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Strengthening scientific integrity through regulation: The cooperation between law and science

Rafforzare l'integrità scientifica attraverso la regolamentazione: La cooperazione tra diritto e scienza

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ABSTRACT

This paper aims to demonstrate that Research Integrity is a vital component that promotes effective collaboration between regulations and scientific inquiry. It begins by defining the concept of Research Integrity, particularly highlighting its relationship with Research Ethics. By positing that the general definition of Research Integrity pertains to adherence to guidelines and professional standards, the analysis focuses on clearly identifying these guidelines. This includes an examination of international codes of conduct and ethical guidelines, on one side, and a discussion of the role of law in regulating Research Integrity on the other side. Ultimately, this analysis seeks to provide a comprehensive understanding of the complex dimensions of Research Integrity.

KEYWORDS

Research Integrity
Regulation
Misconduct
Law and Science

SOMMARIO

Il presente articolo mira a dimostrare che l'integrità della ricerca è una componente fondamentale che promuove una collaborazione efficace tra regole, vincolanti e non, e ricerca scientifica. Si ritiene in primis necessario definire il concetto di integrità della ricerca, sottolineando in particolare la sua relazione con l'etica della ricerca. Partendo dal presupposto che la definizione generale di integrità della ricerca sia strettamente connessa al rispetto delle linee guida e degli standard professionali, l'analisi si concentra sull'identificazione chiara di tali linee guida. Ciò include, da un lato, l'esame dei codici di condotta internazionali e di linee guida etiche e, dall'altro, una discussione sul ruolo della legge nella regolamentazione dell'integrità della ricerca. In definitiva, questa analisi mira a fornire una comprensione completa delle complesse dimensioni dell'integrità della ricerca.

PAROLE CHIAVE

Integrità della ricerca
Regolamentazione
Condotte illecite
Diritto e Scienza

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1. INTRODUCTION

Since the beginning of his second term in the White House, President Trump has initiated significant changes at the federal level that have profoundly impacted research activities and institutions in the United States and beyond. These interventions are strongly opposed by the scientific community, both domestically and internationally, as they represent undue political interference with scientific freedom and research[1]. This current situation illustrates the delicate relationship between politics, legislators, and science, highlighting the crucial importance of scientific and academic freedom, the perils of unsound political interferences with science and the attention and care that regulation of research activities requires.

Despite these challenges, though, it is essential to recognise that a relationship between science and politics must exist: the solution to the problem of excessive political interference in the scientific realm cannot be found in a total separation of the two worlds, which is not feasible in today's world. Science requires political and legislative interventions to protect and promote its freedom while also establishing limits on unacceptable scientific practices[2]. Nevertheless, over the decades, this relationship has consistently shown points of tension and the need to periodically reconfirm the reciprocal boundaries of intervention[3]. As demonstrated by the Trump administration's behaviour, this necessity has become an urgency in the contemporary world of ongoing scientific advancements and increasingly complex technologies.

An additional challenging consequence of the expansion of scientific research is related to the numerous rules being introduced to govern the research process and to prevent or address misconduct. The term "rules" is used hereinafter in a general and non-technical sense, which encompasses all different sources – legally binding or not – that deal with Research Integrity (RI) and its principles. Undoubtedly, scientific, medical, and clinical progress today are regulated by a variety of sources with different levels of legal authority.

On the one hand, there are rules derived from guidelines or acts that are not legally binding or lack direct legal enforcement, but may nevertheless have a significant impact in multiple countries. This is the case, for example, of the European Code of Conduct for Research Integrity, which collects principles on Research Integrity shared among different European research institutions that have formally adhered to it[4]. On the other hand, there are specific laws that have a more defined scope of application and are legally binding. For instance, the European General Regulation on Data Protection (GDPR) is a legally enforceable instrument with a precise focus — the protection of personal data — that has a relevant impact on research activities and processes.

These brief examples highlight that, with different "rules" at play, the research process is guided by a multitude of sources of diverse natures, including ethical, legal, and deontological considerations. This highlights the necessity for researchers and those involved in research activities to be aware of the nature, value and contents of these sources. Understanding and discerning these rules is essential to promote and ensure their adequate application, benefiting both the scientific community and society as a whole.

The well-known case of the experiment conducted by Dr He Jiankui in November 2018, which resulted in the birth of twin girls with modified genes to make them immune to HIV, clearly illustrates this situation[5]. This case highlights the increasing overlap of various rules, including ethical guidelines and national laws, that influence the research process, and it emphasises how crucial it is to have a clear understanding of these regulations to ensure proper execution of research. A correct knowledge and familiarity with all the "rules", along with their thoughtful application, leads to more reliable findings, which serve as a strong foundation for future research. This, in turn, promotes greater social trust, an essential value in an era of growing scepticism towards science and the prevalence of misinformation and pseudoscience[6].

Additionally, it is crucial to recognise that the specific characteristics of these two realms—rules on one side and science on the other—shape a relationship that can either be collaborative or conflictual. To correctly react when the interaction is contentious and to properly incentivise and expand the cases in which the relationship is beneficial, the application of the principles of RI becomes a significant point of reference.

In light of these considerations, this paper seeks to establish how Research Integrity is an essential component that fosters effective collaboration between regulations and scientific inquiry. To achieve this, it will first define the concept of Research Integrity and elaborate on its connection to Research Ethics. In the second section, the paper will examine the various approaches to regulating Research Integrity, beginning with an analysis of international codes of conduct that set forth professional and ethical guidelines. It will then discuss the role of law in connection to the regulation of Research Integrity and propose a potential classification. Ultimately, this analysis aims to provide a comprehensive understanding of the intricate dimensions of Research Integrity.

2. DEFINING RESEARCH INTEGRITY

In instances where the relationship between rules and science is beneficial, a fair balance is achieved through compromise and dialogue, resulting in research that is not only scientifically sound but also aligns with ethical standards and integrity. Unfortunately, these cases are typically the exception rather than the norm. More often than not, this interaction tends to be conflictual, a tension rooted in the fundamental differences between the two domains[7].

Scientific research has primarily aimed to advance societal progress and promote the greater good. However, throughout history, this progress has sometimes occurred without adherence to established rules, often because, in the distant past, such rules did not exist[8]. In some cases, violations of laws or ethical standards have led to discoveries that continue to be utilised today (i.e. the vaccine for Hepatitis A developed on children housed at the Willowbrook State School, or the Tuskegee Syphilis Study conducted on unaware African-Americans)[9]. Although these findings were obtained through methods that we would now classify as "unethical", their current applications have a positive impact. Therefore, while legal restrictions have sometimes limited scientific research, these limitations have primarily aimed to strike a balance between scientific progress and respect for fundamental rights.

