ISTITUTO DI RICERCHE
FARMACOLOGICHE
MARIO NEGRI · IRCCS

CODE OF CONDUCT FOR THE RESEARCH INTEGRITY AT THE MARIO NEGRI INSTITUTE FOR PHARMACOLOGICAL RESEARCH - IRCCS

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CONTENTS

Introduction

Respect for the principles and standards of research integrity is a guarantee of its quality and helps amplify the importance of science. It also reinforces society's expectations. This has far-reaching consequences on the developments of research, hence on society's wellbeing. Respect for the principles of research integrity therefore lays the ground for high-quality research projects coherent with ethical principles and values, deontology and nationally and internationally recognised standards. The principles of integrity in research – reliability, honesty, respect and responsibility – should inspire all the steps in research, guiding Researchers (see Article 2) when their work involves practical, ethical or intellectual challenges from each specific sector.
This Code of Conduct for the Research Integrity (referred to hereinafter as the "Code") defines the basic rules for personnel employed at the ISTITUTO DI RICERCHE FARMACOLOGICHE MARIO NEGRI - IRCCS (hereinafter, "IRFMN"), applying correct practices inspired by the principles of integrity.

IRFMN adopts the present Code in application of the Italian Legislative Decree no. 200, 23 December 2022, entitled *"Riordino della disciplina degli Istituti di ricovero e cura a carattere scientifico"* (Re-order of the discipline of Scientific Institutes for Research, Hospitalization, and Healthcare (IRCCS)). This came into force in 2022 and involved the introduction, in Article 8 of the previous Decree no. 288/2003, of a new para. 5-bis, which specified that "*the Institutes, with reference to Law no. 62, 31 May 2022, guarantee that research and care conform to the principles of* ***correctness, transparency, equity, responsibility, reliability and completeness,*** *recognised internationally. They publish all their data and the sources of research truthfully and objectively, so that its truth and reproducibility can be checked, especially regarding the accuracy of the data presented. With this in mind, to guarantee the assessment of scientific research, and taking account of its effects on the health of the population, they employ internationally accepted indicators of the quality of efficacy and efficiency of their work.* ***Research Institutes adopt and periodically update a code of conduct for the research integrity****. Personnel employed in these Institutes are expected to respect a code of conduct that disciplines behaviours aimed at the correct use of resources and respect of the rules for fair competition".*

Definitions

- *Bad conduct in research:* unethical or deliberate lack of respect for guidelines and codes of conduct for scientific research. This definition includes any failure to report bad conduct by others, but not errors made in good faith or poor-quality results of projects.
- *Conduct harmful to the research integrity ("misconduct")*: violation of good practices in research that damages the integrity of the project or harms researchers. Examples include, for instance, behaviour obstructing research, causing discrimination or abuse of the persons concerned, or harming IRFMN's reputation, compromising its credibility; these are all to be considered harmful to research integrity. See also Part II of this Code.
- *Conflict of interest:* this refers to certain conditions, not only behaviour, that give rise to a real or perceived risk of a person's professional judgement on a matter of primary interest (such as the validity of a research project) being unduly influenced, with or without the person realising it, by a 'secondary' interest, which might involve some economic or financial advantage. The Researcher in this case is induced to behave in a partially inappropriate way to obtain some personal gain (direct or indirect, through other subjects; financial or not, potential or real). This can lead to a conflict of interest if it influences the Researcher's objectivity or professional judgement.
- *Research data:* all the information, in whatever format, employed following a defined protocol, that serves as the basis of a specific research project or is produced by it, and is necessary to validate the research results.
- *FAIR* (see ALLEA report providing key recommendations to make digital data "Findable, Accessible, Interoperable and Reusable": DOI: 10.7486/DRI.tq582c863), referring to research data, stands for:
  - *Findable,* implies it can be found and used by others employing the relative identifiers: examples are DOI and/or descriptive metadata.
  - *Accessible*, accessible to Researchers;
  - *Interoperable*, can be integrated with other data;
  - *Reusable*, can be replicated and/or re-used with the appropriate tools, software or algorithms.

- *Fabrication, falsification and plagiarism*: these are the basic signs of harmful conduct.

  ○ *Fabrication*: production of fraudulent data, documents, or results not related to a research project, when they are presented as reliable products of research.

