Conselho
Nacional de
Ética para as
Ciências da Vida

# Research Integrity

## RECOMMENDATION

February 2018

## 1. INTRODUCTION

If we consider that the intrinsic "Telos" of science is the pursuit of truth, we will have to admit that it has recently suffered serious blows that threaten its integrity (Martinson, Anderson & De Vries 2005; And Le 2012, Open Science Collaboration 2015, Necker 2014, Ioannidis 2017, Munafò et al., 2017)[1]. In fact, as underlined by Lobo Antunes (2008), science "does not only produce knowledge and elucidation, and if it is true that the term *scientifically* has, for all intents and purposes, become a form of epistemic praise that means 'strong, reliable, sure', such exaltation also encouraged their vulnerability; science as fallible, imperfect, sometimes corrupt."

Integrity is an ethical principle to be observed throughout research. Reprehensible behaviors in science are not a phenomenon of our time. However, the truth is that today there is a high level of intolerance towards these practices, whose scrutiny is much more rigorous. Initial publications on this subject have emerged in the United States of America, particularly since the eighties of the twentieth century. However, as science has become an increasingly global activity and practice, it is inevitable that nowadays this matter is universally addressed; furthermore, it has deserved additional concern after several scandals have become public. So today, more than ever, we witness a conflict between the value of truth in science and the logic imposed by the evaluation metrics of researchers and institutions ("you have to do more, better and faster and have results published in high impact scientific journals"). This logic must be revisited in the face of an installed crisis, with overwhelming numbers and consequences.



This document aims, in a necessarily synthetic manner, to establish essential concepts and to stimulate both reflection and discussion on this issue of importance and growing concern in the national and international research community. With the remarkable progress of national scientists in level, productivity and participation in international projects, it is imperative to establish clearly defined rules of conduct regarding the issues of research integrity.

The National Council of Ethics for Life Sciences (CNECV), faced with the lack of guidelines on research integrity in Portugal, which may compromise the credibility of national

[1] Begley CG & Le E. 2012. 'Drug Development: Raise Standards for Preclinical Cancer Research'. Nature 483 (7391): 531–533.
Fanelli D . 2009. 'How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data'. PloS One 4 (5): e5738.
Ioannidis JPA 2005. Why most published research findings are false. Plos Medicine, 2(8), e124. doi:10.1371/journal.pmed.0020124
Ioannidis JPA. 2017. 'The Reproducibility Wars: Successful, Unsuccessful, Uninterpretable, Exact, Conceptual, Triangulated, Contested Replication'. Clinical Chemistry 63 (5): 943–945.
Martinson BC, Anderson MS, and De Vries R. 2005. 'Scientists Behaving Badly'. Nature 435 (7043): 737–738.
Munafò MR, Nosek BA, Bishop DVM, Button KS, Chambers CD, Percie du Sert N, Simonsohn U, Wagenmakers EJ, Ware JJ, and Ioannidis JPA. 2017. 'A Manifesto for Reproducible Science'. Nature Human Behaviour 1: 0021.
Necker S. 2014. 'Scientific Misbehavior in Economics'. Research Policy 43 (10): 1747–1759.
Open Science Collaboration. 2015. 'Estimating the Reproducibility of Psychological Science'. Science 349 (6251): aac4716.

science, and attentive to international developments, especially after the publication of "*The European Code of Conduct for Research Integrity - Revised Edition*"[2] with regard to the requirements and rules that are being developed in the different countries, has decided to elaborate its current reflection.

The Council's objective is to emphasize the importance of this area and the need to promote a sound and ethically robust research integrity policy in the National Science and Technology System, thus providing researchers, higher education research institutions or private entities and funding agencies with a model for responsible research.

## 2. CONCEPTS AND DEFINITIONS

### 2.1 RESPONSIBLE CONDUCT IN RESEARCH

The fundamental ethical principles for responsible research established in the European Code of Conduct for Research Integrity (2017) include the following:

Reliability: in insuring the quality of research, reflected in the experimental design, in the methodologies to be used, in the analysis of the results and in the use of resources;

Honesty: in the development, implementation, review, report and communication of research;



Respect: for colleagues, research participants, society, ecosystems, cultural heritage and the environment;

Accountability: for the research, from idea to publication, for its management and organization, for training, supervision and mentoring, and also for its wider impacts.

