



## Promoting Integrity as an Integral Dimension of Excellence in Research

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### D II.4 Legal analysis

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This deliverable is part of Work Package II of the Promoting Integrity as an Integral Dimension of Excellence in Research (PRINTEGER) research project. Titled *What is integrity? Multidisciplinary Reconnaissance*, Work Package II is devoted to the analytic reconnaissance of research integrity and scientific misconduct. This report contributes to such analytic reconnaissance by analysing the role of law in the existing normative frameworks on research integrity and scientific misconduct in Europe.

## 1. Introduction

There is no universally accepted definition of ‘research integrity’, or of ‘scientific misconduct’. There is also no consensus on their meaning in Europe. Generally speaking, the apprehension of the term ‘research integrity’ is profoundly marked by the ambivalence of the word ‘integrity’. In everyday language, ‘integrity’ has two basic meanings:<sup>1</sup> it can be understood as *‘the quality of being honest and having strong moral principles’*, and thus referring to ‘honesty’, ‘probity’, ‘rectitude’, or even ‘ethics’, ‘morals’, and ‘righteousness’, but also as *‘the state of being whole and undivided’*, encompassing the *‘internal consistency or lack of corruption in electronic data’*, and thus related to ‘soundness’, ‘robustness’, ‘solidity’, or ‘durability’.<sup>2</sup>

These two meanings tend to coexist in the usage of ‘research integrity’. The term is sometimes apprehended as the research’s quality of being ‘honest’, or conducted following ethical or moral principles.<sup>3</sup> ‘Research integrity’, however, might also be conceived as solely referring to sound, scientifically robust research - in the sense of research that is consistent with the constraints that guide and define science, regardless of any ethical or moral considerations.<sup>4</sup>

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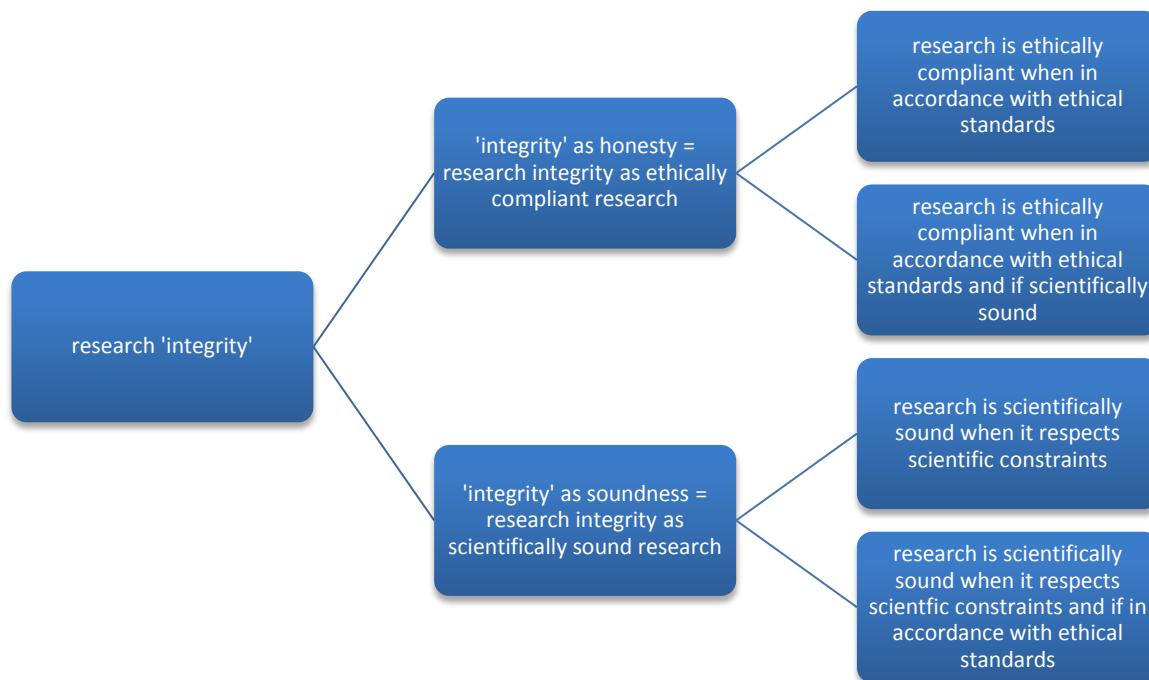
<sup>1</sup> Committee on Assessing Integrity in Research Environments, National Research Council, Institute of Medicine, “Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct” (Washington, D.C.: National Academy of Sciences, 2002), 34.

<sup>2</sup> As documented by the Oxford Dictionary of English and the Oxford Thesaurus of English.

<sup>3</sup> An ethical dimension that some perceive thus as inherent to scientific research; for instance, arguing that research integrity is *‘at the very heart of the research enterprise’*: Maura Hiney, “Research Integrity: What It Means, Why It Is Important and How We Might Protect It” (Science Europe, December 2015), 3.

<sup>4</sup> In this sense, for instance: Mathieu Bouville, “Crime and Punishment in Scientific Research,” *arXiv:0803.4058 [physics.soc-Ph]*, 2008, 7. See also: Serge Gutwirth and Jenneke Christiaens, “Reageren op Problematisch Wetenschappelijk Gedrag Voorbij de Moralisering: Een Ander Wetenschapsbeleid is Mogelijk!”, *Tijdschrift over Cultuur & Criminaliteit* 1, no. 5 (n.d.): 70–91. Stating that defining research integrity in terms of both moral principles and professional standards is problematic: Nicholas H. Steneck, “Fostering Integrity in Research: Definitions, Current Knowledge, and Future Directions”, *Science and Engineering Ethics* 12 (2006): 55. Cf., arguing research integrity goes beyond the strict scientific realm: Martin Letendre and Sébastien Lanctôt, “Le cadre juridique régissant la relation entre le chercheur et le sujet de recherche : la sécurité conférée par le droit canadien et le droit québécois est-elle illusoire ?”, *Les Cahiers de Droit* 48, no. 4 (2007): 595.

