



# Briefing Paper

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**Research Integrity: What it Means, Why it Is Important and How we Might Protect it**

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'Research Integrity: What it Means, Why it Is Important and How we Might Protect it': D/2015/13.324/9

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# Summary

Research integrity lies at the heart of excellent science and scholarship. Researchers must be able to trust and build on the work of others; they must also be trusted by society since they provide knowledge and scientific expertise that may impact people's lives. In the last 20 years some high-profile international cases of research misconduct have come to the fore and these illustrate the damage that misconduct inflicts on research, researchers, institutions and society. Research misconduct also represents a waste of public money invested in research.

This briefing paper looks at developments in efforts to address issues of research integrity. It is not intended to be an exhaustive examination of the growing literature on research integrity. Rather, the paper tries to present exemplars of the evidence and thinking that is emerging in this field. It explores the available data on the frequency of misconduct; why it is thought that researchers would commit misconduct in the first place, given the potential impacts on their careers and those of their students and colleagues; how national and international organisations have approached the promotion of research integrity; and the manner in which allegations of misconduct are handled. The available evidence demonstrates the complexity of this issue and the multiple actors who are required to work individually and collaboratively for its resolution.

# Table of Contents

Summary	1
1. Introduction	3
2. What Are Research Integrity and Research Misconduct?	3
2.1 What Is Research Integrity?	3
2.2 What Is Research Misconduct?	4
2.2.1 Fabrication, Falsification and Plagiarism	4
2.2.2 Questionable Research Practices	5
2.2.3 Regulatory Responses to Research Misconduct	6
2.3 How Common Is Research Misconduct?	7
2.4 Why Does Research Misconduct Happen?	8
2.4.1 Can Pressure to Publish Act as a Perverse Incentive?	8
2.4.2 Can Pressure to Obtain Research Funding Act as a Perverse Incentive?	9
2.4.3 Changing the Paradigm	9
2.5 Research Misconduct and the Role of Self-regulation	9
2.5.1 Peer Review as a Means to Uncover Research Misconduct	10
2.5.2 Replication of Research as a Means to Uncover Research Misconduct	10
2.6 What Are the Impacts of Misconduct?	11
2.6.1 Impacts of Misconduct in the Clinical Research Sphere	11
2.6.2 The Collateral Damage of Misconduct	12
2.6.3 The Financial Costs of Misconduct	13
3. Efforts to Ensure Research Integrity	13
3.1 Promoting Research Integrity and Preventing Misconduct	13
3.1.1 Training as a Tool for Promotion and Prevention	14
3.1.2 How Effective is Training in Changing Behaviour?	14
3.1.3 Creating a Culture of Integrity	15
3.2 International Initiatives to Ensure Research Integrity	16
3.3 National Efforts to Ensure Research Integrity	18
3.3.1 Research Integrity Governance at the Level of the Institution	18
3.3.2 Research Integrity Oversight by National Agencies and Independent Bodies	19
3.3.3 National Research Integrity Offices/Commissions	20
3.4 The Role of Publication Practices in Promoting Research Integrity	21
3.4.1 Ethical Standards in Publication	21
3.4.2 Publishing Policies on Reporting of Research Results	21
3.4.3 The Challenges of Data Management in Research	22
3.4.4 Moving to Open Access Publication	23
4. Conclusions	24
5. Bibliography and Notes	24

# 1 Introduction

The link between high quality research and economic and societal advancement has been accepted across the globe. Research is associated with vast improvements in our living standards, health and wellbeing, substantial technological improvements and advancements in human knowledge. During the last decade, there has been very significant and increasing public investment in European research across all spheres, including humanities and social sciences and the STEM (Science, Technology, Engineering and Mathematics) disciplines. This investment has happened within the wider policy objectives of ensuring that Europe can address its economic and societal challenges, compete effectively with its global neighbours and create high-value, high-skilled employment, based on research-driven innovation and the successful application of research-generated knowledge.