  ○ *Falsification*: fraudolent changes to data, documents or project results, to confirm achievement of the aims of the project. Falsification also involves the use of wrong or inappropriate statistical analysis, leading to false conclusions.

  ○ *Plagiarism*: deliberate presentation of a product of research or a text written by another Researcher or group without giving them credit. Plagiarism is punishable under civil and penal law, and administrative regulations.

- *Whistle-blowing*: a report of illegal wrongdoing made in the general interest by a public employee on the basis of something that came to his knowledge in the course of work; this is set out in italian art. 54 bis of the Legislative Decree no. 165, 30 March 2001, containing *"Norme generali sull'ordinamento del lavoro alle dipendenze delle amministrazioni pubbliche* (General rules on the order of work for public administration employees)*"*; this was modified by Law no.179, 30 November 2017, which set out "*Disposizioni per la tutela degli autori di segnalazioni di reati o irregolarità di cui siano venuti a conoscenza nell'ambito di un rapporto di lavoro pubblico o private* (Rules for protecting anyone reporting crimes or irregularities that have come to their knowledge during public or private employment)". The *whistleblowing procedure* is designed, among other things, to keep the reporter's identity anonymous and prevent them suffering retaliation.

INTRODUCTORY PROVISIONS

Article 1 – Aims

1. By adopting this Code, IRFMN considers the fundamental principles of research integrity and internationally adopted solutions. These include the following:

- *"Codice Europeo di Condotta per l'Integrità della Ricerca"*, European Federation of National Academies of Science and Humanities - ALLEA[1]

- *"Governance of Research Integrity"* – EMBO[2]

2. This Code updates, where necessary, the rules and regulations already in force at IRFMN, in particular the Model of organization, management and control under Italian Legislative Decree no. 231/2001, the Code of Ethics and the Code of Values.[3]

3. The Code aims to ensure correctness, transparency and efficiency in the research work at IRFMN, either individual or in groups, in relation to the importance of the public service provided, and also to inform all those working in various sectors at IRFMN of the values and rules for conduct to which the Institute will regularly refer in its research, upholding its reputation and image.

4. Any behaviour contrary to the principles set out in Part I implies ethical or deontological responsibility. Any harmful conduct coming under Part II will be considered a responsibility and may call for disciplinary measures, as indicated in Part III.

5. The Code does not affect any penal, civil or administrative responsibilities that might result from violations of the principles and behaviour described here.

[1] http://www.allea.org/wp-content/uploads/2017/03/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017-1.pdf
[2] https://www.embo.org/documents/science_policy/governance_of_ri.pdf
[3] https://docs.marionegri.it/website/IRFMN_Carta%20dei%20valori%20e%20Code%20etico_dic%202020.pdf

Article 2 – Area of application[4]

1. The Code applies to personnel affiliated with IRFMN and/or doing research in the Institute, even only temporarily, regardless of their level or functional responsibility, or their type of contract with IRFMN.

2. The Code applies to personnel working as support for research, regardless of the type of contract, and all occasional and professional persons.

3. The Code applies to university personnel doing any type of research at IRFMN.

4. In this Code all the figures listed in points 1-3 above are referred to as Researchers.

Article 3 – Adoption of indicators of efficacy and efficiency for the quality and integrity of research[5]

1. IRFMN adopts the following indicators of efficacy and efficiency for the quality and integrity of its research to assess specific aspects of the scientific work:

a) training courses on research integrity, held at least every two years - in any case, since the Code has been updated - aimed to involve all the research staff (the schedule is established by IRFMN), regardless of their type of contract with the Institute.

b) presence of a Regulation for the management of violations of the Code, including inappropriate behaviour in research (misconduct), reported in Appendix 1. This document:

- is drawn up and managed by functions/figures in the IRFMN, updated periodically together with the Code, and published on the institutional pages;

- it permits the acceptance of well-backed anonymous reports (in agreement with the laws on *whistleblowing*), guaranteeing anonymity and privacy of both the reporter and the person reported, when possible;

- it clearly predetermines the sanctions applicable if the bad conduct is confirmed, ensuring they are proportional to the gravity of the misconduct. Should the procedure conclude that the person accused had no responsibility, IRFMN will ensure their rehabilitation;

- it ensures compliance with the adversarial principle, guaranteeing that subject accused is informed of the reasons for the procedure and the proofs regarding him, and allowing him to present evidence and arguments in defence;

c) the number of clinical trials promoted by IRFMN whose results have been entered in the specific registers (obligatory in the *Clinical Trials Information System* for pharmacological trials) within a year from the conclusion of the trial, regardless of whether or not the results have been published in specialised journals;

[4] Exclusively for the sake of readability, in this document the masculine form will be used to refer to individuals of female, male, or non-binary gender.