Therefore, responsible research should strive to seek the truth (**honesty**), using scientifically (**reliability**) and ethically robust (**respect**) methods that are impactful to the scientific community and to society (**Accountability**).

In view of this purpose, it is important to distinguish between science as knowledge and individual science, also setting those apart from the institution where it is developed. Integrity is articulated in three dimensions: the researcher's relation to scientific truth (science as knowledge), the researcher's ethical relationship with other researchers and research participants (science focused on individual behavior) and the researcher's

[2] ALLEA | All European Academies. (2017) The European Code of Conduct for Research Integrity. Revised Edition. Retrieved from http://www.allea.org/wp-content/uploads/2017/03/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017-1.pdf

relationship with the host and financing (institutionally focused science). Thus, respect for the values that underpin the relationship between researchers and scientific truth, with others (society) and with institutions (research environment and funding), is essential in research and forms the basis of its ethical core.

### **2.2** MISCONDUCT OR SCIENTIFIC FRAUD IN RESEARCH

With regard to research integrity, we can find situations of scientific fraud and other circumstances that are ethically unacceptable. The term "scientific fraud", which has been established in literature as a distinctive label for all such cases, has been gradually replaced by the term "misconduct" (scientific misconduct). On the basis of this conceptual change we can find the normative framework for "fraud". In fact, under US law, "fraud" presupposes verifying the existence of evidence and demonstrating dishonesty and damage caused to the victim. In the vast majority of cases, the requirement of a victim constitutes an inadequate assumption to fulfill the concept of "fraud" in relation to scientific research. In the dictionary of the Portuguese Academy of Sciences (2001), "Fraud" is defined as "an act committed in bad faith, with the intention of deceiving, injuring or harming others." The need to harmonize concepts and denominations notwithstanding, the substitution in the Portuguese language of "scientific fraud" ["fraude científica"] for "misconduct in investigation" ["má conduta em investigação"] would lead to a clear reduction of its rhetorical effectiveness and could result in the loss of its relevance as an objectionable conduct. Thus, regardless of whether the legal framework in Portugal is similar or not to that of the United States, which will not be discussed in this context, the CNECV has decided to use the two terms as synonyms throughout this recommendation.



Scientific fraud is a deliberately false representation of truth. In this regard, it is different from "bad" or "erroneous" science due to methodological or other errors, misinterpretation of data, error in proof, negligence, or ethically objectionable behavior. However, all these aspects upset the concept of integrity and deserve as rigorous an assessment as the most serious – fabrication, falsification and plagiarism. The European Code of Conduct for Research Integrity defines these concepts as follows: "Fabrication is making up results and recording them as if they were real. Falsification is manipulating research materials, equipment or processes or changing, omitting or suppressing data or results without justification. Plagiarism is 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." Consequently, inventing data or results (fabrication), changing or composing data or results (falsification), and using the ideas or words of another without acknowledging proper authorship (plagiarism) - all this harms the core values which should be structuring of science and of scientists[3].

[3] In our understanding, plagiarism lies on a different plane of offense; it is an offense to the scientific community but not to the truth of science. However, for reasons of uniformity, and bearing in mind that the

On the other hand, a conflict of interest happens whenever "an institution or individual has a primary commitment and, at the same time, a secondary commitment that can override the former, or is tempting enough to create the possibility or appearance that this may actually happen " (Hazard Jr G, C., 1996, *apud* Lobo Antunes, 2008). A conflict of interest may refer to situations of conflict between primary interests, which are recognized as being determined by higher moral values and include the promotion and protection of research integrity - for example, patient well-being (in clinical research) (eg. teaching and research) - and secondary interests, which may or may not be illegitimate, but whose relative weight can never jeopardize the primary interest in question - such as financial gain, illicit priority in a discovery or the ambition of public recognition.[4]

However, there are other practices, which are also ethically unacceptable, which include, among others, the following aspects: (1) manipulation and breach of authorship[5]; (2) inadequate protection research participants and insufficient protection of animals in research[6]; (3) lack of adequate publication criteria; (4) inadequate sharing of responsibility between researchers and other team members, and (5) ineffective guidance and supervision. All these situations are ethically relevant and affect the *ethos* of science. These must also be subject to concrete, fair and transparent norms and policies.



acronym "FFP" (fabrication, falsification and plagiarism) has been settled in the scientific debate, we will consider plagiarism in the same category of moral offense.

