RESEARCH MISCONDUCT

Candiolo Cancer Institute FPO-IRCCS is highly committed to the responsible conduct of research. Our medical and scientific community relies on the integrity of its scientists, its clinicians, and its whole staff. Everyone involved in the research process must be compliant with and follow good research practices and policies on responsible research in order not to violate professionals responsibilities and distort research records. Such a misconduct is responsible for jeopardizing public trust in research and may expose research subjects, this Institution, and the whole society to unnecessary harm. Adopting a responsible conduct, governed by basic principles of research integrity helps to ensure the quality and reliability of our research. Principles guide researchers in their work as well as in their engagement with the practical, ethical, and intellectual challenges inherent in research.

MAIN PRINCIPLES TO BE FOLLOWED IN RESEARCH[1]:

Reliability in protecting the quality of research, mirrored in the design, the methodology, the conduct, the analysis, and the use of resources.

Honesty in developing, reviewing, reporting and communicating research in a transparent, fair, and unbiased way. It also involves refraining from making unfounded claims, from fabricating or falsifying data and/or sources and refraining from presenting results more favorably or unfavorably than they actually are.

Respect for colleagues, research participants (patients or healthy volunteers), animals eventually used for research aims, society, and the environment.

Responsibility means conducting research that is scientifically and/or societally relevant by respecting within reasonable limits – the legitimate interests of research participants and animal test subjects, as well as those of funding bodies and the environment.

Accountability for the research from the main idea to publication, for its management, for supervision and mentoring, and for its potential impacts.

[1] Reported principles are listed on the following sources: ALLEA - All European Academies, Berlin 2017, "The European Code of Conduct for Research Integrity Revised Edition", available at: https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf and Netherlands Code of Conduct for Research Integrity (2018) available at: https://www.nwo.nl/en/policies/scientific+integrity+policy/netherlands+code+of+conduct+for+research+integrity

Scrupulousness means, among other things, using methods that are scientific or scholarly and exercising the best possible care in designing, reporting and disseminating research.

Transparency means, among other things, ensuring that it is clear to others what kind of data the research originated from, how the data were obtained and processed, what results were achieved, and how.

WHAT IS RESEARCH MISCONDUCT:

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Fabrication: making up results and recording them as if they were real.

Falsification: manipulating research materials, equipment or processes or changing, omitting or suppressing data or results without justification.

Plagiarism: using other people's work and ideas without giving proper credit to the original source, thus violating the rights of the original author(s) to their intellectual outputs[2].

A finding of misconduct must be shown to be a "significant departure from accepted practices of the relevant research community" and to have been committed "intentionally, knowingly or recklessly"[3]

Besides to Fabrication, Falsification, and Plagiarism, according to the European Code of Conduct for Research Integrity[4], there are further violations of good research practice that may impair the integrity of the research process. Examples of unacceptable practices include, but are not confined to:

• Manipulating authorship or denigrating the role of other researchers in publications.

• Re-publishing substantive parts of one's own earlier publications, including translations, without duly acknowledging or citing the original ('self-plagiarism').

[2] Definitions of Fabrication, Falsification, and Plagiarism are reported from ALLEA - All European Academies, Berlin 2017, "The European Code of Conduct for Research Integrity Revised Edition", available at: https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

[3] PHS (2005), Public health service policies on research misconduct. Department of Health and Human Services – Public Health Service, Federal Register, 70(94).

[4] ALLEA - All European Academies, Berlin 2017, "The European Code of Conduct for Research Integrity Revised Edition", available at: https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

• Citing selectively to enhance own findings or to please editors, reviewers or colleagues.

• Withholding research results.

• Allowing funders/sponsors to jeopardize independence in the research process or reporting of results so as to introduce or promulgate bias.

• Expanding unnecessarily the bibliography of a study.

• Accusing a researcher of misconduct or other violations in a malicious way.

• Misrepresenting research achievements.

• Exaggerating the importance and practical applicability of findings.

• Delaying or inappropriately hampering the work of other researchers.

• Misusing seniority to encourage violations of research integrity.

• Ignoring putative violations of research integrity by others or covering up inappropriate responses to misconduct or other violations by institutions.

• Establishing or supporting journals that undermine the quality control of research ('predatory journals')[5].

IMPORTANT: Please note that research misconduct does NOT include honest error or differences of opinion.

DEALING WITH VIOLATIONS AND ALLEGATIONS OF MISCONDUCT:

Definitions:

- Research Integrity Manager: is in charge of handling the procedure from its submission. The Research Integrity Manager acts as filter between allegations that involve only minor events and allegations that express concern of research misconduct and thus need further investigation.

- Research Integrity Board: is involved only when and if the Research Integrity Manager expresses concern of research misconduct based on a submitted allegation.