These two readings are sometimes combined, leading to the understanding of 'research integrity' as bringing together both dimensions.<sup>5</sup> This combination might in its turn take basically two different shapes. On the one hand, it is possible to contemplate as honest or (ethically) 'good' only the research carried out in full accordance with the principles of scientific practice. On the other hand, from a similar but in a way opposite perspective, it is plausible to view as ('real') scientific research exclusively the research that complies with certain ethical or moral standards.<sup>6</sup>



**Figure 1 - Different understandings of 'research integrity' in light of integrity's inherent ambiguity.**

'Scientific misconduct' is sometimes theoretically construed directly in opposition to research integrity, in any of its senses,<sup>7</sup> and thus defined as the behaviour that encroaches on it. Interestingly, some regulatory frameworks, however, give prominence to the regulation of scientific misconduct (or the imperative to follow up allegations of misconduct), delineating research integrity's contours negatively.

<sup>5</sup> Arguing that 'research integrity' is '*generally understood to relate to the performance of research to the highest standards of professionalism and rigour, in an ethically robust manner*': Hiney, "Research Integrity: What It Means, Why It Is Important and How We Might Protect It", 3.

<sup>6</sup> From this perspective, it can be argued that certain scientific practices might not qualify as such on the basis of moral principles. Arguing that, equally, a fixed tennis match is not a sports event, but a mere performance: Bjørn Hofmann, "That's Not Science! The Role of Moral Philosophy in the Science/Non-Science Divide", *Theoretical Medicine and Bioethics* 28 (2007): 246.

<sup>7</sup> For instance, it might be envisaged as a deviation 'from the ideals of research': Göran Collste, "Principles and Approaches in Ethics Assessment: Research Integrity" (Stakeholders Acting Together on the Ethical Impact Assessment of Research and Innovation (SATORI), June 2015), 3.

It has been claimed that only few cases related to research integrity and scientific misconduct end up in front of a court.<sup>8</sup> It might also be equally maintained that it is not always clear which of the cases that end up or might end up in front of a court fall under what the different European normative frameworks qualify as related to such notions.<sup>9</sup>

This contribution aims to advance in the conceptual reconnaissance of research integrity and scientific misconduct by investigating them from a legal perspective, and, more concretely, through the perspective of European law - and taking into account that the area is marked by complex intersections between science, ethics and law. It looks into existing European normative frameworks by considering two different aspects: first, what is the legal status of the instruments that aim to regulate research integrity and scientific misconduct in European countries (e. g., are they legislative instruments that are legally binding? are they self-regulatory instruments? if so, have these self-regulatory instruments acquired legally binding force?), and, second, how do these instruments depict the role of law in the field of research integrity and scientific misconduct (e. g., do they present research integrity rules as being something different from law, and that would perhaps escape the reach of law? do they reassert the need for researchers to comply with certain legal obligations? if so, which ones? and which legal obligations are identified by those instruments as something different or unrelated?). It constitutes an inaugural mapping exercise that will be followed up by further exploration of the relation between law, research integrity and scientific misconduct in the PRINTEGER project.<sup>10</sup>

First, the report presents the diversity of national normative frameworks in Europe, highlighting that whether some European countries have ad-hoc legislative instruments on research integrity or scientific misconduct, others do not. Second, it explores international instruments in the field, exploring how they depict the relation between existing legislation and the boundaries of research integrity and scientific misconduct. Third, it describes key policy and legislative developments at the level of the European Union. Finally, the contribution discusses what can be inferred from the described panorama in regards the definition of research integrity and scientific misconduct and their integration in legislative instruments.

## 2. A variety of national normative frameworks

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<sup>8</sup> Pieter J. D. Drenth, "Research Integrity; Protecting Science, Society and Individuals", *European Review* 18, no. 3 (2010): 421.

<sup>9</sup> Arguing, for instance, it is debatable whether shall be regarded as contrary to research integrity only the acts that impinge on scientific truth, or more generally also other potentially objectionable acts such as self-plagiarism: Jean-Paul Sculier, "Les manques à l'intégrité scientifique et médicale", *Cahiers de Psychologie Clinique* 1, no. 44 (2015): 18.

<sup>10</sup> This survey will notably be followed by an examination of how issues related to research integrity and scientific misconduct are apprehended in courts, or even, might possibly be apprehended would they be brought to court.



European normative frameworks on research integrity and scientific misconduct are only rarely structured around legislative instruments. Indeed, only a limited number of European countries have adopted legislative instruments explicitly dealing with research integrity and scientific misconduct, or touching upon them in the context of a wider regulation of researchers' activities.<sup>11</sup> This does not mean that the other European countries completely lack normative instruments covering similar or concomitant issues. In those cases, however, it might be necessary to refer to other, non-legislative instruments, in order to determine which rules are to be regarded (in that national normative framework) as related to research integrity or scientific misconduct, and thus to elucidate their legal significance in each national context. Such non-legislative instruments, which can include codes of conduct, charters or sets of principles, may actually also have legally binding force, as they can acquire it through different mechanisms, such as, for instance, the contractual obligations linking researchers with their employers or funders.<sup>12</sup> As 'soft-law', such instruments may also guide the judicial interpretations within the boundaries of binding sources of law like statutes or treaties having direct effect ('hard law').

In any case, the absence of ad-hoc statutory provisions formally presented as referring to research integrity or scientific misconduct does not imply, as such, that a national legal order fails to provide legal solutions for issues in this area, as other mechanisms might nevertheless be applicable.<sup>13</sup>

In this context, it is important to note that the performance of research activities – just as the performance of any other activity - is subject to multiple 'common' legal requirements, the violation of which could potentially be the result of acts that can also be coined as scientific misconduct, be it from a legal perspective, or from another point of view.<sup>14</sup> Some legal orders may explicitly codify them as such, whereas others do not, but this does not imply that in the latter case no binding rules apply to the same acts.<sup>15</sup> Among the many relevant fields can be mentioned rules on human subject research in biomedical research or on protection of animals used for scientific purposes, environmental law, intellectual property law, personal data protection law and privacy law. These might derive from national, EU or international instruments. There are as a matter of fact many and varied issues that can trigger the legal responsibility of

<sup>11</sup> A 2013 report document that 53% of countries had ad hoc legislation on research integrity and scientific misconduct, but the figure refers to the number of respondents of a voluntary survey encompassing non-European countries: The Danish Agency for Science, Technology and Innovation, "National Systems for Handling Cases of Research Misconduct", January 2013.