In this context, Research Integrity (RI) started to play a crucial role and has been increasingly continuing to do so today. To fully grasp its significance, it is important to understand what the term entails. Although RI is defined in many texts at both national and international levels, it encompasses both legally binding norms and non-binding principles. As a result, the definition may vary depending on the context and the purpose for which the concept is referenced.

For example, some definitions aim to describe the concept extremely broadly. According to the United Kingdom Research Integrity Office, "Research integrity covers all research and the whole lifecycle, from the initial idea and design of the project through the conduct of the research and its dissemination. It also covers making sure that environments and systems for research safeguard and enhance good research practice, rather than hinder it – often described as 'research culture'." It is an extremely wide concept, as it "refers to all of the factors that underpin good research practice and promote trust and confidence in the research process. Research integrity covers all disciplines of research and all sectors where research is carried out"[10].

Similarly, but with different terminology and with more emphasis on the regulatory component of RI, the Italian Research Council defines it as "the body of principles and ethical values, deontological obligations and professional standards that form the basis of the responsible and correct conduct of those who carry out, finance or evaluate scientific research, as well as the institutions that promote and perform it. The application of principles and values, and the respect for deontology and professional ethics and standards, guarantee the quality of the research and enhance the reputation and public image of science, greatly contributing to its advancements and to progress in society"[11].

In sum, Research Integrity could be defined as a "set of moral and ethical standards that serve as the foundation for the execution of research activities"[12]. The concept is deeply related to self-regulation, as RI has traditionally served to formalise rights and responsibilities in the field of research[13].

2.1 THE INTERLACES WITH RESEARCH ETHICS

In general, there is no shared and official definition of Research Ethics (RE) and Research Integrity (RI). The deep interconnection of the two

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concepts and the different perspectives from which they could be dealt with do not ease the distinction. To clarify their respective fields of application, it could be argued that, while both are interdependent and pertain to scientific activities, they emphasise different aspects.

When applied to behaviour, integrity refers to an individual who embodies qualities such as sound moral principles, uncorrupted virtue, and honesty. As explained above, integrity in the context of research involves consistently adhering to high moral standards and professional guidelines established by organisations, institutions, and relevant authorities. However, this broad definition can lead to challenges: while moral principles raise important questions about researchers' responsibilities and can lead to varying interpretations of ethical considerations, professional standards and regulations provide clear guidance on their roles, and are rarely open to contradicting evaluations[14].

Under those circumstances and to better understand professional research behaviour, some interpret Research Integrity as abiding by professional standards and guidelines, differentiating it from Research Ethics, which focuses on the moral issues that arise during research[15]. More specifically, Research Ethics could be defined as "essential for maintaining the integrity and credibility of scientific inquiry. Adherence to ethical standards ensures that the research process is conducted transparently and that the findings are reliable and trustworthy. It is both a moral duty and a legal necessity, enforced by many institutions and regulatory authorities"[16].

As mentioned, given the lack of consensus on the topic, a formal definition of Research Ethics, as an autonomous concept, is not expressed in official guidelines. Yet, international codes of conduct outline and regulate key principles that embody RE. For example, fundamental ethical principles such as respect for persons, beneficence, non-maleficence, justice, the importance of informed consent and confidentiality – which all descend from the application of Research Ethics – are all outlined in various international ethical guidelines, including the Declaration of Helsinki[17], the European Convention on Human Rights[18], and the Singapore Statement on Research Integrity[19].

Thus, given its strict connection to key ethical principles, the concept of RE is additionally closely linked to the establishment of Ethics Committees, which were introduced to ensure a correct application of such principles and to promote the protection of fundamental rights of subjects involved in research practices. These committees play a crucial role in promoting ethical research by evaluating research protocols and providing general opinions on key topics within the research agenda.

Historically, Ethics Committees arose from the need for the scientific community to develop guidelines that ensured the ethical conduct of research and prevented violations of basic human rights in the name of scientific progress[20]. Because they comprise members with expertise in both scientific and nonscientific fields, by bringing together diverse perspectives and knowledge, they aim to strike a fair balance between the scientific goals of a trial and the protection and respect for the well-being of human subjects[21]. In this sense, Ethics Committees represent a valuable application of RI as a place of communication and confrontation between law, science, and other areas of knowledge involved in scientific research. They ensure that the correct protocols and guidelines are followed in studies presented to them. Primarily, though, they are an expression of RE because they address ethical issues that may arise during the research process and offer guidance.

3. PROFESSIONAL AND ETHICAL GUIDELINES FOR FOSTERING RESEARCH INTEGRITY

If we refocus the discussion on the main subject of Research Integrity, we can summarise the definitions above by stating that it involves "possessing and steadfastly adhering to professional standards established by professional organisations, research institutions, and, when relevant, government and public entities"[22]. In light of this comprehensive definition, it is crucial to examine the origins and consistency of the professional standards cited.

As mentioned in the introduction, there is a distinction between different types of rules that govern RI: some are derived from acts that do not possess direct legal enforcement, whereas others are legally binding and have a clearly defined scope of application. This paragraph will address the first category, focusing in particular on the European scenario. However, given the international significance of research, it is essential to cite worldwide meetings and documents related to the subject.

In the past, ethics and integrity in research were seen mainly as individual virtues, focusing on the researcher's behaviour. However, this view has evolved; it is now recognised that both institutions performing and funding research share equal responsibility with researchers, as they all play a key role in promoting responsible practices and ensuring the proper use of research results[23]. The need to start working on commonly agreed-upon and harmonised integrity research rules was first officially recognised in 2007, with the organisation of the First World Conference on Research Integrity in Lisbon, Portugal, held by the European Science Foundation (ESF) and the US Office of Research Integrity (ORI, Department of Health and Human Services). The global forum welcomed participants from 47 countries to discuss and promote an exchange about ways to foster responsible research practices[24]. The conference was a joint effort by the scientific community to address the growing number of scandals related to ethical and research misconduct that frequently made the headlines[25]. Moreover, the conference's objective was to initiate a global dialogue on Research Integrity as it served primarily as a venue for discussion and confrontation, aiming to identify the key issues that needed to be addressed within the community[26].