[5] These indicators were identified using the following sources:

i i. Regulation (EU) no. 536/2014 of the European Parliament and Council, 16 April 2014, on clinical studies with medicinal products for human use; it abrogates Directive 20017107CE.

ii ii. BIH QUEST Center, *Clinical trial reporting manual for universities*, available at the following link: https://www.transparimed.org/_files/ugd/01f35d_01cf8d6e9b344fe5973ee80976a00b64.pdf?index=true.

iii iii. *Joint letter by European Commission, EMA and HMA to stakeholders regarding the requirements to provide results for authorised clinical trials in EUDRACT*, available at link: https://www.ema.europa.eu/en/documents/other/joint-letter-european-commission-ema-hma-stakeholders-regarding-requirements-provide-results_en.pdf.

iv iv. Kelly D. Cobey et al., *Community consensus on core open science practices to monitor in biomedicine*, 24 January 2023, available at the following link: https://doi.org/10.1371/journal.pbio.3001949.

v v. Standard Operating Procedures for Research Integrity (SOP4RI), *Toolbox for Research Integrity*, available at the following link: https://sops4ri.eu/toolbox/.

vi vi. European Molecular Biology Organization (EMBO), *Governance of Research Integrity*, available at the following link:: https://www.embo.org/documents/science_policy/governance_of_ri.pdf.

vii vii. European Commission, *EU Grants – Annotated Model Grant Agreement for Funding Programmes 2021-2027, Pre-Draft,* 30 November 2021, available at the link: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/aga_en.pdf.

d) the number of clinical trials promoted by IRFMN whose results have been published as peer-reviewed articles in specialised scientific journals within two years from the conclusion of the trial;

e) specific regulation on the management of laboratory registers and records of their storage when required by current legislation (Centro di Farmacocinetica e Bioanalisi, Centro di Ricerche Cliniche per le malattie rare Aldo e Cele Daccò) and number of laboratory notebooks in relation to the staff directly involved in the specific experimental work;

f) registration of Researchers with Orcid (percentage of reseachers with Orcid numbers);

g) sharing of research data applying the FAIR principles (see Definitions and Article 7) (number of articles with shared data/year).

Article 4 – Procedures for promoting the research integrity

1. Within 60 days from the date the Code comes into force, IRFMN will set up a Working Group dedicated to the integrity of research, if it does not already exist.

2. This Group will deal with questions and activities inherent to integrity in research at IRFMN, organising training courses for Researchers, when necessary, appointing experts from outside the Institute. This Group will also organise and manage the activities mentioned in this Code.

SPECIFIC PROVISIONS
PART I: PRINCIPLES OF RESEARCH INTEGRITY

SECTION 1 - General rules

Article 5 – Fundamental values

1. The Researcher must observe the ALLEA European Code of Conduct for Research Integrity (see Article 1), whose basic principles are the following:

− reliably guaranteeing the quality of the research, implying the quality of its planning, methodology, analysis, and correct use of resources;

− honesty in developing, conducting, reviewing, presenting and communicating the data in a transparent, equable, complete and objective manner;

− respect for colleagues and all those involved in the research, for society, ecosystems, the cultural patrimony, and the environment;

− responsibility for research from conception to publication, for its management and organization, training, supervising and tutoring those involved, and assessing its broader impacts on society.

2. The Researcher must also ensure he upholds the reputation of IRFMN, and so doing sustains the credibility and authority of its scientific work.

3. In any case, the research must always respect the dignity of the persons involved, the health of mankind and other living species, and adopt good bioethical practices.