<sup>12</sup> Or any other mechanism granting legally binding force to self-regulatory instruments.

<sup>13</sup> Citing, for instance, the fact that serious scientific misconduct can qualify as reason for dismissal from service under the civil service law of Lower Saxony in Germany: Xavier Bosch, "Safeguarding Good Scientific Practice in Europe", *EMBO Reports* 11, no. 4 (2010): 256.

<sup>14</sup> See notably: Gutwirth and Christiaens, "Reageren Op Problematisch Wetenschappelijk Gedrag Voorbij de Moralisering: Een Ander Wetenschapsbeleid Is Mogelijk!", 71.

<sup>15</sup> Which indeed implies that the non-existence of legislative norms explicitly targeting scientific misconduct does not mean that there is a legal vacuum for acts that would be understood as scientific misconduct. The need for specific legislation must be pondered against the potential of existing law.



researchers - be it under civil, criminal and administrative/disciplinary law. What is generally debatable is exactly which subset of issues specifically relate to 'research integrity' concerns as opposed to other, non-integrity issues.<sup>16</sup>

Ultimately, general legal principles as well as fundamental rights and freedoms could also be invoked in some situations potentially related to research integrity or scientific misconduct. In this context, for instance, the very right to life might be at stake when the wrong decisions are taken on the basis of falsified data.

## 2.1 Normative frameworks based on statutory approaches

Historically, the first country to put in place a statutory approach in this area were the United States (US), where the legislator's interest focused on the obligation to follow up allegations of scientific misconduct.<sup>17</sup> In 1992, the Office of Research Integrity (ORI)<sup>18</sup> was set up to promote research integrity and investigate misconduct in research supported by the US Public Health Service. The ORI announces publicly its misconduct findings, as well as the related sanctions. In 2000, the Office of Science and Technology Policy in the White House published a Federal Research Misconduct Policy requiring implementation (either through policies or regulations) by all federal agencies or departments supporting research. Despite its encouragement of a consensual definition of research misconduct, the US landscape is still marked by a proliferation of definitions, both at the federal and institutional levels.<sup>19</sup>

International discussions around research integrity and scientific misconduct in the 2000s generated the picture of a divide between the US approach and European approaches, whereby the latter would be less 'legalistic'<sup>20</sup> and rely on self-regulation of researchers. In reality, it would be more appropriate to distinguish between countries where the legislator has adopted specific legal instruments on research integrity or scientific misconduct, and those where this has not occurred, but where law might nevertheless regulate multiple issues that some countries regard as related to research integrity of scientific misconduct.

In Europe, Scandinavian countries were among the first to engage in the direction of specific legislation,<sup>21</sup> sometimes in combination with the setting up of national

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<sup>16</sup> On this issue, see also: Etienne Vergès, "Quelles sanctions dans le droit de la recherche ?," in *Quel Droit Pour La Recherche ?* (Littérature, 2006).

<sup>17</sup> Bratislav Stankovic, "Pulp Fiction: Reflections on Scientific Misconduct" *Wisconsin Law Review* 3 (2004): 989.

<sup>18</sup> ORI website: <https://ori.hhs.gov/>.

<sup>19</sup> Editorial Policy Committee of the Council of Science Editors (CSE), "White Paper on Promoting Integrity in Scientific Journal Publications, 2012 Update", 2012, 57.

<sup>20</sup> Krista Varantola, "What Does the Global Scene Look like," in *Research Integrity in the Nordic Countries – National Systems and Procedures, NordForsk Expert Seminar Oslo 9 April 2014* (NordForsk, 2015), 8.

<sup>21</sup> Hiney, "Research Integrity: What It Means, Why It Is Important and How We Might Protect It" 19.



structures that have been described as ‘quasi-judicial’.<sup>22</sup> A few examples will illustrate how this statutory approach can operate in practice<sup>23</sup> - but also how legally and non-legally binding instruments are nonetheless often intertwined.

### 2.1.1. Denmark

In Denmark saw the light in 1992 the Danish Committees on Scientific Dishonesty, a set of national-level committees tasked with handling allegations on research misconduct based on complaints brought by individuals or institutions.

Currently, a particularly important document in the country is the Danish Code of Conduct for Research Integrity.<sup>24</sup> The Code of Conduct is not legally binding in itself, but researchers can adhere to it and public and private research institutions can integrate the document in their institutional frameworks.<sup>25</sup> The Code establishes six basic principles of responsible conduct of research (on research planning and conduct, data management, publication and communication, authorship, collaborative research, and conflicts of interest), but observes that researchers and institutions ‘should also be aware of co-existing and legally binding regulations that have an impact on research, e.g. regulation on processing of personal data, intellectual property rights, ethics reviews, etc.’.<sup>26</sup>

The Danish Code of Conduct for Research Integrity sets out that ‘*institutions and researchers should support initiatives for handling breaches of the responsible conduct of research*’, which are defined as ‘*breaches of current standards on responsible conduct of research, including those of the Danish code of conduct, and other applicable institutional, national and international practices and guidelines on research integrity*’. <sup>27</sup> The most serious of those breaches of responsible conduct of research might qualify as research misconduct as defined by the Danish Committees on Scientific Dishonesty.<sup>28</sup>

The Danish Committees on Scientific Dishonesty deal exclusively with ‘scientific dishonesty’ defined as falsification, fabrication, plagiarism and other serious violations

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<sup>22</sup> Ben R. Martin, “Whither Research Integrity? Plagiarism, Self-Plagiarism and Coercive Citation in an Age of Research Assessment,” *Research Policy* 42 (2013): 11.