In 2010, the Second World Conference on Research Integrity was held in Singapore. This conference led to the creation of a document known as the Singapore Statement on Research Integrity, marking the first international effort to encourage the development of unified policies, guidelines, and codes of conduct aimed at promoting greater integrity in research worldwide. The Singapore Statement received global recognition, and sought to provide ethical guidance that research organisations, governments, and individual scientists could use to formulate their own policies[27]. Thus, although it was a broad initiative, it represented a significant first step toward the harmonisation of regulations regarding research integrity.

The same goal of harmonisation was also pursued in Europe. In one of the first surveys on research integrity standards, the European Science Foundation – a non-profit, non-governmental organisation that provides support and management throughout the research process – found a wide variety of approaches used across different European countries. To address the problem, the European Code of Conduct for Research Integrity was created, initially published in 2011 and updated in 2017, with the most recent revision in 2023[28]. The code was developed by ALLEA (All European Academies), an association of over fifty scientific and humanities academies from around forty countries, which aims to ensure the production of trustworthy science through "education, promoting a culture of integrity, and by development of and compliance with joint rules and norms"[29].

The ALLEA Code strives to promote proper conduct and principled practices in systematic research across medical, natural, social sciences, and humanities, aiming to represent a consensus among European researchers and research infrastructures on a set of principles and recommendations for the research community[30].

In addition, in 2019, the European Network of Research Integrity Offices (ENRIO)[31] developed a Handbook focused on misconduct as a further specification of the section of the ALLEA European Code of Conduct, to define a set of guidelines specifically concerning research misconduct and other unacceptable practices[32].

While the ALLEA Code emphasises RI in a broad sense, the ENRIO Handbook provides practical guidance on addressing misconduct. Together, the two texts define a comprehensive normative framework for applying and regulating Research Integrity across Europe. Nevertheless, it is essential to note that neither document carries direct legal value: European states are not obligated to apply or enforce either text but may use them as inspiration for their own national legislation.

Interestingly, despite originating from the same place and during the same time, the principles outlined in the ALLEA Code and the Singapore Statement do not perfectly align. The Singapore Statement specifies fourteen responsibilities for ethical research conduct, including integrity, adherence to regulations, authorship, and publication acknowledgement. In contrast, the European document presents a broader list of principles. Most importantly, the

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Code of Conduct includes honesty, essential in conducting and reporting research transparently and fairly; respect, which should be shown to colleagues, participants, and the environment; accountability, in the whole research process from concept to publication; and reliability, to ensure quality through careful design, robust methodology, analysis, and effective use of resources. These fundamental principles represent the basis for further development of additional conceptual frameworks and definitions included in the Code.

Although relatively minor, these differences are significant because they highlight the challenges in defining research integrity. While the principles in both documents are largely similar, the existence of even a small difference underscores the lack of a general consensus on the true meaning of Research Integrity[33].

The diversities do not stop here. In fact, no national-level leading document fully adopts the formulation of the ALLEA Code in relation to the core elements of Research Integrity, as there is significant variation in the principles and types of misconduct identified. On one side, concerning the latter, the only clear consensus is that Fabrication, Falsification, and Plagiarism (FFP) are considered misconduct, but this consensus is global and not particularly surprising. On the other side, regarding the principles of RI, the closest to a quasi-consensus that can be found in the national codes is the principle of honesty. However, even here, the agreement on such a principle feels predictable as well[34].

Although the differences may appear to stem from variations in expressions and formulations, a deeper analysis reveals a lack of harmonisation among national codes regarding fairness and credibility. This lack of consistency can lead to unjust outcomes, as differing national documents create opportunities for varying assessments of joint misconduct in international collaborations. More troubling, some argue that this situation fuels scepticism towards self-regulation. Critics contend that the primary function of a code of conduct is merely to create a façade of integrity, implying that the relentless pursuit of competitive advantage ultimately governs research behaviour[35].

The Singapore Statement of RI and the ALLEA Code were essential steps to start building a harmonised and prosperous research environment respectful of integrity and ethics. However, they were supposed to be the ground core from which nations should have built their own codifications coherently. Instead, the differences, even just between European States, are considerable, and this necessarily negatively impacts the overall application and respect of RI.

On the bright side, these documents signalled the beginning of an era in which the respect of RI principles, and the consequent opposition to misconduct, has been increasingly expanding through a multitude of initiatives, such as the Coalition for Advancing Research Assessment (CoARA). This project, initiated by the European Commission to reform the research assessment landscape, requires its signatories to create and publish an action plan, commit to reviewing their assessment criteria within a year of signing the agreement, and share and report on their approaches within five years[36].

Even outside of Europe, there are several international initiatives aimed at transforming the way research is conducted, shared, and evaluated, such as the San Francisco Declaration on Research Assessment (DORA), which outlines 18 recommendations for changing how researchers and their outputs are assessed, and other initiatives that advocate for a holistic assessment approach, like the Hong Kong Principles which suggest that research assessment should reward responsible research conduct, open science, transparent reporting, and various other scholarly contributions[37]. It is undeniable that, as of late, the scientific community has been strongly reacting towards major violations by stigmatising these sorts of behaviours or by establishing rules and principles to prevent new wrongdoings. Adopting the policies described in some of the relevant documents, both at the European and international levels, exemplifies the scientific community's need for shared rules and principles to promote responsible research.

4. THE REGULATION OF RESEARCH INTEGRITY AND THE ROLE OF LAW

The presented scenario shows how much science needs and deserves regulation. It is necessary, indeed, to prevent fraud and misconduct and also to ban inhuman or unethical behaviours. Historically, the number of breaches of basic rules concerning experiments, trials, or research has been countless and the scientific community or the legal and political level started to address these issues basically as a reaction towards gross violations and some scandals[38]. These experiences raised the attention on the need for efforts and interventions to promote public trust in science, which is necessary to nurture the relationship between science and society and is the first antidote to pseudosciences and to the spread of fake news[39].

Ensuring that researchers and institutions act in a respectful, honest, rigorous and righteous manner contributes to the building and enforcement of social trust in science. In the contemporary era, the broad access to the internet and information has brought the possibility of wider access to data and scientific knowledge, favouring a democratisation of science with positive outcomes and access to the benefits of scientific development to a broader population, especially in underdeveloped countries[40]. But it has, nevertheless, contributed to the spread of questionable attitudes towards science. The wide accessibility of scientific publications makes science more to scientific knowledge, in fact, entails the possibility of freely raising objections to scientific works, without having the appropriate background to do so.