The achievements of research are built up over time on a stock of accumulated knowledge worldwide. The integrity of this 'research record' is based on the assumption that the knowledge presented is true, complete and unbiased by ideological, economic or political influences. In the context of European innovation and economic advancement – including the importance of self-reflection within European society – the reliability of the stock of knowledge and its preservation are becoming more and more crucial. For an activity that is increasingly collaborative, anything less has serious implications for researchers' ability to work with, and build on, the outputs of their peers. Therefore, research integrity is at the core of science and scholarship. It is the basis for researchers to trust in each other as well as in the research record. Equally importantly, it is the basis of society's trust in the research system.

## 2 What Are Research Integrity and Research Misconduct?

### 2.1 What Is Research Integrity?

There is no universally accepted definition of research integrity, although it is generally understood to relate to the performance of research to the highest standards of professionalism and rigour, in an ethically robust manner. The behaviours espoused by ethics and research integrity should ultimately ensure the accuracy and truth of the research record in publications and elsewhere. Luhmann called this 'system trust', which facilitates researchers, policy makers, educators and the public on to confidently draw from, and build on, the research results of others without needing to check their reliability before they use them.<sup>1</sup> Therefore, research integrity is at the very heart of the research enterprise and is intrinsic to the value of research to society, and society's trust in the outcomes of this enterprise.

Godecharle et al. have noted that there is some variation in the principles that are considered to constitute research integrity.<sup>2</sup> For example, widely accepted global principles, set out in seminal documents such as the Singapore Statement on Research Integrity<sup>3</sup>, the ESF/ALLEA European Code of Conduct for Research Integrity<sup>4</sup>, the Montreal Statement on Research

Integrity<sup>5</sup> and the Global Research Council Statement of Principles on Research Integrity<sup>6</sup> are similar in intent but not identical in their content. Honesty and reliability appear in each statement, while other principles variously espoused include objectivity, impartiality and independence, open communication, duty of care, fairness and responsibility for future generations of researchers. As far back as 1942 Merton<sup>7</sup> described four ‘norms of science’ that should govern the behaviour of researchers, namely: Communalism, Universalism, Disinterestedness and Organised Scepticism (CUDOS).<sup>8</sup> These CUDOS principles were subsequently updated by Ziman<sup>9</sup> to include Originality, Specialism and Advocacy, and Anderson et al.<sup>10</sup> have proposed that Governance and Quality should be added to this list. These norms are, of course, ideals that may be impossible to fully achieve in the real world, but researchers should at least be aware of them as guiding principles for their behaviour.

Even with some convergence on guiding principles there is still significant national variation in the policies, codes of conduct and frameworks that exist to implement these principles. Similarly, there is no universal agreement on what constitutes good research practice and no globally accepted definition of research misconduct. These issues are more fully explored in this paper.

## 2.2 What Is Research Misconduct?

While there is no globally accepted definition of research misconduct, there is common agreement that the core of misconduct is constituted by Fabrication, Falsification and Plagiarism – often referred to as FFP. Outside FFP there are other deviations from good research practice that are sometimes included in misconduct definitions (usually only serious deviations) and sometimes handled through a different framework. Such deviations are internationally termed questionable research practice.

### 2.2.1 Fabrication, Falsification and Plagiarism

Most definitions of research misconduct include FFP in proposing, performing, or reporting of research results,<sup>11</sup> because these violations distort or damage the research record, the very foundation of scholarship and scientific progress. The OECD<sup>12</sup> defines FFP as:

- ▶ **Fabrication of data:** i.e. making up results and recording or reporting them.
- ▶ **Falsification of data:** i.e. manipulating research, materials, equipment or processes; changing or omitting data or results such that the research is not accurately represented in the research record.
- ▶ **Plagiarism:** i.e. the appropriation of another person’s ideas, processes, results, or words without giving due credit, including those obtained through confidential review of others’ research proposals and manuscripts.