<sup>23</sup> Other examples could be Sweden and Poland. See, on this issue: Nicole Foeger, “With Joined Forces For Research Integrity in Europe: European Network of Research Integrity Offices”, in *Integrity in the Global Research Arena*, ed. Nicholas Steneck et al. (London: World Scientific Publishing, 2015), 14–15.

<sup>24</sup> Ministry of Higher Education and Science, “Danish Code of Conduct for Research Integrity” November 2014

<sup>25</sup> Ibid., 5.

<sup>26</sup> Ibid., 7.

<sup>27</sup> Ibid., 20.

<sup>28</sup> Ibid., 21.



of good scientific practice committed intentionally or due to gross negligence during the planning, implementation or reporting of research results.<sup>29</sup>

### 2.1.2. Norway

Norway put in place in the 1990s a centralised system of national committees for research ethics.<sup>30</sup> In 2006 was adopted a Law on Ethics and Integrity in Research,<sup>31</sup> developing the previous system and introducing a National Commission for the Investigation of Scientific Misconduct.

The 2006 Law on Ethics and Integrity in Research defines its object as '*to ensure that research carried out by public and private institutions is conducted in accordance with recognised ethical standards*'.<sup>32</sup> It foresees the establishment of national research ethics committees and regional committees for medical and health research ethics, stating the two types of committees shall have expertise on relevant discipline and ethics, but also on law.<sup>33</sup>

Scientific misconduct, to be investigated by the National Commission for the Investigation of Scientific Misconduct, is defined as '*falsification, fabrication, plagiarism and other serious breaches of good scientific practice that have been committed wilfully or through gross negligence when planning, carrying out or reporting on research*'.<sup>34</sup> Said National Commission must be chaired by a person with judicial experience,<sup>35</sup> and its decisions can be appealed before the Ministry of Research, that shall appoint a special commission for such purpose.<sup>36</sup>

### 2.1.3. Finland

In Finland, the Finnish Advisory Board on Research Integrity (TENK), was established by decree in 1991<sup>37</sup> to promote the responsible conduct of research, to prevent research misconduct, to promote discussion and to spread information on research integrity in Finland and to monitor international developments in the field of research integrity. The Advisory Board makes proposals and issues statements concerning research integrity. In

<sup>29</sup> Act on the Research Advisory System, etc. (consolidated act no. 1064 of 6 September 2010), Section 2 (3).

<sup>30</sup> European Science Foundation, "Stewards of Integrity: Institutional Approaches to Promote and Safeguard Good Research Practice in Europe" (Strasbourg, 2008), 33.

<sup>31</sup> Law on Ethics and Integrity in Research, Act of 30 June 2006, which entered into force in July 2007.

<sup>32</sup> Section 1.

<sup>33</sup> Sections 3 and 4.

<sup>34</sup> Section 5.

<sup>35</sup> Judicial expertise is also integrated in similar structures in Sweden.

<sup>36</sup> Ibid.

<sup>37</sup> Decree 1347 of 15 November 1991, on the National Advisory Board on Research Ethics; the Board's name was modified in 2012.

1994, it formulated national guidelines to handle cases of alleged research misconduct, which were updated in 2012.

The 2012 guidelines, titled *Responsible conduct of research and procedures for handling allegations of misconduct in Finland*,<sup>38</sup> note that the TENK is not concerned with all issues related to research ethics in general but only with the following of '*an ethically responsible and proper course of action in research*', as well as with '*identifying and preventing fraud and dishonesty in all research*', a matter usually described in English as research integrity.<sup>39</sup> They also explicitly point out that the TENK '*does not address alleged violations of the law, such as copyright law or patent law*'.<sup>40</sup> When describing the '*premises for the responsible conduct of research*' '*from the point of view of research integrity*', the guidelines do nevertheless include among such premises the need for research organisations to take '*into account the data protection legislation*'.<sup>41</sup>

#### 2.1.4. Spain

In Spain, a Law adopted in 2011<sup>42</sup> details the obligations of researchers working at public universities, public research institutions and research bodies of public administrations. The 2011 Law does not refer to research integrity or scientific misconduct, but its preamble alludes to the objective of integrating a professional ethics dimension, leading notably to the creation of a Committee to apply internationally accepted criteria and guidelines. Obligations mentioned in the Law's provisions include complying with recognised ethical practices and the ethical principles of their disciplines, as well as the ethical rules established by applicable deontological codes,<sup>43</sup> taking measures to avoid plagiarism,<sup>44</sup> and ensuring compliance with data protection and confidentiality rules.<sup>45</sup> The instrument explicitly refers to the fact that additionally researchers might be subjected to the general rules applying to the staff of public administrations, as well as additional rules depending on their institution and activities.<sup>46</sup>

## 2.2 Normative frameworks based on other approaches

<sup>38</sup> Finnish Advisory Board on Research Integrity (TENK), "Responsible Conduct of Research and Procedures for Handling Allegations of Misconduct in Finland," 2012.

<sup>39</sup> Ibid. 29.

<sup>40</sup> Ibid.

<sup>41</sup> Premise #9.

<sup>42</sup> Ley 14/2011, de 1 de junio, de la Ciencia, la Tecnología y la Innovación.

<sup>43</sup> Art. 15(1)(a).

<sup>44</sup> Art. 15(1)(f).

<sup>45</sup> Art. 15(1)(l).

<sup>46</sup> Art. 15(2).



In some European countries lacking ad-hoc national legislation on research integrity or scientific misconduct have nevertheless been drafted special agreements, charters or memoranda to which stakeholders can commit, thus framing the policies in the field.<sup>47</sup> In Europe, since the 1990s several countries and organisations have indeed been adopting self-regulatory instruments, publishing guidelines and codes on good research practice and related subjects.<sup>48</sup> These instruments might be labelled as 'soft law', although they do not present themselves as such - sometimes, actually they explicit attempt to mark a boundary between their scope and the scope of law.

These self-regulatory instruments often refer to legislation, be it to declare they regard some legal obligations under the realm of scientific integrity or research misconduct (for instance, recalling they are an element of what constitutes scientific integrity), to proclaim they exclude them under such scope (for instance, marking a distinction between what the notions of research integrity or scientific misconduct are about, on the one hand, and (wider) legal obligations of researchers, on the other), or even to characterise them as encompassed by research integrity, but not constitutive of its very core.