4 Conflicts of interest and peer reviews and conflicts of interest with the pharmaceutical industry have deserved special attention in recent times and have been the object of a more extensive reflection in Opinion 72/CNECV/2013. National Council of Ethics for the Life Sciences. Opinion on Declaration of Interest and Conflict of Interests in Health and Biomedical Research (July 2013).
http://www.cnecv.pt/admin/files/data/docs/1413216720_P%2072%20CNECV%202013.pdf

5 A frequently asked question concerns the authorship and the order in which authors are to appear in scientific articles. Although this does not affect the quality of the research or take value from the knowledge it generates, it affects the researchers' careers and the reputation of the research institution. The International Committee of Medical Journal Editors (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html) argues that authorship credits should be based only on substantial contributions to: (a) design, planning, analysis or interpretation of data, (b) drafting the article or its critical review, (c) responsibility for final publication approval, and (d) responsibility for the integrity of the results to be published to ensure that the related issues are properly investigated and resolved. The contribution of people who do not meet the above criteria should be listed, with their permission, in the acknowledgments section.
The emergence of multicentric research, divided into areas of specialization, has demanded special attention be paid to these criteria. Drummond Rennie (2000), deputy editor of the Journal of the American Medical Association (JAMA), suggested replacing "authors" with "collaborators", explaining on the front page the contribution of each collaborator in the research concerned. This proposal, already partially adopted by some newspapers, essentially in the biomedical area, would solve this question efficiently, as well as the one related to the order in which the authors are listed; if it is clear what each participation will be, it will not matter in which order the name appears.

6 We refer to the ethical issues identification forms and their requirements, adopted by the Foundation for Science and Technology, which comply with the ethical evaluation criteria in force in the European funding program H2020 https://www.fct.pt/apoios/unidades/avaliacoes/2017/docs/EthicsGuide2017.pdf

## 3. CAUSES, NUMBERS AND IMPACT[7]

### 3.1 CAUSES

The reason for the reoccurrence of ethical misconduct may include several aspects, which we will attempt to group into three factors, varying in nature (Davis et al., 2007, Kaiser, 2014):

(1) Individual – in that, being science a human activity, there will always be individuals who exhibit deviant behavior. Therefore, there will always be deceitful behaviors within the scientific community, which are intrinsically immoral or amoral. The traits of socially unfit personality, vanity or the desire to achieve a high scientific reputation and peer recognition, as well as the passionate conviction about a particular theory, research line or scientific thesis may, among others, be grouped in this category.

(2) Organizational - the nature of human relationships within an organization has been pointed out as one of the pertinent motives for integrity failures. Among the factors described in scientific literature that are included in this category we can highlight: (a) the lack of ethically robust and fair institutional policies regarding integrity; (b) inadequate communication, supervision and mentoring; (c) inadequate training and skills in ethics and research integrity, both at the level of formal education and at the level of education by example (the role of the supervisor / tutor as a model of ethically correct behavior); (d) the way of doing science, corseted between teams, between areas, between institutions and between countries, which hampers the possibility of ethically objectionable behavior being discovered.



(3) Structural - the assessment of the researcher's prestige, and the scientific impact of his work, based on the "publish or perish" standard, is undoubtedly one of the main threats to the *ethos* of science. The evaluation criteria of science and the activity of scientists must be rethought. The appraisal of the research centered on bibliometric indicators, their citation indexes and impact factors, the pressure to obtain results, to finance projects or to achieve self-financing through grants - all these factors force us to question whether the present way to evaluate science and scientists poses by itself a serious threat to the robustness of the scientific enterprise.