Article 6 – Doing research

1. The Researcher starts out from the state of the art to develop his own research ideas. While respecting the principles of freedom and independence in research, each Researcher defines his own objectives and aims, assesses the feasibility and the potential impacts of the research, and identifies the resources and organisation modalities most appropriate for achieving its efficacy and sustainability.

2. The research must employ the appropriate methods and tools for the topic of study, and they all must be fully and correctly documented.

3. The Researchers' roles and tasks are agreed clearly and impartially, respecting each person's skills and qualifications.

4. The Researcher makes informed and appropriate use of research funds.

Article 7 – Management of research data[6]

1. The data from clinical trials regard personal details and the patient's health, and must be managed following the General Data Protection Regulation (EU) 2016/6792 (GDPR) (Regulation (EU) 2016/679 of the European Parliament and of the Council, https://eur-lex.europa.eu/eli/reg/2016/679/oj/eng) which ensures data protection and the rules of Good Clinical Practice (GCP) (https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice-scientific-guideline).

2. All the data from the experiments in a research plan, whether published or not, must be filed in laboratory registers, so the experiments can always be traced, in line with the procedures set out in the IRFMN Code of Ethics and Code of Values, and in the specific procedures issued by IRFMN.

3. General access of research data to the public may be limited if the Researchers are bound by confidentiality restraints, regulated by financing sources, or based on the decision to valorize the results with a view to obtaining patents. These limits no longer apply when the research findings are published in specialised journals.

4. When sharing research data, IRFMN adopts the appropriate measures to create and keep the data "FAIR" (*Findable, Accessible, Interoperable, Reusable*).

Article 8 – Scientific publications

1. Unless bound by the conditions listed in the previous Article, the Researcher is expected to share the findings of his own studies with the scienfic community, in a recognised form, usually a peer-reviewed article in a scientific journal.

2. This sharing must be honest, accurate and compatible with the standards of the discipline involved and all the information on methods required to verify and reproduce the results must be provided.

3. The Researcher must respect the confidentiality of data and/or results when legitimately requested (see Article 7, point 3).

4. The Researcher must avoid duplication of research findings and must not divide them unjustifiably with the aim of obtaining more scientific outputs.

5. The Researcher must cite fully and faithfully all sources employed in his research.

6. Bearing in mind the details provided in the following Article 20, scientific publications must report as co-auhors all the Researchers who have made a substantive contribution to the project or provided significant input to the manuscripit. The order of the authors, the name of the author for correspondence, and any individual contributors

[6] For further questions related to the management and protection of personal data, readers are referred to the following sources:

i Regolamento (UE) 2016/679, *Regolamento Generale sulla Protezione dei Dati*;

ii Decreto legislativo 30 giugno 2003, no. 196, recante il *Code in materia di protezione dei dati personali*, come modificato dal successivo decreto legislativo 10 August 2018, no. 101, recante *Disposizioni per l'adeguamento della normativa nazionale alle disposizioni del regolamento (UE) 2016/679 del Parlamento europeo e del Consiglio, del 27 April 2016, relativo alla protezione delle persone fisiche con riguardo al trattamento dei dati personali, nonche' alla libera circolazione di tali dati e che abroga la direttiva 95/46/CE;*

iii Garante per la Protezione dei Dati Personali, *Regole deontologiche per trattamenti a fini statistici o di ricerca scientifica pubblicate ai sensi dell'art. 20, comma 4, del d.lgs. 10 August 2018, no. 101*, 19 December 2018, available on the link https://www.garanteprivacy.it/home/docweb/-/docweb-display/docweb/9069637;

iv Garante per la Protezione dei Dati Personali, *Provvedimento recante le prescrizioni relative al trattamento di categorie particolari di dati, ai sensi dell'art. 21, comma 1 del d.lgs. 10 August 2018, no. 101*, in particular *Prescrizioni relative al trattamento dei dati personali effettuato per scopi di ricerca scientifica* e *Prescrizioni relative al trattamento dei dati genetici per clinica e ricerca* scientifica, 5 giugno 2019, available on the link https://www.garanteprivacy.it/home/docweb/-/docweb-display/docweb/9124510;

v European Data Protection Board, *Linee guida 5/2020 sul consenso ai sensi del regolamento (UE) 2016/679;*

vi www.garanteprivacy.it.

is decided on the basis of shared rules, clearly defined preferably at the beginning of the project, as it is done in various disciplines.