These different perspectives can be explained by different conceptions of how research-related ethical issues intersect with legal issues: legislation related to the performance of research, despite applying as such regardless of any ethical considerations, is indeed sometimes described and envisioned in these frameworks as being part of a wider notion of 'research ethics'.<sup>49</sup> A few examples will illustrate how all this occurs in practice.

### 2.2.1. Germany

In Germany, the Deutsche Forschungsgemeinschaft (German Research Foundation, DFG), a national funding body for academic research, elaborated in 1997 a set of Recommendations for Safeguarding Good Scientific Practice,<sup>50</sup> which were updated in 2013 and presented in a larger Memorandum.<sup>51</sup> The document portrays the Recommendations as being fundamentally concerned with '*good scientific practice*', the opposite of which would be '*scientific dishonesty*', and marks a distinction between this

<sup>47</sup> Hiney, "Research Integrity: What It Means, Why It Is Important and How We Might Protect It" 19.

<sup>48</sup> European Science Foundation, "Stewards of Integrity: Institutional Approaches to Promote and Safeguard Good Research Practice in Europe" 6.

<sup>49</sup> For instance, describing personal data protection law as an element of research ethics: Claudia Oellers and Eva Wegner, "Does Germany Need a (New) Research Ethics for the Social Sciences?" Working Paper Series (German Council for Social and Economic Data (RatSWD), June 2009), 3.; as an element of research integrity and responsible conduct of research: Ann Nichols-Casebolt, *Research Integrity and Responsible Conduct of Research* (Oxford: Oxford University Press, 2012), 96.

<sup>50</sup> Generally followed by German research institutes (Saskia K. Nagel et al., "Ethics Assessment in Different Countries: Germany" (Stakeholders Acting Together on the Ethical Impact Assessment of Research and Innovation (SATORI), June 2015), 19.).

<sup>51</sup> Deutsche Forschungsgemeinschaft (DFG), "Safeguarding Good Scientific Practice: Memorandum" (Bonn, 2013).









'scientific misconduct').<sup>73</sup> An independent charity, the UK Research Integrity Office (UKRIO), provides guidance in the field since 2006.

A Concordat to Support Research Integrity was nevertheless signed in 2012 by a number of institutions.<sup>74</sup> The Concordat notes the existence of '*[e]xtensive statutory and regulatory standards*' governing research practice, pointing out it does not supersede or replace these.<sup>75</sup> By signing the Concordat, the parties commit themselves to '*ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards*'.<sup>76</sup> These are thus regarded as relevant for ensuring research integrity, although they are presented as something different, complementary '*to the core principles that underpin integrity*'.<sup>77</sup>

Signatories of the Concordat also commit to '*using transparent, robust and fair processes to deal with allegations of research misconduct should they arise*'.<sup>78</sup> Research misconduct is defined as '*behaviour or actions that fall short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld*',<sup>79</sup> and presented as encompassing '*failure to meet ethical, legal and professional obligations: for example failure to declare competing interests; misrepresentation of involvement or authorship; misrepresentation of interests; breach of confidentiality; lack of informed consent; misuse of personal data; and abuse of research subjects or materials*'.<sup>80</sup>

## 2.2.6. France

In France, there was until recently no general reference document on research integrity (or rather 'scientific integrity', as the widely used *intégrité scientifique* might be translated), even though some initiatives on the deontology of research practices surfaced already in the 1990.<sup>81</sup>

In 2015, seven research institutions signed a *Charte nationale de déontologie des métiers de la recherche*, or National Deontological Charter of Research Professionals, inspired in international and European developments in the area of research integrity, and putting

<sup>73</sup> In this sense: Koninklijke Nederlandse Akademie Van Wetenschappen, Vereniging van Samenwerkende Nederlandse Universiteiten, and Netherlands Organisation for Scientific Research, "Standard Evaluation Protocol 2015 – 2021: Protocol for Research Assessments in the Netherlands" July 2015, 8.

<sup>74</sup> The Department for Employment and Learning, Higher Education Funding Council for England, Higher Education Funding Council for Wales, National Institute for Health Research, Research Councils UK, Scottish Funding Council, Universities UK, Wellcome Trust.

<sup>75</sup> Ibid., 10.

<sup>76</sup> Ibid., 13.

<sup>77</sup> Ibid.

<sup>78</sup> Ibid., 17.

<sup>79</sup> Ibid.

<sup>80</sup> Ibid.

<sup>81</sup> Martine Bungener and Michelle Hadchouel, "Rôle des institutions dans la gestion de la fraude scientifique : l'exemple de la délégation à l'intégrité scientifique de l'INSERM," *La Presse médicale* 41, no. 9P1 (2012): 2.

forward a number of '*integrity principles*'.<sup>82</sup> The first of such principles refers to the researchers' obligation to know and respect all applicable legal and regulatory mechanisms, notably for research on human beings, animals or the environment.

## 2.2.7. Italy

In Italy, only a few institutions have adopted any instruments related specifically to research integrity. In 2015, the Commissione per l'Etica della Ricerca e la Bioetica del Consiglio Nazionale della Ricerca (CNR) elaborated its own Guidelines on Research Integrity.<sup>83</sup> The Guidelines explicitly exclude from their scope any behaviours governed by civil and criminal law as well as those governed by international legal instruments.<sup>84</sup>

# 3. International instruments on research integrity

National normative frameworks are generally influenced by supranational developments in the area of research integrity, and can also explicitly refer to specific supranational instruments. Several international and European organisations have indeed been actively involved in this field for a number of years. The Organisation for Economic Cooperation and Development (OECD) has produced guidance already since the end of the 2000s.<sup>85</sup> Taking into account their significance in Europe, the Singapore Statement and the European Code of Conduct for Research Integrity deserve special attention.