How to report a research misconduct:

[5] ALLEA - All European Academies, Berlin 2017, "The European Code of Conduct for Research Integrity Revised Edition", available at: https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

Immediately notify the Research Integrity Manager by completing this form, if you detect or if you have a valid reason to suspect any of the following kinds of misconduct:

- Misconduct (fabrication; falsification; plagiarism) in proposing, performing, reviewing, or reporting research. Please consider that research misconduct does not include honest error or differences of opinion.
- Whistleblower retaliation for reporting misconduct
- Awardee or staff with an unreported foreign affiliation, component, support, funding, or other form of scientific overlap
- Human subjects potentially at risk in an ongoing study

Revealing your identity is optional when completing the form. Every allegation submitted will be identified by a code in order to be traceable. After you report an allegation from the list above to the research integrity manager, he/she will take action within three business days. The Integrity Research Manager will treat any information about such allegations as strictly confidential.

Please note that only allegations reported through the specific form will be considered and processed by this Institution.

If you are considering an allegation submission or if you have already submitted one **do not** take any of the following actions:

- Divulge any other information
- Express personal opinions
- Attempt to investigate the allegation
- Request supporting documentation
- Contact a principal investigator, extramural institution official, contractor, reviewer or any other professional other than the research integrity manager.

What happens next?

Handling of allegations may be articulated in different steps and foresees two different bodies. This Institution follows the procedure reported by the ENRIO[6] Handbook which involve:

1. Initial evaluation and screening inquiry
   Once an allegation is submitted to the manager of research integrity, it is firstly reviewed to verify the consistency and the seriousness of the potential allegation. As suggested by the

[6] ENRIO Handbook, Recommendations for the Investigation of Research Misconduct, available at: http://www.enrio.eu/wp-content/uploads/2019/03/INV-Handbook_ENRIO_web_final.pdf

ENRIO, in making an initial evaluation and establishing whether further action will be needed, the following questions should be considered:

• Does the allegation involve research? Is/Are the alleged person(s) researcher(s)? Has the allegation already been dealt with or is another institution presently dealing with the allegation?

• Does the allegation concern possible serious breaches of good research practice or irresponsible research practices?

• Are there implications for notifying external funders based on terms of funding agreements?

• How serious is the allegation? This could determine how and by whom it should be further handled.

• Does it fall within the definition or description in guidelines of unacceptable practices/research misconduct?

• Is there sufficiently evidence to support an in-depth investigation, or is further documentation required before deciding on this? [7]

This step will determine whether allegations submitted concern events of research misconduct or minor breaches that will not proceed to further stages of this procedure.

2. <u>Investigation and inquiry</u>

Where, based on the submitted allegation, a case of concern is detected by the research integrity manager, the research integrity board is involved in order to proceed to investigation and determine the extent of the misconduct. Within this delicate passage, the following questions should be considered:

• Does the responsible board have the necessary expertise or is there a need for external experts?

• Has the board documented their real or perceived conflicts of interests?

• Has the board been advised of their role and which standards they should apply in assessing the allegation(s)?

• Does the board require training in the national/institutional policy/guideline and in handling allegations of this sort?

• Is there a need for further documentation? How should it be obtained?

• Is it possible to expand the investigation during the process if “new evidence or allegations” occur?

• Is there an established timeline for completion of the investigation and a mechanism for extending timelines when justified?

[7] ENRIO Handbook, Recommendations for the Investigation of Research Misconduct, available at: http://www.enrio.eu/wp-content/uploads/2019/03/INV-Handbook_ENRIO_web_final.pdf

3. Formal hearings of involved parties or witnesses
   • This could be done in writing and/or in verbal hearings.
   • Documentation of written/oral hearings to maintain an accurate record (record/transcribe) should be considered.
   • It should be ensured that due process/procedural fairness and all relevant employee/grantee contractual agreements have been considered.

4. Writing of a report including a conclusion
   Investigations require careful analysis of the facts and thorough application of the pertinent standards (rules, regulations, guidelines) and end with a clear and concise conclusion based on the opinion of the board. If necessary, communication to other parties involved (Supervisors, Journals, Publishing House, Funding Body etc.) is required and is managed by the Research Integrity Manager.
   In this phase, the following questions should be taken into account:
   • Is this misconduct (e.g. FFP) or other unacceptable/irresponsible research practices?
   • Did the researcher's actions demonstrate intent to deceive or distort?
   • Other behaviours or misbehaviour?
   • What is the basis for the decision?

   The report should include the kind of misconduct, the research record in which the misconduct occurred (progress reports, publications, etc?), relevant dates and description of standards applied.
   It is a good practice to give parties involved the chance to comment on the facts of the case before disseminating the report.
   With respect to this, any mitigating factors should be considered.