Falsification is perhaps the most problematic of these behaviours, given that research data can be manipulated in many very subtle ways that, while not perhaps falsification in its strictest sense, can still distort the research record.<sup>13</sup> These include data ‘cooking’ (giving

data more weight than it deserves), data ‘mining’ (searching for a statistically significant relationship that is then presented as the original purpose of the study), selective publication of only the results that support the hypothesis, data smoothing (unjustified omission of ‘outliers’), concealing conflicts of interest and so on. Fanelli has, in fact, suggested that research misconduct should be redefined as distorted reporting, arguing that this places the responsibility squarely with researchers to accurately and fully record and report their data.<sup>14</sup>

### 2.2.2 Questionable Research Practices

In addition to FFP there are many other questionable practices that, while they may not directly and/or fundamentally distort the research record, still damage the reputation of researchers and the research community, and ultimately societies’ trust in research. The OECD has categorised such questionable research practices to include (but not be limited to):

- ▶ **Research practice misconduct:** e.g. poor research design; using inappropriate (harmful or dangerous) research methods; experimental, analytical or computational errors.
- ▶ **Data-related misconduct:** e.g. not preserving primary data; poor data management and/or storage; withholding data from the research community.
- ▶ **Publication-related misconduct:** e.g. claiming undeserved authorship; denying authorship to contributors; artificially proliferating publications; failure to correct the publication record.
- ▶ **Personal misconduct:** e.g. inadequate leadership/mentoring of next generation of researchers and scholars; inappropriate personal behaviour and harassment; insensitivity to social or cultural norms.
- ▶ **Financial and other misconduct:** e.g. peer review abuse, non-disclosure of a conflict of interest, misrepresentation of credentials; misuse of research funds for unauthorised purchase or for personal gain.

These practices sit on the continuum between what is truly correct and truly deceptive. Whether a questionable research practice qualifies as research misconduct is often determined by the seriousness of the incident and the culpability and intent of the researcher. Of course, the difficulty with the concept of ‘intentionality’ is that it can be very hard to prove whether a researcher was simply sloppy or incompetent or whether they set out to intentionally deceive. Questionable research practices can also be difficult to detect and the very nature of these practices, which can be ambiguous rather than blatantly improper, can afford researchers the opportunity to rationalise their behaviours.<sup>15</sup> Crocker argues that taking questionable research practice seriously at an early stage in a researcher’s career is vital, since every minor transgression that goes against the norms of behaviour of the ‘good’ researcher and is uncorrected, can become part of a self-deceptive narrative that will make the next transgression easier – the so-called ‘slippery slope’.<sup>16</sup>

Questionable research practices are likely to be far more prevalent and, therefore, ultimately more damaging to the research enterprise than FFP. A study by Martinson et al. of several thousand early and mid-career researchers in the US, who were funded by the National Institutes of Health (NIH), found that the range and prevalence of questionable research

practices was striking.<sup>17</sup> The survey reported that over their career to date, respondents reported frequencies of about 2% for serious misconduct (FFP) but greater than 10% for other questionable research practices. Another study that measured the prevalence of questionable research practices among 2,000 academic psychologists, using truth-telling incentives, found that approximately 10% had introduced false data into the research record and that the majority had engaged in questionable research practices at some point in their career.<sup>18</sup>

### 2.2.3 Regulatory Responses to Research Misconduct

It is important to stress that honest error in research practice or interpretation of data should not be considered research misconduct. Therefore, all definitions of misconduct need to draw a clear distinction between such honest errors and acts by researchers constituting misconduct. According to US Federal standards a finding of misconduct must be shown to be “a significant departure from accepted practices of the relevant research community” and to have been committed “intentionally, knowingly or recklessly”.<sup>19</sup> The concept of intentionally also assumes that all researchers agree on what constitutes good research practice, and hence undesirable or questionable breaches. In reality, scholars in different disciplines or in different cultures may differ on what they think are appropriate standards of good research practice, and therefore of what constitutes a serious deviation from those standards.

Regulatory responses to misconduct also reflect diverse cultural approaches across the world, for example between the US and Europe. In the US, FFP are the only research offences that are subject to regulation. Europeans and others are starting to consider other forms of misconduct as part of their regulatory frameworks. However, even within Europe there is considerable variation in how similar forms of misconduct are perceived and sanctioned.<sup>20</sup>

While definitions of misconduct may have evolved differently in each country that has them<sup>21</sup>, two common issues are apparent when translating these definitions into guidelines or regulations. Firstly, how broadly should research misconduct be defined in regulatory frameworks? Should it be restricted to FFP, which directly distorts or damages the research record, or should it include any potential breach of integrity, unethical or immoral behaviour? Secondly, should the level of culpability or intentionality be considered? Should this include intentional acts of deception, grossly negligent acts done in flagrant disregard for the truth and/or carelessness or lesser negligence?<sup>22</sup>

At the core of these issues is what is being sought by the definition. Efforts to promote responsible research and ethical behaviour and to protect the research record need broad definitions of misconduct and a lower intentionality threshold. However, if the objective of a policy or regulation is to hold researchers accountable only for fraudulent behaviours that damage the research record, then it may be appropriate to define misconduct within the narrow confines of FFP, and with a high threshold of culpability. It is common to want the same definition to both catch bad behaviour and promote good behaviour. However, the two objectives are different and may require separate definitions.