In this complex scenario, promoting public trust in science is crucial for maintaining a balanced role for the scientific community within society.

For all these reasons, regulating the way in which research is performed has required a growing involvement of professional, ethical and, most interestingly, legal rules. Yet, the scientific community does not always positively welcome a legal regulation of science, because it may perceive it as an external intrusion that could interfere with scientific freedom.

On the contrary, addressing research integrity and preventing breaches requires an intense collaboration between science and the law. From the scientific side, a rigorous research approach, transparency and a change in research culture are the main ingredients to promote accountability and reliability. On the institutional and legal side, clear guidelines, robust training on honesty and respect, and raising awareness on the value of legal sources regulating scientific integrity[41] are the key factors to boost it.

The regulatory autonomy of research performing institutions, from this perspective, is the first step to ensure solid research activities, in a research environment that fulfills necessary integrity requirements. These regulations alone are not enough. For example, the risk of misbehaving could be linked to career aspirations and to the system for recruitment, and this obviously goes beyond the autonomous regulatory framework of a single research institution. In these cases, legal regulation at the state level could help in addressing the problem, by promoting a balanced and rational way for professional enrollment and career progression, through good incentives and merit recognition, in accordance with scientific standards[42]. The law could for example regulate conflict of interests that in several fields of research could undermine integrity; it can also intervene to protect whistleblowers and researchers in a more vulnerable position[43].

The law is also regulating topics that are crucial for scientific advancement, such as artificial intelligence, data protection, data sharing, etc. As we will better explain in the next paragraph, in these fields the legal regulation does not have research integrity as a primary objective but nevertheless interlaces it.

To clarify the point, legal intervention in the field of research integrity is already in place, in some circumstances with this precise focus, in other cases marginally or tangentially touching it.

On the premises of being aware of the advantages and disadvantages of legal regulation of scientific activities and research integrity, a classification of the ways in which law can interlace research integrity could be useful to better rationalize the role of law in this field and to understand the limitation it should respect in order not to interfere with scientific freedom.

In this perspective, advantages of legal regulation of scientific integrity could be spotted in legal certainty and in the relationship between rules' breach and sanction. Effectiveness and legal enforcement, in other words, are key features of a functional legal intervention in this field. By providing clear rules and an enforceability system, the legal regulation offers a system of legality that could strengthen responsible conduct in

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research.

These aspects can also have a positive effect towards society as a whole, as a more responsible behaviour of researchers raises public trust in science and works as an incentive to promote public involvement in research and in its funding.

On the other hand, though, legal regulation could also be thorny, as its rigid categories do not always easily address the concrete problems of the research realm. To make an example, state boundaries and legal jurisdictions act often as an obstacle, rather than as a companion of research activities. Indeed, for several scientific disciplines, frontiers do not matter, whereas legal regulation is by nature state-related. As an added value for the research, scientific activity could be developed by research groups operating in different countries. Being strongly national-based; therefore, legal regulation may sometimes drastically slow the conduction of research activities and, finally, discourage international research, with the risk of being counter-productive and incentive misconducts instead of preventing them.

These dangers could be avoided by a tight dialogue with the scientific community: law-makers should be amplifiers for the scientific community and should only intervene respecting scientific autonomy and after appropriate consultancies. This can bring to enforceable and binding legal norms with a strong scientific background and a due consideration and balancing of all interests involved (i.e. respect for vulnerable subjects, for the ecosystem, for resources, public accountability, prevention and management of conflicts of interests, etc.).

To clarify this concept, considering embezzlement of public funds as a research integrity issue could point out the role of legal intervention in this field. If a researcher receives money from a public institution to conduct a research project, and iInstead of performing the proposed research, he commits misconduct and either falsifies the experiments or pretends they have been conducted differently than the truth, he commits a misconduct. This behaviour not only has scientific consequences that lead to unreliable results, but it also has a relevant and social impact, as funds have not been appropriately used and this behaviour cheated the relationship between the researcher and the institution, but also the responsibility that the research institutions has towards the society.

Recently the well-known Dana-Farber Cancer Institute has agreed to pay $15,000,000 to resolve allegations against some of its researchers accused of publishing papers with manipulated data between 2014 and 2024[44]. The Institute has its internal clear and complete research integrity policy[45] , but Federal allegations concern the False Claims Act, because of false statements and certifications related to National Institutes of Health (NIH) research grants that accompanied those papers[46]. This demonstrated how the reputation and public trust of a wide-world recognised research institution could easily be blown by an individual's misconduct and how this is relevant both for internal disciplinary policies and externally under legal norms.

A further disadvantage of legal regulation that should be considered concerns the respect of scientific and professional autonomy. Having a general nature, the law has always the downside of interfering with other disciplines. From this viewpoint, a balanced and reasonable approach to scientific issues and – most importantly – to the ways in which scientific activities are performed should orient the exercise of political discretion. Legal scholars have referred to this as a "scientific reasonableness approach", arguing that "intervention in these areas cannot be the result of a purely political discretionary assessment by the legislature itself, but should be based on the examination of the state of scientific knowledge and of the experimental evidence acquired, by institutions and bodies – normally national or supranational – designated for that purpose"[47]. This is also the consolidated approach of the Italian Constitutional Court that, since 2002, has stated to assess the "scientific reasonableness" of law, finding a violation of the Constitution any time in which the law-maker had not properly assessed all scientific factors at stake[48].

The complexities of the interaction between legal regulation and research integrity call for a rationalisation. The following paragraph offers a possible classification of the different ways in which legal regulation intercepts research integrity and the rules that the scientific community agrees on to ensure responsible conduct.

5. A POSSIBLE CLASSIFICATION OF LEGAL REGULATION OF SCIENTIFIC INTEGRITY

As mentioned before, the relationship between legal regulation and the rules that the scientific community agrees on for responsible, transparent and honest research has grown in tightness and intensity. Especially in the last decade, the overwhelming impact of the technological transition in daily life and in the world of research has required a pervasive and intensive legal regulation. Just to give a few examples, European regulations such as the GDPR, the AI Act or, recently, the European Health Data Space Regulation are answers to the urgent need to provide legal rules in fields in which the fast highly technological development is worryingly interfering with fundamental rights.

A classification of the different levels of intensity of legal regulation in the field of research integrity could serve the scope of offering a map of the different legal instruments to boost responsible scientific conduct. Furthermore, this possible taxonomy demonstrates how broad research integrity is and its impressive legal relevance.

