_Misconduct_Policy_FINAL_170630-24schs9.pdf
4. Columbia University, USA. Institutional Policy on Misconduct in Research http://www.columbia.edu/research/policy_misconduct.pdf
5. The Extent and Consequences of P-Hacking in Science http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002106
6. Italian "Whistleblowing" law 30/11/2017 n° 179, G.U. 14/12/2017.