7. The author who takes the responsibility as the contact person (“*corresponding author”)* is the is the sole point of contact for any communications from the editor referring to the article. This author must make sure all the co-authors have read and approved the manuscript before it is submitted to the journal selected and is the person who passes editorial communications on to the other authors. The corresponding author is the scientific readership’s main contact for requests of information, material or clarifications regarding the study once published. This author is also responsible for the correctness and scientific validity of the information in the article and ensures that data and any material produced are available.

8. The co-authors all share responsibility to ensure the publication is scientifically valid and correct. Each co-author must not only ensure that his own contribution to the publication is correct, but must also check that it appears scientifically coherent and rational when published.

9. In selecting where to publish an article, the Researcher must assess the reputation of the journal in the pertinent scientific community, and, when possible, give priority to the one likely to circulate the ideas and results of the research most widely. The Researcher must try to identify and avoid illegitimate or predatory journals. If possible, *open access* channels or journals should be used, to ensure the results are freely available to anyone interested, following a principle of equity and community return.

10. Research results should be published promptly, as any unjustified delay slows scientific progress and, in the case of clinical studies, may directly or indirectly harm patients.

11. If a Researcher, after the publication of his own scientific contribution, notes errors or suspects misconduct regarding the reliability or originality of the results, must inform the co-authors and the organization/office for research integrity for which the research was done (See Article 4, point 2) and assess how best to correct or retract the published article.

Article 9 – Assessment of publications or projects

1. When serving as a reviewer, editor or member of an editorial committee for journals or scientific collections, the Researcher must be careful and accurate, applying his own competence and scientific knowledge, making clear decisions based solely on objective assessment of the quality and integrity of the research, its originality and importance.

2. The same principles and behaviours come into play when the Researcher is required to express an assessment of projects, scientific output, or the work of other Researchers.

Article 10 – Dissemination of scientific knowledge and public communications

1. The Researcher has a general responsibility to participate in communicating science and making the results of his own research available to an unskilled public that might benefit from the information. This will help expand the habits of health knowledge and evidence-based medical information.

2. While respecting this requirement, the Researcher must ensure, as far as possible, that the communication of research findings to the public does not exagerate or distort them, and the conclusions are directly upheld by the evidence.

3. The Researcher who states his affiliation with the IRFMN is not expressing the IRFMN’s official position, unless they are formally authorised to do so.

SECTION II – Collaborative research groups

Article 11 – Roles, tasks and objectives

1. Researchers working on a research project in a group are expected to display a spirit of collaboration, with a view to obtaining results without pursuing individual interests.

2. Each group member's tasks must be agreed clearly, preferably at the start of the project, on the basis of the competence of each Researcher. The management and coordination roles should be rotated periodically, when possible, maintaining a gender balance.

3. Transparency and sharing are particularly important when applying for funding, for the approval and accounting of expenditures, treatment, sharing, storage of the material and data employed in the research, approval of articles to be submitted for publication, and management of communicating the results (see Articles 8 and 10).

Article 12 – Dissemination of results

1. Scientific publications follow the general rules set out in Article 8.

2. Without authorisation from the research group and colleagues, a Researcher cannot disseminate unpublished results of the group's work and their methods.

3. The research group must always be mentioned in public presentations.

PART II
CONDUCTS HARMFUL TO THE RESEARCH INTEGRITY

Article 13 – Funding and assignments

1. Funding or assignments for research are to be authorised by IRFMN, to ensure there is no conflict with its objectives and output.

Article 14 – Conflicts of interest

1. Reports of cases involving conflict of interest are managed according to the procedures established by IRFMN in the document entitled *Gestione e dichiarazione dei conflitti di interessi* (Declaration and management of conflicts of interest).

2. In any case, the Researcher must declare the conflict of interest, of any nature, whether effective or potential, financial or not, that becomes evident during institutional work, research, review of articles, projects or scientific work of colleagues, in order to enable third parties to assess the possible influence or distorting effect of such interests.

Article 15 – Respect for other Researchers and research facilities

1. The work of other Researchers must not be slowed or hindered intentionally.

2. The Researcher must not intentionally issue reports or make unfounded accusations regarding behaviours of other Researchers allegedly harmful to research integrity, nor voluntarily harm their reputation. This conduct is considered even more serious if it is aimed at obtaining some personal or professional gain.