## 3.1. The Singapore Statement

The Singapore Statement on Research Integrity represents the first international effort to encourage the development of unified policies, guidelines and codes of conduct to foster greater integrity in research worldwide.<sup>86</sup>

Under the title 'Responsibilities', the Singapore Statement puts forward 'integrity' as the need for researchers to '*take responsibility for the trustworthiness of their research*'.<sup>87</sup>

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<sup>82</sup> 'Principes d'intégrité'.

<sup>83</sup> Commissione per l'Etica della Ricerca e la Bioetica del CNR, "Linee guida per L'integrità nella ricerca" 2015.

<sup>84</sup> Ibid., 2.

<sup>85</sup> See notably: *Best Practices for Ensuring Scientific Integrity and Preventing Misconduct* (2007) and *Research Integrity: Preventing Misconduct and Dealing with Allegations* (2010).

<sup>86</sup> The Singapore Statement can be accessed here: <http://www.singaporestatement.org/statement.html>. It was developed at the 2nd World Conference on Research Integrity in 2010. It was followed up by the Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations, developed at the 3rd World Conference on Research Integrity in 2013.



Researchers '*should be aware of and adhere to regulations and policies related to research*',<sup>88</sup> and report '*[ir]responsible research practices*', which would encompass '*research misconduct, including fabrication, falsification or plagiarism*', but also '*other irresponsible research practices that undermine the trustworthiness of research, such as carelessness, improperly listing authors, failing to report conflicting data, or the use of misleading analytical methods*'.<sup>89</sup>

The Singapore Statement establishes that research institutions, journals, professional organisations and agencies that have commitments to research '*should have procedures for responding to allegations of misconduct and other irresponsible research practices and for protecting those who report such behaviour in good faith*'.<sup>90</sup>

### 3.2. European Code of Conduct for Research Integrity

The European Code of Conduct for Research Integrity<sup>91</sup> is consensus document prepared in 2011 by the European Science Foundation (ESF)<sup>92</sup> Member Organisation Forum on Research Integrity together with All European Academies (ALLEA).<sup>93</sup>

The first sentence of the Preamble to the European Code for Research Integrity notes it is '*not a body of law, but rather, a canon for self regulation*'.<sup>94</sup> The Code presents itself as concerned with the '*principles of scientific integrity*', defined as including honesty in reporting and communicating, reliability in performing research, objectivity, impartiality and independence, openness and accessibility, duty of care, fairness in providing references and giving credits, and responsibility for future science generations.<sup>95</sup> According to the Code, these principles and violations thereof have a universal character, whereas practices such as '*poor data practices and inadequate data management, inappropriate research procedures, including questionable procedures for obtaining informed consent, insufficient respect and care for participants in the research, improper research design and carelessness in observation and analysis, unsuitable authorship or publishing practices, and reviewing and editorial derelictions*' may be subject to different national traditions, legislative regulations or institutional

<sup>87</sup> Point 2 of the Singapore Statement.

<sup>88</sup> Point 1 of the Singapore Statement.

<sup>89</sup> Point 11 of the Singapore Statement.

<sup>90</sup> Point 12 of the Singapore Statement.

<sup>91</sup> European Science Foundation (ESF) and ALL European Academies (ALLEA), "The European Code of Conduct for Research Integrity" (Strasbourg, March 2011).

<sup>92</sup> ESF, established in 1974, brings together research funding organisations and research performing organisations, academies and learned societies from 30 countries.

<sup>93</sup> ALLEA is a federation of European academies, founded in 1994 and bringing together academies in more than 40 countries from the Council of Europe region.

<sup>94</sup> European Science Foundation (ESF) and ALL European Academies (ALLEA), "The European Code of Conduct for Research Integrity" 8.

<sup>95</sup> Ibid.



provisions.<sup>96</sup> The Code therefore suggests that, '*except for gross violations of ethical principles or the law*', these latter issues shall be addressed through national good practice rules.<sup>97</sup> The need to respect national laws is emphasised in relation to the form in which investigations shall be carried out.<sup>98</sup>

## 4. European Union

The institutions of the European Union (EU) have come into the issue of research integrity and scientific misconduct through different pathways.<sup>99</sup> The resulting policies have an impact across EU Member States, but also sometimes potentially beyond the borders of the EU. This section provides an overview of relevant EU-level activities.

### 4.1 European Charter for Researchers

In 2005, the European Commission put forward a European Charter for Researchers and a Code of Conduct for the Recruitment of Researchers. They were introduced by a Recommendation<sup>100</sup> noting that when Member States '*endeavour to transpose these general principles and requirements within their area of responsibility into national regulatory frameworks or sectoral and/or institutional standards and guidelines (charters and/or codes for researchers)*', they should '*take into account the great diversity of the laws, regulations and practices which, in different countries and in different sectors, determine the path, organisation and working conditions of a career in R&D*'.

The European Charter for Researchers is a set of principles and requirements specifying the roles, responsibilities and entitlements of researchers, employers and funders of researchers. It formally distinguishes issues related to '*ethical principles*', '*professional responsibility*', and '*contractual and legal obligations*'. Regarding researchers' '*ethical principles*', it foresees researchers '*should adhere to the recognised ethical practices and fundamental ethical principles appropriate to their discipline(s) as well as to ethical standards as documented in the different national, sectoral or institutional Codes of Ethics*'. Professional responsibility is presented as encompassing the avoidance of plagiarism and the respect of intellectual property, an issue nevertheless remerging under the heading on contractual and legal obligations, which declares that researchers '*must be familiar with the national, sectoral or institutional regulations governing training and/or*

<sup>96</sup> Ibid., 9.

<sup>97</sup> Ibid.

<sup>98</sup> Ibid.

<sup>99</sup> On this subject, see also: Andy Stainthorpe, "Integrity in Research - A Rationale for Community Action", Expert Group Meeting Brussels (BE), 22-23 March 2007 - Final Report", September 2007.

<sup>100</sup> Commission Recommendation of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers, OJ L75, 22.3.2005, 67-77.

'working conditions', including intellectual property rights regulations and the requirements and conditions of any sponsor or funders.