Thus, three possible categories can describe the legal regulation of research integrity and could be summarised as follows:

(i) "intersections", meaning laws having a general nature, that are addressed to a variety of matters and that that find application also in this field, such as the US Federal False Claims Act mentioned above;

(ii) "specific objects", meaning legal acts that regulate specific fields of research and that, by regulating also research activities, give legal nature to research procedures, such as the regulation of clinical trials;

(iii) "Research Integrity Laws", that are acts expressly aimed at regulating research integrity.

5.1. INTERSECTIONS

More specifically, the first category, "intersections" , includes legal acts of general nature that, nevertheless, can also find application in the legal regulation of RI. In some cases, they provide rules, prohibitions and sanctions for behaviours that are also regulated by the scientific community, by professional codes of conduct or by institutional policies. In these circumstances, it could happen that the same "rule" is provided by professional codes of conduct or in institutional policies, and is also included among the uncodified rules that the scientific community agrees on. At a legal level, though, it is described in rather general terms, often without specific references to research integrity of scientific activities in general. The difference between these sources is that the violation of codes of conduct causes professional and disciplinary sanctions, and that the fraudulent researcher loses scientific reputation and could be marginalised by the community. Yet, these "rules" are neither legally binding nor effective, and codes of conduct are limited to the professional field. Legal provisions, instead, have a totally different range and, when a misconduct falls under such legal provisions, the effects of normative sanctions could have a wider relevance.

For example, the most severe research misconducts, such as plagiarism, falsification and fabrication, are prohibited and sanctioned by the scientific community, by professional codes and by legal acts, and each of these sources provides a different sanction with different levels of effectiveness.

Plagiarism, in particular, represents a disvalue at a scientific level, violates the principle of honesty and accountability, and is a research misconduct[49], but the scientific community cannot do anything more than marginalise the dishonest researcher or act for the retraction of plagiarised material[50]. From the professional code of conduct viewpoint, there could be more effective sanctions that are relevant within the professional world. In some cases, they might be even very severe, to the point of providing for the exclusion of the guilty researcher from the professional board, such as in the already mentioned case of Dr. Wakefield, accused of falsification of research data. In a similar turn of events, Francesca Gino, a distinguished Harvard researcher accused of plagiarism and research misconduct, had her tenure eventually revoked by the University once proven at fault[51].

At a legal level, plagiarism finds a general discipline. In most legal orders, it is regulated as a copyright infringement, entailing the possibility of a civil legal action for damages compensation and as a criminal offence. The legal provision does not exclusively apply to scientific works, but it has a more general nature. It

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is only the legal provision that gives the person whose work has been plagiarised the possibility to have compensation; moreover, it is only under civil or criminal provision that the consequences of the ascertainment of responsibility have relevance for the wider public and for society as a whole. Essentially, this first category, "intersections", shows that some general legal disciplines can find application in some cases of violation of the principles of research integrity.

A further example is provided by the EU General Data Protection Regulation (GDPR)[52], which offers an exhaustive and overall discipline on data protection, is another significant example of this sort of intersection. The GDPR is not exclusively designed for research activity, but several of its provisions are inevitably very relevant in scientific activity and cross several research integrity principles. The same can be said for the very recent Artificial Intelligence Act (AI Act)[53], the first European comprehensive discipline on AI, with the scope of promoting "the development and uptake of safe and trustworthy artificial intelligence (AI) systems"[54] in the EU. Considering the increasing impact of AI tools in scientific research and its threats to research integrity, the interpretation and application of the AI Act to this field will be crucial for developing research integrity in the EU[55].

5.2. SPECIFIC OBJECTS

The second category, previously referred to as "specific objects", includes legal acts designed appropriately for regulating research activity. The legal intervention is due to the need to protect the fundamental rights of the people involved, including researchers and research participants. It has scientific activity as its central focus, but only implicitly deals with research integrity. To put it clearer, by regulating what scientists do, it boosts, forces and promotes their integrity.

The field of biomedical research offers several practical examples, such as the EU Clinical Trial Regulation[56], that provides a uniform discipline for clinical trials in the EU, by introducing a single submission authorisation procedure, clarifying and simplifying rules on clinical trials, providing protection for vulnerable groups, and establishing a EU database for clinical trials with the scope to promote research transparency and accessibility. Among other acts with similar features that could be listed are the Biomedical Research Law and the Biobanks Regulation[57], which offers a specific discipline for the collection and storage of biological samples, as well as for biobanking; it also provides rules for the donation and use of embryos, cells, tissues and genetic testing[58].

This category highlights the complex potentials of the legal regulation of science.

On the one hand, it is necessary to offer scientists and researchers a clear and specific perimeter of what is permitted and forbidden. It is also essential to provide legal protection to vulnerable categories and groups and promote equality in scientific research by forcing researchers to avoid illegal discrimination. On the other hand, the fact that some scientific disciplines could raise ethical concerns or be controversial might lead to strict legal regulations perceived as too restrictive and limiting by the scientific community. Finally, the inherent national (or, at most, supranational) nature of law might lead to different regulations for the same objects, thereby complicating the work of research groups with international collaborations.

5.3. RESEARCH INTEGRITY LAWS

The third proposed category concerns the specific legal regulation of scientific research and RI, a field where law still has room for development. Indeed, there are not so many countries in which research integrity, in general terms, finds dedicated legal regulations.

A relevant example is represented by Scandinavian legislations on research integrity[59]. The Norwegian Act on the Organization of Research Ethics and Integrity[60], which took effect in 2017, gives a legal regulation to the principles of research integrity and establishes different National Research Ethics Committees and the National Commission for the investigation of Research misconduct[61]. It formalises responsibilities of researchers, research institutions and research ethics committees. Its main focus is, indeed, good research standards. To this end, the law provides that all research institutions must have an integrity committee and should handle cases of possible violations of recognised research ethics standards (Article 6)[62].