### 3.2 NUMBERS

A systematic review (Fanelli, 2009) has found troubling results: 2% of the scientists confessed to having fabricated or falsified results and 34% admitted other ethically questionable behaviors. However, when questioned about the behavior of other scientists,

[7] This chapter was based on the Declaration on research integrity in responsible research and innovation by Casado, M., Patrão Neves, MC, Lecuona Ramírez, I., Carvalho, AS, Araújo, J., UNESCO Bioethics, Bioethics Institute - Portuguese Catholic University and the University of Barcelona, 2016. https://cdn-61ba.kxcdn.com/wp-content/uploads/2016/11/declaracion-integridad-cientifica-investigacion-innovacion-responsable.pdf

the numbers were much more disturbing: the percentage of fraud rised to 14% and that of ethically questionable conduct to 72%.

Data obtained from the Office of Research Integrity (ORI) in the United States of America indicate results that should be carefully considered: in 2012, the number of complaints compared to the previous year rose by 56% (423 complaints in 2012), having been verified that of the 29 cases investigated 40% had, in fact, serious failures of research integrity. More recently (2015) the ORI carried out an investigation with 2212 researchers and found that, of these, 201 had been involved in probable cases of scientific fraud in the previous three years, ie two incidents per 100 investigators, a rate considerably higher than the annual number of denunciations submitted to the ORI.

### 3.3 IMPACTS

Scientific misconduct is not a crime without victims. Misconduct impacts researchers and research participants, institutions, research areas and society.

#### 3.3.1 Impacts of scientific misconduct in the field of clinical research

Patients may be negatively affected when the treatments they receive are based on false or incomplete data. According to Lehman and Loder (2012) "a large number of evidence from clinical trials in humans is not stated, and much of what is reported is done inappropriately." The impact of these practices is that "lack of data on adverse effects in clinical trials may harm patients, and incomplete data on the benefits can lead to unnecessary costs to health systems."



The retraction of an article presenting a clinical study may take between 22 and 79 months[8, 9]. In addition, it is often not absolutely clear what has become of the retracted article, as well as the reasons for such retraction[10]. Taking into consideration the impact the results of a clinical study may have on society, the fact that the news of the retraction may not reach as many readers as the article itself should, among others, be grounds for apprehension.

#### 3.3.2 The collateral effect of scientific misconduct for research and researchers

An accusation of serious misconduct harms the researcher's career and reputation. He may lose his job, see his medical license and funding be withdrawn, become *persona non grata* to the scientific community, and in some serious cases may even be subject to

[8] Trikalinos N.A., Evangelou E. and Ioannidis J.P.A. (2007), Falsified papers in high-impact journals were slow to retract and indistinguishable from nonfraudulent papers. Journal of Clinical Epidemiology, 61(5):464-470.
[9] Abdiel Foo J.Y. (2011), A retrospective analysis of the trend of retracted publications in the field of biomedical and life sciences. Science and Engineering Ethics, 17:459-468.
[10] Davis P.M. (2012), The persistence of error: a study of retracted articles on the internet and in personal libraries. Journal of the Medical Library Association, 100(3):184-189.

conviction by the judiciary system (although this is rare). More difficult to quantify is the collateral damage that scientific misconduct may cause to fellow researchers, the host institution and the study area where misconduct was practiced by the researcher found guilty.

Doctoral students advised by a discredited senior researcher may be prevented from posting joint papers, their doctoral thesis may be affected by fraudulent data provided by their advisor and their prospects of future employment may be affected[11]. There is also a penalty for authors linked to works that have been published and retracted[12]. Rather unfairly, many "whistleblowers" suffer negative consequences in their personal and professional lives. At best, an informer may find discomfort in the workplace, forcing him or her to look for work elsewhere. Even where legislation is in place to protect the rights of "whistleblowers", these regulations do not always work[13]. Also, in scientific systems where there is competition for funds or prestige, situations of bad faith, where complaints are used in an ethical and deontological illegitimate way as a form of competition, cannot, in this context, be disregarded.