   The figure below, presented within the ENRIO Handbook, pictures the phases for handling research misconduct allegations:

Figure 1. Prototypical process in handling research misconduct allegations.

MAIN PRINCIPLES TO BE FOLLOWED IN HANDLING ALLEGATIONS:

Handling Research Integrity Allegations requires guiding principles to govern the whole process. Such principles are:

Integrity:

• Investigations are fair, comprehensive and conducted expediently, without compromising accuracy, objectivity or thoroughness.

• The parties involved in the procedure declare any conflict of interest that may arise during the investigation.

• Measures are taken to ensure that investigations are carried through to a conclusion.

• Procedures are conducted confidentially in order to protect those involved in the investigation.

• Institutions protect the rights of 'whistleblowers' during investigations and ensure that their career prospects are not endangered.

• General procedures for dealing with violations of good research practice are publicly available and accessible to ensure their transparency and uniformity.

Fairness

• Investigations are carried out with due process and in fairness to all parties.

• Persons accused of research misconduct are given full details of the allegation(s) and allowed a fair process for responding to allegations and presenting evidence.

• Action is taken against persons for whom an allegation of misconduct is upheld, which is proportionate to the severity of the violation.

• Appropriate restorative action is taken when researchers are exonerated of an allegation of misconduct.

• Anyone accused of research misconduct is presumed innocent until proven otherwise.[8]

RESEARCH INTEGRITY MANAGER – CONTACTS:

USEFUL RESOURCES:

Websites:

- ENRIO 2020 Congress on Research Integrity Practice
- European Network of Research Integrity Offices (ENRIO)
- USA - Office of Research Integrity (ORI)
- ALL European Academies (ALLEA)
- ENERI
- World Conferences on Research Integrity Foundation (WCRIF)
- Comité d'éthique du CNRS (COMETS)
- German Research Ombudsman
- UKRIO

Documents:

- The Hong Kong Manifesto for Assessing Researchers: Fostering Research Integrity
- Recommendations for the Investigation of Research Misconduct by ENRIO (2019) http://www.enrio.eu/wp-content/uploads/2019/03/INV-Handbook_ENRIO_web_final.pdf

[8] ALLEA - All European Academies, Berlin 2017, "The European Code of Conduct for Research Integrity Revised Edition", available at: https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf and OECD Global Science Forum. Investigating Research Misconduct Allegations in International Collaborative Research Projects. A PRACTICAL GUIDE. April 2009, 6 ff.

- Integrity in Practice toolkit by UKRIO (2018) https://ukrio.org/wp-content/uploads/UKRIO-Royal-Society-Integrity-in-Practice.pdf
- EGE - Statement on the formulation of a code of conduct for research integrity for projects funded by the European Commission https://ec.europa.eu/research/ege/pdf/research_integrity_ege_statement.pdf
- ALLEA - European Code of Conduct for Research Integrity 2017
- Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations https://wcrif.org/montreal-statement/file
- Singapore Statement on Research Integrity https://www.jsps.go.jp/english/e-kousei/data/singapore_statement_EN.pdf
- ESF Report Fostering Research Integrity in Europe http://www.esf.org/fileadmin/user_upload/esf/ResearchIntegrity_Report2011.pdf
- COPE A Short Guide to Ethical Editing for New Editors https://publicationethics.org/files/A_Short_Guide_to_Ethical_Editing.pdf
- Science Europe Working Group on Research Integrity- Seven Reasons to Care about Integrity in Research https://www.scienceeurope.org/our-priorities/research-integrity-and-ethics/
- OECD on investigating research misconduct in international collaborative research projects
- (2007). Best Practices for Ensuring Scientific Integrity and Preventing Misconduct. https://www.oecd.org/sti/sci-tech/40188303.pdf
- COPE Code of Conduct and Best Practice Guidelines for Journal Editors https://publicationethics.org/files/Code%20of%20Conduct.pdf
- Responsible Research Publication: International Standards for Editors https://www.elsevier.com/__data/promis_misc/JACS-Ethics_in_Publishing_Statement.pdf
- ORI Guidelines for Institutions and Whistleblowers https://ori.hhs.gov/documents/guidelines_whistle.pdf
- Regno Unito: Code of Practice for Research. Promoting Good Practice and Preventing Misconduct https://ukrio.org/wp-content/uploads/UKRIO-Code-of-Practice-for-Research.pdf
- Regno Unito: Guidance for Researchers on Retractions in Academic Journals https://ukrio.org/wp-content/uploads/UKRIO-Guidance-for-researchers-on-retractions-in-academic-journals.pdf

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