In Denmark, a similar law, entitled *Act regarding Scientific Dishonesty*, was approved by Parliament in April 2017[63]. It establishes the Danish Committee on Research Misconduct, defines research misconducts and codifies misconduct proceedings and procedures. Its main purpose is "to strengthen the trustworthiness and integrity of Danish research" (para. 1). As well as in the Norwegian law, the Danish legislation holds researchers, the research community in general and research institutions primarily responsible for good research practices, and it applies both to public and private research institutions. Article 2 of the law recalls the most traditional definition of misconduct, providing that "Fabrication, falsification and plagiarism committed intentionally or with gross negligence when planning, conducting or reporting research" and adds that "Questionable research practices" are defined as "Violation of generally accepted standards for responsible research practices, including the standards in the Danish Code of Research Integrity and other applicable institutional, national and international practices and guidelines for research integrity"

A Board of Scientific Dishonesty is established, with the duty to handle cases of misconduct in scientific products (notion that also includes applications for research fundings). The Board is a national body, composed by a judge and 8–10 professionals, all appointed by the Ministry of research; its decisions cannot be appealed (para. 18). It is interesting to note that it does not impose sanctions: as provided by para. 16, it can recommend to the researcher to withdraw the scientific product and can inform the research institution or other stakeholders (such as publishers of funding foundations) concerned. Questionable research practices are dealt by committees established within research institutions, whose internal policies provide for more detailed definitions and applicable procedures.

Sweden has enacted the Act on Responsibility for Good Research Practice and the Examination of Research Misconduct in 2020 (2019:504)[64]. It defines research misconduct as "a serious deviation from good research practice in the form of fabrication, falsification or plagiarism that is committed intentionally or through gross negligence when planning, conducting or reporting research" (section 2). The act identified misconduct with falsification, fabrication and plagiarism and also recognises that other "deviations from good research practice" (section 11) may exist. Misconducts are investigated by an independent Board (section 7), the Swedish National Board for Assessment of Research Misconduct, that has been established in 2020, as a central government agency subordinated to the Ministry of Education and Research[65]. The Board is chaired by a judge and composed of a maximum of ten professionals, appointed by the Government on proposals from universities. Its decisions can be appealed to the Administrative Tribunal.

Similarities among the three acts are quite evident. From our viewpoint, it is interesting to note that in all Scandinavian countries, national bodies are established with the duty to investigate on research misconducts, which act under detailed procedures and have examination powers, to assess whether a misconduct has been committed, but do not have sanctuary powers. They basically refer their decision to involved researchers and to the institutions concerned that will take the final decision.

All in all, these acts demonstrate that they recognise the complexities of the regulation of scientific research, thereby providing for independent bodies and investigation procedures, but providing for a tight relationship between legal norms and self-regulatory instruments of research institutions. On this respect it has been stated that these "laws both empower research institutions and formalize their role in promoting research integrity"[66].

Another interesting discipline concerning research integrity is the one adopted in France. Article L211-2 - Research Code[67], introduced in 2020, explicitly provides that research work must respect scientific integrity and must be scientifically honest and rigorous to consolidate social trust in science. The scope of scientific integrity is to guarantee impartiality of research, and public research institutions and foundations must promote scientific integrity and be compliant with its principles. Every two years, these institutions must submit a report to the competent Ministry on the action undertaken to fulfil the objectives provided by law. Moreover, Article L612-7 of the Education Code[68] provides that at the end of the thesis defence, the candidate must take an oath on the respect of the principles of research integrity. Despite being more symbolic than effective[69], this instrument shows that RI is increasingly permeating the legal regulation of scientific activity.

6. CONCLUSIONS

This essay aimed at systematising the different sources of regulation of scientific activity and research integrity.

At first instance, the need for adopting shared rules and principles stems from the scientific community as a reaction against negative episodes and serious violations that, across the years, have profoundly undermined public trust in science and the role of scientific research within the community. For example, the long-lasting side effects of the Tuskegee syphilis study over the years have been distancing the African American community in the US from public health intervention, including the Covid-19 vaccination hesitation[70].

Promoting honest and reliable science is, first of all, an interest of the scientific community. On this respect, as research integrity concerns all stages of the research path, from the initial idea to publication and dissemination, all stakeholders are involved in promoting good research practices, to ensure quality and trustworthiness of the research[71].

A requirement for scientific advancement and for the development of research is definitely represented by public trust in science. Without it, research with human participants would not be possible, the funding of scientific research would significantly drop, and several other alarming consequences would follow.

At the same time, the regulation of scientific research and integrity is also a professional matter, as it entails conforming to professional codes of conduct and practice, which include, but are not limited to, codes of conduct of research performing organisations or professional ethical codes.

With a para-juridical nature, these codes offer a discipline for the conduct of specific disciplines (i.e. physicians, nurses, biologists, etc.), or provide indications for the correct conduct in a given work environment (i.e. a research institution or a University). Violating these rules may impact the professional status of the involved researcher or may have internal disciplinary consequences. These codes are widely considered to be crucial for the promotion of research integrity, serving as structural and institutional support providing clear and operative rules for researchers[72].

Against this scenario, the role of law offers a further level of regulation of research integrity, by offering binding rules. Legal provisions are also abstract and general in nature, meaning that their effectiveness goes beyond research performing institutions or work environments. They produce their effects to all subjects in the legal order and this is a factor that strengthens the connection between science and society and makes legal rules addressed to research activities a means to promote public trust in science.

The proposed classification has highlighted that the different ways in which law can regulate scientific activities could have different levels of intensity with specific regard to their focus on research integrity. An advantage of considering legal regulation of scientific research concerns the fact that law is general (i.e. it is applicable to all subjects in the legal order) and can provide rights protection for third subjects involved in research activities and for the social impact of research. On the other hand, though, legal regulation of research requires a thorough dialogue between the scientific community and the lawmaker, to avoid unreasonable legal solutions and to promote harmonisation of legal rules among different countries. Moreover, the presented examples show legal rules on research integrity must leave due space to the scientific definition of substantial elements, first because this is a field exposed to continuous development and secondly - and most importantly - for the respect that must be necessarily given to scientific autonomy and freedom.

Above all, a proper respect for norms, principles and rules on research integrity requires all researchers, from mentors to PhD candidates, to have a deep familiarity with them. Raising awareness on existing documents and applicable rules empowers researchers, making them more aware of their role, not only within the scientific community but within society as a whole[73]. Education and continuous training are therefore the first instruments that contribute to the spread of good research practices and prevent misconducts.

In recent years, several projects and tools aimed to foster the knowledge on RI principles have been implemented in most technologically advanced countries, and the EU is promoting "good science" through several initiatives[74]. The promotion of more awareness on the principles of RI is definitely necessary to ensure that research activities are performed responsibly and to prevent misconduct; furthermore, the same object should be pursued also with the general public, by promoting a better understanding of scientific methodology and integrity, in order to build a deep public trust in science in a collaborative way[75], as a fundamental tool to ensure scientific development especially in the face of the opportunities and threats that Artificial Intelligence is raising.