3. The Researcher must make appropriate use of IRFMN's facilities, including laboratories, offices, ancillary spaces, research instruments, and equipment, paying particular attention to their safety so as not to interfere with or compromise research activities.

Article 16 – Coordination of projects or collaborative research groups

1. The Researchers who coordinates a research project or holds a similar role must not take advantage of his position. He must not impose tasks not in line with the roles defined for a project; he must not take expenditure decisions not shared, or out of line with the project budget; he must not use the results of collective research for personal purposes and must forbid or limit the use of data or research findings not justified by Institutional regulations or indicated by Funding or European bodies.

Article 17 – Fabbrication, falsification and data theft

1. The Researcher must not fabricate research data nor purposely alter or omit data; he must not publish misleading or incomplete results using methods other than those described in Article 8, under the heading 'Scientific publications". Data, methods and research results must not be used without the consent of whoever planned or produced them, unless they have already been published.

Article 18 – Storage and elimination of research data
1. It is forbidden for the Researcher to deceptively select or destroy material, data, registers and any other sources of information essential for verifying research findings.

2. Any elimination may take place following internal regulations or other agreements with funders or sponsors of the research.

Article 19 – Plagiarism and citations
1. The Researcher must not purposely present as his own ideas, data, results or projects of other Researchers.

2. The Researcher must not impose the citation of non-essential work with a view of increasing the impact of his own or others' scientific output, the prestige of a journal or a research group.

Article 20 – Criteria for authorship attribution
1. A researcher who has not contributed to a scientific publication cannot be listed as a co-author. There are well-defined, irrevocable criteria for the attribution of authorship, indicative of the contribution to the research (https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html).

2. To be considered an author, a Researcher must have made substantial contributions to the idea or plan of the work. This may imply the acquisition, analysis or interpretation of data, the creation of new software employed in the research, writing up the article or substantially reviewing it. In addition, he must have approved the submitted version (or any subsequent one, modified in response to editorial comments) and accepted personal responsibility for his own contributions. The Researcher must also ensure that any criticism about the accuracy or integrity of any part of the work, including those in which the author was not personally involved, are adequately investigated, clarified, and documented in the literature.

Article 21 – Patents
1. To protect the intellectual property of the research, with a view to patenting it, the Researcher follows the rules and indications set out in the Code of Values and Code of Ethics adopted by IRFMN. IRFMN does not apply for patents and only protects the right of its Researchers to be acknowledged as authors of the invention, so that all research results can be made promptly public, to the advantage of the scientific community.

Article 22 – Alteration of titles or credentials
1. The Researcher must not attribute to himself false titles and scientific credentials.

Article 23 - Declaration of affiliation
1. The Researchers must always indicate in scientific publications his affiliation with IRFMN.

Article 24 – Assessment of persons, projects and publications
1. The Researcher must not make wrong or deceptive judgments of projects, persons, or research output.

2. The Researcher must not disclose data or confidential information about projects or their results, nor break the rule of confidentiality until the results have been published.

3. The Researcher must not impede or slow the publication of scientific articles.

PART III
MEASURES TO DEAL WITH VIOLATIONS OF THE CODE

Article 25 – Procedures

1. Any reports or detection of hypothetical misconduct or disrespect of the principles of research integrity are dealt with as specified in the *Regulation for the management of violations of the Code of Conduct for Research Iintegrity*, adopted by IRFMN (Appendix 1).

2. Conducts harming the research integrity, dealt with in Part II of this Code, must be divided according to their severity and sanctioned, if necessary, as specified in Article 1.

3. The Researcher with reliable reasons or objective findings of conduct by other Researchers likely to damage research integrity (from IRFMN or outside), with whom they currently or have in the past collaborated on scientific work, is expected to report these cases.

PART IV
FINAL PROVISIONS

Article 26 – Entry in force, publication and updating of the Code

1.The Code comes into force the 15th day after its approval by IRFMN Board of Directors.