### 3.3.3 The financial costs of scientific misconduct

There are direct and indirect financial costs associated with scientific fraud. A 2014 study of publications retracted on grounds of serious misconduct calculated that the direct cost to the National Institute of Health (NIH) was approximately $425,000 per article[14]. The study also estimated that the waste of total NIH funding with articles retracted between 1992 and 2012 was $1.67 billion. Another study looked at how much a case of misconduct can cost a research institution and calculated that the direct cost is approximately $500,000, and that the total cost of all claims reported to the ORI in 2009 was about $110,000,000[15].



These estimates do not include the costs of loss of public trust / willingness and damage to the reputation of laboratories or institutions, nor the indirect costs of unproductive research by other scientists who have based their work on fabricated and / or falsified data. These estimates also do not include the overhead costs of scientific fraud to society, such as disease or avoidable loss of life due to misinformation in medical literature. The European research system is considerably larger and more complex than that of the United States of America. The cumulative costs of scientific fraud for Europe, both direct

[11] Editorial Comment (2010), Collateral damage. Nature, 466:1023. doi: 10.1038/4661023a.
[12] Feng Lu S., She Jin G., Uzzi B. and Jones B. (2013), The retraction penalty: Evidence from the web of science. Scientific Reports, 3:3146 doi: 10.1038/srep03146.
[13] Faunce T.A. and Jefferys S. (2007), Whistleblowing and scientific misconduct: Renewing legal and virtue ethics foundations. Medicine and Law, 26:567-584.
[14] Stern A.M., Casadevall A., Steen R.G. and Fang F.C. (2014), Financial costs and personal consequence of research misconduct resulting in retracted publications. eLife, 3:e02956.
[15] Michalek A.M., Hutson A.D., Wicher C.P. and Trump D.L. (2010), The costs and underappreciated consequence of research misconduct: A case study. PLoS Medicine, 7(8):e1000318.

and indirect, will be much greater if no effort is made to promote a culture that covers research integrity and shuns all negative impacts of scientific fraud.

## 4. THE EUROPEAN CONTEXT

In Europe, a recently published study indicated some heterogeneity (Godecharle, Nemery & Dierickx, 2013)[16]. In the Nordic countries, as well as in most countries of central and Western Europe, there are national guidelines for cases of research misconduct and for promoting research integrity. However, only Denmark and Norway have specific legislation in place to deal with cases of scientific fraud, and many of the mentioned countries include a number of guidelines with apparent lack of national consensus. With the exception of Denmark and Norway, there is no uniformity of principles or definitions. The study also indicates the lack of research integrity guidelines in seven countries (Bulgaria, Cyprus, Lithuania, Portugal, Romania, Slovenia and Luxembourg); however, the situation has recently been amended in Luxembourg and Slovenia. Four countries were not considered, either because of lack of recommendations in English language (Slovakia) or because the documents collected / submitted were considered outside the scope of research integrity (Italy, Malta and Iceland). The absence of a national policy framework in this area does not preclude the existence of local guidelines at universities or research and educational institutions and does not imply that research in these countries is not carried out with high standards of integrity. Indeed, it should be noted that several countries, such as Germany, Austria and Norway, have established national documents only after scandals of serious cases of misconduct were revealed.



In Portugal, breaches of research integrity are usually assessed by *ad hoc* committees set up in the institutions where the studies take place. The assessment criteria and the manner in which they are used are rarely known and the findings of the possible investigation are rarely published. With the remarkable progress of national scientists, their high level, their productivity and their participation in international projects, it is urgent to establish clearly defined rules of conduct, as well as to define and implement a robust policy in this area.

[16] Godecharle, S., Nemery, B., & Dierickx, K. (2013). Guidance on research integrity: no union in Europe. *The Lancet*, *381*(9872), 1097-1098.