NOTE

***** The article represents the result of joint reflections by the two authors. Nevertheless, paragraphs 1, 2 and 3 have been written by Marianna Bergamaschi, while paragraphs 4, 5 and 6 by Lucia Busatta.

1. Relevant instances involve budget cuts that have affected funding for hundreds of research projects, see Kozlov, M. and Ryan, C., "How Trump 2.0 is slashing NIH-backed research—in charts", *Nature*, *640*(8060), 2025, pp.863-865.

2. Lynch H.F., Largent E.A., McCoy M.S., Joffe S, "Advancing Trust in Science: Institutional Obligations to Promote Research Integrity", *Journal of Law, Medicine & Ethics*, 2025, 53(1), pp.1-5.

3. An example to prove the constant tensions of the relationship between politics, legislation and science: Weinberg, A.M., "In defense of science", *Science*, *167*(3915), 1970, pp.141-145.

4. ALLEA, *The European Code of Conduct for Research Integrity*. 2017.

5. Raposo, V.L. "The First Chinese Edited Babies: A Leap of Faith in Science." *JBRA Assist Reprod* 23, no. 3 (2019): 197–99.

6. Muthanna, A., Chaaban, Y. and Qadhi, S., "A model of the interrelationship between research ethics and research integrity" *International journal of qualitative studies on health and well-being*, *19*(1), 2024. pp.16-34. On populism and science see also: Penasa S., "The Role of Science in the Constitutional Interpretation of Gender-Related Rights: Science For and Against the Risk of Populist Drifts?", *European Constitutional Law Review*, 2025, 21(1), pp.90-111.

7. National Academies of Sciences, Engineering, and Medicine, "Fostering Integrity in Research", *Washington, DC: The National Academies Press,* 2017, pp.77-91.

8. National Research Council, "Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct", *Washington, DC: The National Academies Press* 2002, specifically "The changing Research environment", pp.25-26.

9. A fairly old but still relevant example is represented by the Willowbrook experiment, in which mentally retarded children housed at the Willowbrook State School in Staten Island, New York, were intentionally given hepatitis in an attempt to track the development of the viral infection. The study, which began in 1956, lasted for 14 years and was conceived in clear violation of any ethical guidelines; on the other hand, the results from the study allowed for the development of vaccines still in use today. For more on the study: Liu, E. "Willowbrook State School: Institutional Abuse, Medical Ethics and the Rise of Disability Rights in the United States." In *Critical Debates in Humanities, Science and Global Justice*, 2025. See also: Brandt, A.M., "Racism and research: the case of the Tuskegee Syphilis Study", *Hastings center report*, 1978, pp.21-29.

10. UKRIO, "What is Research Integrity?", *Research Integrity Office*. Available at: https://ukrio.org/research-integrity/what-is-research-integrity/

11. Consiglio Nazionale delle Ricerche, "Research Integrity", updated as of 03/02/2025. Available at: https://www.cnr.it/en/research-integrity

12. Zhaksylyk A., Zimba O., Yessirkepov M., Kocyigit B.F., "Research Integrity: Where We Are and Where We Are Heading", *J Korean Med Sci*, 2023 Dec 4, 38(47).

13. Armond, A.C.V., Cobey, K.D. and Moher, D., "Research Integrity definitions and challenges", *Journal of Clinical Epidemiology*,Volume 171, 2024.

14. Steneck, N. H. "Fostering integrity in research: Definitions, current knowledge, and future directions." *Science and engineering ethics* (2006), 12(1), 53-74.

15. Ibid.

16. Abu-Shaheen, A.K., Hamza, M.A. and Marar, S., "Introduction to

Research Ethics and Academic Integrity.", *Springer,* 2025.

17. World Medical Association. "Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects." Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and subsequent amendments. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki/

18. Council of Europe, "European Convention for the Protection of Human Rights and Fundamental Freedoms", Nov. 4, 1950, E.T.S. No. 5., 213. Available at: https://www.echr.coe.int/documents/d/echr/convention_ENG

19. World Conference on Research Integrity, "Singapore Statement on Research Integrity., *WCRI*, 2010. Available at: https://www.wcrif.org/statement

20. World Medical Association. "Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.", *op. cit.*

21. Mehta, P., O. Zimba, A.Y. Gasparyan, B. Seiil, e M. Yessirkepov. "Ethics Committees: Structure, Roles, and Issues." *Journal of Korean Medical Science* 38, no. 25 (2023).

22. Steneck, Nicholas H. "Fostering integrity in research: Definitions, current knowledge, and future directions." *op. cit.*, p. 55.

23. Iphofen, R., O'Mathúna, D., "Ethical Evidence and Policymaking", *Policy Press,* 2022, pp. 101-123.

24. Mayer, T., Steneck N. , "Final report to ESF and ORI First World Conference on Research Integrity: fostering responsible research", *World Conference on Research Integrity,* June 2007. 4:2010.

25. Von Elm, E. "Research integrity: collaboration and research needed.", *The Lancet* 370, no. 9596 (2007): 1403–1404.

26. Mayer, T., Steneck N. , "Final report to ESF and ORI First World Conference on Research Integrity: fostering responsible research", *op. cit.*

27. Resnik, D.B., e A.E. Shamoo. "The Singapore Statement on Research Integrity." *Accountability in Research* 18, no. 2 (2011): 71–75.

28. Desmond, H., & Dierickx, K. "Research integrity codes of conduct in Europe: Understanding the divergences.", *Bioethics*, 35(5), 2021, 414-428.

29. ALLEA - All European Academies. *The European Code of Conduct for Research Integrity,* 2023.

30. Ibid.

31. ENRIO is the European Network of Research Integrity Offices, funded in 2007, after the 1st World Conference on Research Integrity in Lisbon, Portugal. More information on its institutional website: https://www.enrio.eu/

32. ENERI Consortium. "Recommendations for the Investigatfoundion of Research Misconduct." In *ENRIO Handbook*, 2019. Available at: https://www.enrio.eu/first-publication-from-enrio-recommendations-for-the-investigation-of-research-misconduct/

33. In addition to uncertainty in the definitions and principles of research integrity, identifying the definition of research misconduct has also been an issue, as some do not believe the traditional FFP category (Falsification, Fabrication and Plagiarism) as sufficient. See National Academies of Sciences, Engineering, and Medicine. "Fostering Integrity in Research", *op. cit.*

34. Desmond, H., & Dierickx, K. "Research integrity codes of conduct in Europe: Understanding the divergences.", *op. cit.*

35. Ibid.

36. Armond, A.C.V., Cobey, K.D., Moher, D., "Research Integrity definitions and challenges", *op. cit.*

37. Ibid.

38. Beecher, H. K., "Ethics and Clinical Research", *New England Journal of Medicine,* 274, no. 24, 1966, 1354–60. Veatch, R.M., "Henry Beecher's Contributions to the Ethics of Clinical Research", *Perspectives in Biology and Medicine,* 59, no. 1, 2016, 3–17.