2. The Code will be published on the intranet page and public IRFMN website and distributed as considered appropriate.

3. The IRFMN updates the Code periodically, at least every three years.

4. All the Researchers at IRFMN must give their specific acceptance to the regulations in this Code.

APPENDIX 1
REGULATION FOR THE MANAGEMENT OF VIOLATIONS OF THE CODE OF CONDUCT FOR RESEARCH INTEGRITY

This Regulation follows the indications set out in Article 3 of this Code of Conduct for the Research Integrity.

1. AIM

IRFMN, in line with the basic principles set out in its Code of Values and Code of Ethics, and the main documents regarding transparency, ethics and integrity in research[7], has issued the present *Regulation for the management of violations of the Code of Conduct for Research Integrity* (hereinafter, "the Regulation").
The main purpose of the Regulation is to define the criteria, methods, and responsibility regarding the reporting, assessment and management of any violation of the *Code of Conduct for the Research Integrity*.
Should any violation give rise to penal, civil, administrative or disciplinary responsibility, this Regulation governs the discipline and sanctions applicable to the personnel, in line with the obligations set out in italian Legislative Decree no. 231/2001.

2. AREA OF APPLICATION

The Regulation is applicable to IRFMN Researchers, as defined in Article 2 of the *Code of Conduct for the Research Integrity*.
The situations in which the Regulation is applicable are set out in PART I (Principles of research integrity) and II (Conducts harmful to the research integrity) of the *Code of Conduct for the Research Integrity*.

3. ROLES AND RESPONSIBILITIES

Each Researcher is required to report any critical issues related to research activities that could constitute a violation of the *Code of Conduct for Research Integrity*, such as, for example, the compromise of research results, improper management of funding, or the misrepresentation of scientific results in publications. Such reports must be made in good faith, without using offensive language or including personal attacks, and must be specific and based on precise and consistent factual elements, possibly accompanied by documentation useful to substantiate their validity. Reports will be handled with the utmost confidentiality and anonymity, where requested.
Reports (both anonymous and confidential) submitted through the dedicated IT platform and in compliance with the provisions of Legislative Decree no. 24, 10 March 2023, on "Whistleblowing" are handled by the Reporting Officer (hereinafter, the "Officer"), a function formally appointed by IRFMN, who is responsible for receiving, analyzing, and verifying the contents of the report.
The Officer avails itself of the Research Integrity Committee established within IRFMN (hereinafter, the "Committee") whenever reports concern alleged violations of the Code of Conduct, in accordance with the principles of impartiality, fairness, and confidentiality, both regarding the reporting parties and the reported parties.
The Committee is composed of the Director of IRFMN, the Research Coordinators for the Milan and Bergamo sites, and a representative of the researchers with expertise in the field of research integrity.

[7] ALLEA, The European Code of Conduct for Research Integrity, 2017 (https://allea.org/code-of-conduct/)
OECD, Global Science Forum – Investigating Research Misconduct – Allegations in International Collaborative Research Projects, April 2009 (http://www.oecd.org/science/sci-tech/42770261.pdf)
OECD, Global Science Forum – Best Practices for Ensuring Scientific Integrity and Preventing Misconduct (http://www.oecd.org/science/sci-tech/40188303.pdf)
NIH, Investigation of Allegations of Research Misconduct 2018 (https://oir.nih.gov/system/files/media/file/2021-08/policy-nih_irp_research_misconduct_proceedings.pdf)
COPE, UK Committee on Publication Ethics (http://publicationethics.org/)
ORI, U.S. Office of Research Integrity (http://ori.hhs.gov/)

4. OPERATIONAL PROCEDURE

4.1 Reporting of potential violations

In compliance with the provisions of the above-mentioned Legislative Decree no. 24/2023, IRFMN expressly prohibits any act of retaliation or discrimination, whether direct or indirect, against reporting individuals for reasons directly or indirectly related to the reports made. IRFMN has adopted a specific procedure on "Whistleblowing" that describes the methods for handling reports.[8] Specifically, reports (both anonymous and confidential) must be submitted through the dedicated IT platform accessible at the following link: https://irfmarionegriircccs.signalact-inaz.it/whistleblowing, in order to guarantee the confidentiality of the reporting party. As an alternative to the platform, the reporting party may request a direct meeting with the Officer at the Institute via email, in full compliance with the utmost discretion.