## 4.2 European Research Council (ERC)

The European Research Council (ERC) was established by the European Commission in 2007 to deal with the funding of scientific and technological research.<sup>101</sup> In 2009, the ERC's governing body, the Scientific Council, committed to formulating guidelines on conflict of interest, fraud and ethical matters. In this context, the Scientific Council finally adopted in 2012 a Scientific Misconduct Strategy.<sup>102</sup>

The ERC Scientific Misconduct Strategy recommends host institutions to have structures in place to uphold scientific integrity, to deal with all cases of scientific misconduct that may come to the attention of the ERC, and to report to the ERC on what actions they have taken to deal with any relevant scientific misconduct problems. Nevertheless, it also points out that all concerns about potential scientific misconduct or suspected breaches of research integrity regarding an ERC applicant or project shall be addressed by the ERC within the applicable legal and procedural framework, and the ERC will, through the ERC Executive Agency (ERCEA), take follow-up actions.<sup>103</sup>

## 4.3 Horizon 2020

The European Commission operates the EU Framework Programmes for Research and Innovation, mobilising significant funds. Horizon 2020, the current EU Framework Programme for Research and Innovation, is the first where the Rules for Participation<sup>104</sup> explicitly mention research integrity.<sup>105</sup> Article 18(5) of the Rules for Participation notes indeed that grant agreement shall, where appropriate and to the extent possible, '*reflect the general principles laid down in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers*', as well as '*principles of research integrity*'. The preamble to the Rules for Participation

<sup>101</sup> See also, on this subject: Alessandra Ferrari, "Research Ethics and Research Integrity at the European Research Council" in *Integrity in the Global Research Arena*, ed. Nicholas Steneck et al. (London: World Scientific Publishing, 2015), 21–26.

<sup>102</sup> European Research Council (ERC), "ERC Scientific Misconduct Strategy", October 5, 2012.

<sup>103</sup> Regarding the procedure, see notably: European Data Protection Supervisor (EDPS), "Opinion on a Notification for Prior Checking Received from the Data Protection Officer of the European Research Council Executive Agency Regarding the 'Procedure on How to Deal with Information on Scientific Misconduct'" (Brussels, July 9, 2014).

<sup>104</sup> Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006, OJ L347, 81-103.

<sup>105</sup> Hiney, "Research Integrity: What It Means, Why It Is Important and How We Might Protect It", 17.



depicts '*avoiding any breach of research integrity*' as an element of '*ethical principles*', to be respected by all actions together with fundamental rights and principles acknowledged by the EU Charter of Fundamental Rights, as well as any legal obligations including international law and European Commission decisions.<sup>106</sup>

The Model Grant Agreement to be used under the Horizon 2020 Programme<sup>107</sup> refers to 'research integrity' in a provision about ethics. More concretely, under Article 34 *Ethics* there is Article 34(1) *Obligation to comply with ethical principles*, which establishes that '*beneficiaries must carry out the action in compliance with: (a) ethical principles (...) and (b) applicable international, EU and national law.*' Said point (a) specifies, between brackets, that the '*ethical principles*' at stake include '*the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct*'. In case of breach, different sanctions are possible, such as a reduction of the research grant be reduced or the termination of the agreement.

There have been calls for further integration of research integrity and scientific misconduct concerns in Horizon 2020, notably through the mechanisms currently in place for ethics review of research proposals and projects.<sup>108</sup> This position appears to be shared by the European Commission, which has notably called for further research on what it expressly designates as the '*ethics/integrity normative framework*', aiming to support the work of '*ethics/integrity experts*' and '*ethics/integrity review committees*'.<sup>109</sup>

The European Group on Ethics in Science and New Technologies (EGE) published a Statement on the Formulation of a Code of Conduct for Research Integrity for Projects Funded by the European Commission,<sup>110</sup> where it supports the idea of requiring adherence by beneficiaries of EU funds to a Code of Good Scientific Practice and Research Integrity, to be defined in the contracts of research projects. The EGE suggests it might be useful to use as general reference the European Code of Conduct for Research Integrity, but also provides a series of substantial recommendations.

A European Ethics and Research Integrity Network (ENERI) was set up with EU-funded support. The call for proposals for the Network<sup>111</sup> emphasised that it was expected to give priority '*to the development of training courses/material*', for training activities that would '*mainly focus on existing European legislation (i.e. Charter of human rights, data protection legislation, dual use export regulation etc.)*'. In a first definition managed by

<sup>106</sup> See Recital (9).

<sup>107</sup> European Commission, "H2020 General Model Grant Agreement — Multi (H2020 General MGA — Multi), Version 2.1" October 1, 2015.

<sup>108</sup> Xavier Bosch, "Research Integrity on the Horizon," *The Lancet* 379, no. 9827 (2012): 1679.

<sup>109</sup> Topic *Mapping the Ethics and Research Integrity Normative Framework* of Call H2020-SwafS-2016-17, Work Programme Part Science with and for Society, Work Programme Year H2020-2016-2017, Pillar Science with and for Society of Horizon 2020.

<sup>110</sup> European Group on Ethics in Science and New Technologies, "Statement on the Formulation of a Code of Conduct for Research Integrity for Projects Funded by the European Commission", 2015.

<sup>111</sup> Topic *European Ethics and Research Integrity Network* (GARRI-10-2015).



the ENERI, legal aspects are mentioned as an element of research integrity but the notion is put forward more widely as '*the attitude and habit of the researchers to conduct research according to appropriate ethical, legal and professional frameworks, obligations and standards*'.<sup>112</sup>

#### 4.4 Ethical standards and Regulation (EU) 2016/679

The EU legislator has recently adopted a General Data Protection Regulation (GDPR)<sup>113</sup> aiming to strengthen the harmonisation of personal data protection rules among EU Member States, to apply from 25 May 2018. The GDPR does not address research integrity but Recital 33 of its preamble puts forward that individuals '*should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research*'.<sup>114</sup> This allusion inscribes itself the context of a series of derogations allowed by the Regulation for the processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.<sup>115</sup>

The aim of Recital 33 is to nuance the need for specificity of the individuals' consent that can be regarded as rendering lawful the processing of personal data: as a general rule, individuals ('data subjects') can consent to the processing of their personal data, but only for one or more *specific* purposes. The Recital hints that exceptionally it shall be possible for individuals to consent to the processing of personal data not just for one or more *specific* purposes,<sup>116</sup> but to '*certain areas of scientific research*' in general, on the condition that such research is carried out in accordance with recognised ethical standards for scientific research.