39. Haven, T., Gopalakrishna, G., Tijdink, J., van der Schot, D. and Bouter, L., "Promoting trust in research and researchers: How open science and research integrity are intertwined", *BMC Research Notes,* 15.1, 2022, 302.

40. Kerasidou A., "Trustworthy Institutions in Global Health Research Collaborations", in: Laurie G, Dove E, Ganguli-Mitra A, et al., eds. *The Cambridge Handbook of Health Research Regulation*, Cambridge Law Handbooks. Cambridge University Press, 202, 81-89.

41. Similar factors and spotted by Armond, A.C.V., Cobey, K.D., Moher, D., "Research Integrity definitions and challenges*", op. cit.*

42. Bouter, L., "Why research integrity matters and how it can be improved", *Accountability in Research*, 31.8, 2024, 1277-1286.

43. Zhaksylyk A., Zimba O., Yessirkepov M., Kocyigit B.F., "Research Integrity: Where We Are and Where We Are Heading", *op. cit.*

44. See the relevant press release issued by the US Department of Justice on December 16th, 2025: https://bit.ly/49BbnHx

45. Publicly available on the Institute's website: https://www.dana-farber.org/research/our-researchers/administration/research-integrity

46. Armitage H., "Danish Neuroscientist Gets Court Sentence for Doctoring Data," *Science*, October 1, 2015, https://www.science.org/content/article/danish-neuroscientist-gets-court-sentence-doctoring-data.

47. Penasa S., "The Role of Science in the Constitutional Interpretation of Gender-Related Rights: Science For and Against the Risk of Populist Drifts?", *op. cit.*

48. The landmark decision by the Constitutional Court is Judgement no. 282 of 2002.

49. ALLEA - All European Academies. *The European Code of Conduct for Research Integrity, op. cit.,* p. 10.

50. Shen, Q., Gao, X. and Xiong, X., "A data mining-based study on academic publication retractions in the 21st Century", *Accountability in Research*, 2025, pp.1-23. Fanelli, D., Wong J., Moher D., "What Difference Might Retractions Make? An Estimate of the Potential Epistemic Cost of Retractions on Meta-Analyses", *Accountability in Research,* 29, n. 7 2021, 442–59.

51. O'Grady, C., "Embattled Harvard honesty professor accused of plagiarism", *Science,* 384, no. 6692, 2024, 148-149. O'Grady, C., "Honesty researcher committed research misconduct, according to newly unsealed Harvard report.", *Science*, March 15, 2024.

52. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

53. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828.

54. See the Eur-lex Summary of the Act, available at: https://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:32024R1689

55. Bizzaro, P. G., Napolitano, M., "Balancing Innovation and Regulation: A Critical Look at the AI Act's Research Exemptions",. *BioLaw Journal - Rivista Di BioDiritto*, (3), 2025, 289–292.

56. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

57. Act 14/2007 of July 3 on Biomedical Research and the Royal Decree 1716/2011 of November 18.

58. de Melo-Martín, I., "Research integrity in Spain: Great expectations, mediocre results.", *Accountability in Research* (2025), 1–21. de Melo-Martín, I., Ortega-Paíno E., "Biobanking Legislation in Spain: Advancing or Undermining Its Ethical Values?", *Biopreservation and Biobanking,* 22, no. 3, 2024, 242–47.

59. Vie, K.J., "Empowering the Research Community to Investigate Misconduct and Promote Research Integrity and Ethics: New Regulation in Scandinavia", *Sci Eng Ethics* ,28, 59, 2022.

60. Commonly referred to as *Research Ethics Act*, Prop 158 L (2015–2016). Froud, R., Meza, T.J., Ernes, K.O., et. al., "Research ethics oversight in Norway: structure, function, and challenges. *BMC Health Serv Res* 19, 24 (2019).

61. Norwegian National Research Ethics Committees. “The Act on Ethics and Integrity in Research.” Forskningsetikk.no.

62. The text of the law is available at https://lovdata.no/dokument/NL/lov/2017-04-28-23. No official translations are available.

63. Law no. 383 of 26/04/2017. The text is available here: https://www.retsinformation.dk/eli/lta/2017/383. No official translations are available.

64. See the country report on Sweden on Enrio website: https://www.enrio.eu/country-reports/sweden/. An unofficial translation is available here: https://www.uhr.se/en/start/laws-and-regulations/Laws-and-regulations/act-on-responsibility-for-good-research-practice/.

65. The Board has been established by the Swedish Ordinance (2019:1152) with directives for the National Board for Assessment of Research Misconduct (Npof), available here: https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/forordning-20191152-med-instruktion-for-namnden_sfs-2019-1152/

66. Vie, K.J., “Empowering the Research Community to Investigate Misconduct and Promote Research Integrity and Ethics: New Regulation in Scandinavia”, *op. cit.*, p. 14.

67. France, *Code de la recherche*, Article L211-2, consulted via Légifrance, https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000042753467.

68. France. *Code de la recherche*, Article L112-1. Consulted via Legifrance. https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000042813268.

69. Rabesandratana, T., “France Introduces Research Integrity Oath.”, *Science*, 377 (6603), 2022, 251.

70. Shen, Q., Gao, X. and Xiong, X., “A data mining-based study on academic publication retractions in the 21st Century”, *op. cit.*

71. Armond, A.C.V., Cobey, K.D. and Moher, D., “Research Integrity definitions and challenges”, *op. cit.*

72. Ibid.

73. Goldenberg, M. J., “Public Trust in Science.”, *Interdisciplinary Science Reviews,* 48 (2), 2023, 366–378.

74. Bouter, L., “Why research integrity matters and how it can be improved”, *op. cit.*

75. De Peuter, S., Conix S., “Fostering a Research Integrity Culture: Actionable Advice for Institutions.”, *Science & Public Policy,* 50 (1), 2023, 133–145.