Such reports are promptly examined by the Officer, supported by the Committee and, where appropriate, the Research Integrity Working Group (see Article 4 of the Code), the Department Directors, and other internal professional figures within IRFMN useful for evaluation purposes, such as, for example, the Data Protection Officer or library services, ensuring the confidentiality of the reporting party's identity and the anonymization of any personal data contained in the report or of other elements from which such identity may be inferred, directly or indirectly. The Data Controller is IRFMN, and the personal data collected are processed in compliance with Regulation (EU) 2016/679 (GDPR).[9]

If reports are submitted outside the channels provided for by the internal regulations governing the management of reports, the recipient (for example, the Direction or members of the Research Integrity Working Group) must forward them without delay, in their original form and with any attachments, to the Reporting Officer. Such transmission must take place in accordance with the highest confidentiality standards and using methods suitable to protect the reporting party and the identity of the reported individuals, without prejudice to the effectiveness of subsequent verification activities.

4.2 Assessment of potential violations

Once the report and the supporting documentation have been received, the Officer initiates a preliminary assessment phase to appraise the nature and seriousness of the event and may obtain further evaluations, including through additional discussions with the reporting party. The assessment is conducted in accordance with the principles of integrity, fairness, confidentiality, and protection of individuals.[10]

Specifically, the Officer, with the possible support of the Research Integrity Committee:
a) assesses the admissibility and substantiation of the report;
b) identifies responsibilities;
c) verifies the content of the reports and gathers all elements useful for their assessment.

The act of reporting alone is not sufficient to initiate any disciplinary proceedings against the reported individual. In order to avoid prejudicial consequences, the reported individual is also entitled to protection of confidentiality. Only after the verification phase has identified critical issues or responsibilities attributable to the reported individual ~~is~~ will the latter be informed of the investigation concerning them and, in turn, given the opportunity to be heard to provide any information and their response.
Individuals involved in the assessment of the report must disclose any actual or potential conflicts of interest, which must be managed in an appropriate manner.

4.3 Outcome of the assessment and application of sanctions

At the conclusion of the assessment, the Officer prepares a report describing the context of the report (scope of application of the violation), the analytical activities carried out, and the related results obtained.

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[8] https://docs.marionegri.it/website/PRO_whistleblowing_FINALE.pdf
9 http://www.marionegri.it/media/privacy/Informativa_privacy_trattamento_dati_Whistleblowing.pdf
[10] OECD Global Science Forum Investigating Research Misconduct – Allegations in International Collaborative Research Projects, April 2009

Within three months of receipt of the report, the Officer communicates to the reporting party information regarding the follow-up given or intended to be given to the report.[8] The assessment phase conducted by the Committee is carried out in a timely manner in accordance with the timeframe indicated above.If a violation of the Code of Conduct is ascertained, the report is forwarded to the IRFMN Direction, which is responsible for decisions regarding any measures or sanctions that should respect the principles of graduality and proportion, and to the reporting party. Should the violation not be confirmed by this assessment (for instance, because of a lack of proofs), the procedure will be considered closed.
The IRFMN Direction reserves the right to take measures against the person(s) who raised the case, if they are found to have acted in bad faith, following an assessment based on concrete evidence and clear intent.

Should the violation be ascertained during the assessment phase, without prejudice to contractual provisions and disciplinary measures provided for by other laws and regulations, the sanctions may include the following actions:

- removal from a research project;
- closer and more detailed supervision at work;
- official reprimand*;
- reassignment to a different work area*;
- temporary suspension from work*;
- termination of the employment contract.

**in coordination with the Head of Human Resources.*

5. LIMITING RISKS AND CORRECTIVE MEASURES

The main aim of managing violations of the *Code of Conduct for Research Integrity* is primarly to prevent future critical situations, boosting awareness and knowledge on integrity, and, ultimately, raising the quality of research processes. With this in mind, in addition to the measures outlined in the *Code* and on the basis of practical experiences, the Committee may implement specific actions and procedures, including, for instance, training for staff.

6. RECORDING AND FILING

Reports and the supporting documentation must be appropriately archived in electronic and/or paper format by the Reporting Officer and retained for no longer than five years from the date on which the final outcome of the reporting procedure is communicated, without prejudice to any ongoing litigation that may require a longer retention period.