This allusion triggers two fundamental questions. First, it is not clear what should be regarded as a '*recognised ethical standard*' for the purposes of the Regulation, and whether such standard shall be recognised at international, European or national level. Second, it remains to be seen how could be addressed the circularity created by the fact that the Regulation refers to the need to comply with '*ethical standards*' that, most often, do not incorporate any substantial data protection clause but merely remind

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<sup>112</sup> ENERI homepage, <http://www.eurecnet.org/eneri/>.

<sup>113</sup> 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 (General Data Protection Regulation), OJ L119, 4.5.2016, 1-88.

<sup>114</sup> Recital 33.

<sup>115</sup> See Art. 89 of Regulation (EU) 2016/79, explicitly referring to possible derogations to Articles 15 (right of access), 16 (right of rectification), 18 (right to restriction of processing) and 21 Right to object and automated individual decision-making).

<sup>116</sup> Art. 6(1)(a) of Regulation (EU) 2016/79.

researchers of the need to comply with applicable data protection laws, such as, precisely, this Regulation.

## 5. Concluding remarks

This report completes Task II.4 of Work Package 2 of the PRINTEGER project. Work Package 3, titled *What Happens In Practice? Institutional Responses to Misconduct*, aims to gather information on the investigation and sanctioning of scientific misconduct in practice, and will explore institutional responses to misconduct and their relation with law, focusing on the existence of fair procedures.

The main concern of this report was to investigate the conceptualisation of research integrity and scientific misconduct from a European legal perspective. As described, in Europe coexist different approaches, but as a matter of fact the normative framework of all European countries might be regarded to a large extent as a combination of legislative and non-legislative (but sometimes nevertheless binding) mechanisms. If in some countries there are legal provisions that attempt to circumscribe research integrity, scientific misconduct or related notions, most of the time such provisions do nevertheless refer to self-regulatory instruments and do not allow, by themselves, to fully determine the content of such notions.

Instruments addressing research integrity or scientific misconduct, and in particular self-regulatory instruments, do not just fail to provide harmonious definitions of these notions.<sup>117</sup> The truth is that they actually embody contrasted visions of what these notions are supposed to encompass. Sometimes, self-regulatory instruments (including for instance codes of conduct self-labelled as 'ethics' or 'ethical' codes) claim that the notion of research integrity must be understood as including compliance with any legislation that applies to the researcher's work (for instance, depicting data protection laws as falling under the scope of research integrity). Other instruments, however, situate themselves as having different objectives and a different scope (for instance, excluding compliance with data protection laws from the scope of research integrity).

Both tendencies are challenging from a legal perspective. The first one introduces a problematic re-labelling of existing legal obligations as 'ethics/ethical standards', while the second puts forward the existence of a possible alternative set of norms (implicitly assuming that for sciences law should not and does not apply, at least in certain circumstances).

This discussion is of crucial relevance for any discussion about the possible strengthening of the EU-level legislative framework on research integrity, as it should be

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<sup>117</sup> Which had already been highlighted, for instance, in S. Godecharle, B. Nemery, and K. Dierickx, "Guidance on Research Integrity: No Union in Europe" *The Lancet* 381, no. 9872 (March 30, 2013): 1097–98.

clarified, first and foremost, what shall be the substantial and policy purpose of such a framework, and in particular whether it would be targeting the regulation of compliance of researchers (and research associations) with existing legislation and/or (or even 'as') 'ethical' standards, or perhaps something else. In the first hypothesis, should be elucidated the added value of a legislative framework that restates already existing legal obligations - as well as the *rationale* for adopting legal provisions that refer to so-called 'ethics' instruments that (ethically) refer to the (ethical) need to comply with legal provisions. In the second case, should be considered the legitimacy of widening existing legal obligations, as well as the logic of rendering legally binding rules that were originally explicitly put forward as something different from legally binding rules.<sup>118</sup>

The clarification of the framework's purpose shall also address the exact relationship between research integrity and scientific misconduct. Sometimes envisioned from a theoretical perspective as two faces of a same coin, they do not emerge as symmetrically opposed notions in the majority of the described normative frameworks. If an allegory could be developed, it might be argued that research integrity is rather the purse that sometimes contains the coin of scientific misconduct, occasionally in addition to others.

Just as there are varied understandings on what research integrity is and how any normative framework aiming guaranteeing it should be designed, there are in Europe notable discrepancies on how scientific misconduct should be determined, investigated and sanctioned - and, in particular, the role that courts can or should play in this respect.<sup>119</sup>

All in all, it emerges that the regulation of research integrity and scientific misconduct in Europe leaves open numerous questions regarding the relationship science, ethics and law.

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<sup>118</sup> Discussing the '*(u)ndesirable, inappropriate juridification of research ethics*': Ragnvald Kalleberg, "Plagiarism as Violation of Law in Norway: On Inappropriate Juridification of Research Ethics" in *Integrity in the Global Research Arena*, ed. Nicholas Steneck et al. (London: World Scientific Publishing, 2015), 125–40.

<sup>119</sup> This is actually a global debate. Echoing this controversy: Collste, "Principles and Approaches in Ethics Assessment: Research Integrity" 8.). Calling for a criminalisation of scientific misconduct: Benjamin K. Sovacool, "Using Criminalization and Due Process to Reduce Scientific Misconduct" *The American Journal of Bioethics* 5, no. 5 (2005): W1–7. Noting the divergent approaches towards the requirement of intentionality for the sanctioning of misconduct: Göran Hermerén, "Integridad y mala conducta en el ámbito investigador" *Revista de la sociedad española de Bioquímica y Biología Molecular* 156, no. junio (2008): 5–10.



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