**RECOMMENDATION**

Considering that:

a) the objective of scientific research is the pursuit of knowledge, using methods that are scientifically and ethically robust and have an impact on the scientific community and society;
b) in science, truth is an ethical imperative that can only be guaranteed with the highest standards of ethics and integrity in research;
c) the known cases of lack of integrity in science have had a significant increase, with an obvious individual, social and economic impact;
d) with the remarkable progress of national scientists in number, level, productivity and participation in international projects, it becomes urgent to establish clearly defined rules of conduct and to implement a robust policy in this area, as is now the case in most Member States of the European Union;
e) the European Commission intends to ensure a culture of research integrity in all Member States;
(f) the revised version of "The European Code of Conduct for Research Integrity" was published in 2017;
g) the European Commission, through the European Commissioner for Research, Science and Innovation, encourages the signing and implementation of the European Code of Conduct for Research Integrity at national level;
(h) the European Commission will require all participants in projects funded by European H2020 funds to commit themselves to following the principles and rules laid down in the European Code of Conduct for Research Integrity;



The CNECV recommends:

1. Research institutions, as well as public and private higher education institutions, industry, researchers from all fields of knowledge and funding agencies shall ensure and promote ethical principles and standards of integrity as specified in the European Code of Conduct for Research Integrity. These principles are: (1) **Reliability** in ensuring the quality of research, reflected in the experimental design, the methodology, the analysis and the use of resources; (2) **Honesty** in developing, undertaking, reviewing, reporting and communicating research; (3) **Respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment; (4) **Accountability** for the research from idea to

publication, for its management and organization, for training, supervision and mentoring, and also for its wider impacts (scientific, social and economic).

2. In this regard, research and higher education institutions, funding agencies, scientific societies and policymakers in Portugal should make clear their commitment to respect for research principles and good practices contained in The European Code of Conduct for Research Integrity, with the appropriate amendments, thus contributing to reinforce confidence in the Research & Innovation System.
3. After public consultation and appropriate involvement of the main actors of the National Scientific and Technological System, this Code should be approved and used as a reference model in the development or adoption of the policies and codes of each research and higher education institution.
4. All research and higher education institutions shall be committed to the promotion of a national culture of research integrity. They shall, *inter alia*: (a) establish clear, objective, transparent and fair procedures for investigating potential breaches of research integrity; (b) promote the appropriate training of all researchers in the area of ethics and research integrity; (c) ensure that the allocation of supervisors or tutors does not compromise the capacity for responsible guidance and supervision; (d) to establish fair and equitable criteria for the recruitment and promotion of researchers, which do not rely exclusively on quantitative parameters.
5. A culture of scientific integrity should be promoted, enabling excellence and maintaining public trust in science; this calls for an open and active statement of the interests involved, thus fulfilling the principles of responsibility, public accountability and transparency in scientific research.
6. In all research and higher education institutions, it is desirable to establish an entity (a commission or a personality, eg an "Ombudsman for Research Practice") to monitor potential misconduct. He / she must report directly to the head of the institution, having the power to mediate and evaluate, without decision-making power, the complaints addressed to him / her and to make inquiries, being able to request the data and information indispensable for the performance of his / her function. The members of the Commission or the Ombudsman shall conduct their conduct according to the following principles: impartiality, availability, responsibility, confidentiality, lack of conflict of interests and promptness in procedures and decisions.
7. The investigation of claims of misconduct to be carried out in each institution should be consistent with national law. All investigations must be accomplished in accordance with the highest standards of integrity, also at the procedural level, within an area of competency and justice for all parties. They must be prompt and lead to adequate and equitable results and sanctions.

**8.** In more serious situations, with a view to ensure an appropriate, fair and uniform procedure, with adequate and equitable results and sanctions, a National Commission for Scientific Integrity may be established. Fourthermore, all cases of suspected fabrication, falsification and deliberate omission of undesirable data, which are serious breaches of the research *ethos*, require a differentiated procedure. In such situations, following the internal procedures developed by the institutions, any proposed sanctions should be the subject of a mandatory opinion issued by the National Commission for Scientific Integrity before the final decision is made public.

**9.** The different areas of research should be represented in this Committee as they are organized in the respective funding agencies (Exact Sciences and Engineering, Life Sciences and Health, Environmental Natural Sciences and Social Sciences and Humanities), which should progressively adopt evaluation parameters for institutions and researchers that favor a culture of research integrity.

Lisbon, February 5, 2018.

The President, Jorge Soares.
Rapporteur: Ana Sofia Carvalho.