## 2.3 How Common Is Research Misconduct?

An often-heard argument against implementing guidelines, frameworks or governance structures to ensure research integrity is that it is an over-reaction, since serious misconduct is so rare. However, there is evidence that the frequency of research misconduct is considerably higher than society, the research community or those who fund research should be comfortable with. For example:

- ▶ From all sources, the US NIH Office of Research Integrity (ORI) received 423 allegations of misconduct in 2012, an increase of 56% over the 240 allegations handled in 2011, and well above the 1992-2007 average of 198. Of the 29 cases that proceeded to a full investigation, a finding of research misconduct was made in 40%, which is just above the historical annual average of 36% of cases investigated.<sup>23</sup>
- ▶ In 2012, 59 new allegations of research misconduct were referred to the German Research Foundation's (DFG) Ombudsman for Science for mediation.<sup>24</sup> Of these, 21 were referred to the relevant board (usually the concerned university) for further investigation, and a finding of misconduct was made in five (Pers. Comm., Ombudsman for Science Office.).
- ▶ In 2014, the US National Science Foundation (NSF) Office of Inspector General (OIG) closed 128 investigations, had 19 cases of proven research misconduct and recovered over \$2.3 million in fraudulently handled research funds.<sup>25,26</sup>

The numbers might not seem impressive given, for example, that the US National Institutes of Health is responsible for many thousands of researchers. Based on these figures one could argue that research is more honest than most professions. However, these statistics do not reflect the mounting evidence of under-reporting of both serious misconduct and questionable research practices by individuals and institutions. There has been no systematic study of the reasons for such under-reporting, although many authors speculate on possible causes, such as the fear of career damage faced by young researchers, or the desire of institutions to minimise reputational damage. Whatever the reasons, the issue of under-reporting appears to be very real. To quantify the real levels of research misconduct, a number of large surveys of researchers' direct experience of research misconduct have been carried out in the last decade, primarily in the US, and these tell a worrying story. For example:

- ▶ A 2005 ORI survey of 2,212 researchers found that these researchers had observed 201 likely instances of misconduct over three years; that is, two incidents per 100 researchers, a considerably higher rate than the annual number of allegations submitted to the ORI.<sup>27</sup>
- ▶ A survey of 1,645 co-ordinators of clinical trials in the US found that 20% of respondents had encountered misconduct of some type at work.<sup>28</sup>
- ▶ A survey of Research Integrity Offices in 90 major US universities revealed that of a total of 553 allegations received for consideration, 38% revealed problems with the documentation of research.<sup>29</sup>
- ▶ A survey of 194 newly-appointed medical consultants in the UK reported that 5.7% admitted to past personal misconduct and that 55.7% of respondents had observed some form of

research misconduct in a colleague, with 10.8% having first-hand knowledge of the intentional altering or fabrication of data.<sup>30</sup>

- ▶ A survey of 384 management science faculty in 104 US colleges reported that almost 73% had knowledge of their colleagues engaging in FFP in the past year, and the survey noted that tenure-track and non-tenure-track faculty were equally likely to commit research misconduct.<sup>31</sup>

The weakness of surveys that report self-observed misconduct numbers is that they are subjective and difficult to verify. In addition, there have been few large-scale surveys of university researchers in Europe that could confirm differences in levels of misconduct between the US and Europe. Perhaps the most compelling evidence of actual levels of misconduct worldwide is a 2009 meta-analysis by Fanelli of 21 surveys on research integrity over the previous 25 years.<sup>13</sup> The review confined itself to fabrication, falsification or other forms of data modification. It reported that an average of 1.97% of scientists admitted to fabrication, falsification or modifying data or results at least once, while up to 33.7% admitted to other questionable practices. When asked about the behaviour of colleagues, these statistics jumped to 14.2% for falsification and fabrication, and up to 72% for other questionable practices. A 2011 meta-analysis of 17 surveys specifically on plagiarism found very similar results, namely that 1.7% of researchers admitted having plagiarised but had witnessed plagiarism in 30% of colleagues.<sup>32</sup>

## 2.4 Why Does Research Misconduct Happen?

The research community often views serious cases of misconduct as just ‘a few rotten apples’ tainting research for everyone else. But if researchers are basically honest, why are the self-observed levels of misconduct, in particular questionable research practices, so high? The answer may lie partly in the structure of today’s academic world, which may have created perverse incentives for researchers to be less than honest. The most commonly-cited incentives are performance-related, namely: greater competition to attract research funding and publish in high impact journals; and the career system and metrics used to assess research quality and excellence. These pressures may, collectively or individually, increase the temptation occasionally to side-step proper procedures, even in the most honest of researchers.

### 2.4.1 Can Pressure to Publish Act as a Perverse Incentive?

The pressure to ‘publish or perish’ is particularly pernicious, forcing researchers to produce ‘publishable’ results if they wish to advance in their careers.<sup>33</sup> The 2005 ORI survey of US scientists, mentioned in Section 2.3, found that 33% of respondents admitted to engaging in one or more types of questionable research behaviour, and 15.5% admitted to changing trial design, methodology and results in response to such pressures.

A 2012 survey of academic economists showed that perceived pressure to publish was directly related to an admission of being involved in several unacceptable research practices.<sup>34</sup> Not surprisingly, a 2010 study of retractions from the PubMed database between 2000 and 2010 showed that fraudulent authors targeted journals with a high impact factor, had written other

fraudulent papers ('repeat offenders') and had retracted their papers more slowly than authors of papers with honest errors.<sup>35</sup>

### **2.4.2 Can Pressure to Obtain Research Funding Act as a Perverse Incentive?**

Another big challenge for researchers is the level of competition for national and international research funding, and the 'winner takes all' approach to funding. Success rates for funding applications rarely rise above 20% of total applications and are considerably less in many cases, for instance 14% on average for EU Horizon 2020 programme<sup>36</sup> and less than 10% for some schemes. To be funded, research must be innovative and important. Faced with the challenge of sustaining one's research, the temptation to oversell the significance of the proposed work or to 'beef up' the preliminary data could be hard to resist.

Studies show that a significant number of researchers in the US admit to bending the rules, for example on the use of human participants to get a project finished or use the funding from one project to generate preliminary data for the next project.<sup>37</sup> The expectation that researchers will obtain competitive external funding for their research work, and in some instances a portion of their salary, has been linked to significantly higher reports of serious misconduct and questionable research behaviour, in particular if that funding came from federal sources<sup>19</sup> or industry<sup>38</sup>. There is little equivalent data for practices in Europe, but it is probably fair to assume that European researchers experience similar pressures.

### **2.4.3 Changing the Paradigm**

Steneck argues that eradicating dishonest behaviour completely may, in fact, be impossible in today's competitive environment and that the solution may be to change the way research is planned, funded and rewarded.<sup>39</sup> The current resource (career, money) distribution models are determined by peer-review systems and other competitive features of the funding and publishing environment. As Martinson et al. observed, from a study of 5,000 biomedical and social science faculty, "the free play of university and individual self-interests, combined with and contributing to the intense competition for research funding, may be undermining scientific integrity".<sup>40</sup>

Since significant links have been found between research misconduct and perverse incentives for researchers, some serious consideration of the structural elements of the career and advancement system for researchers, and of the metrics used to assess research quality and excellence, may be required.

## **2.5 Research Misconduct and the Role of Self-regulation**

If, as many believe, research misconduct is a problem of individuals with selfish motives, the solution is surely to have proper control and evaluation mechanisms that allow researchers to better police themselves. This assumes a number of things: that research misconduct is rare (see Section 2.3 for an examination of that assumption); that the risk of being caught and the severe repercussions that follow will deter most researchers from misconduct; and that serious misconduct is quickly

detected and stopped.<sup>41</sup> Most researchers believe that false findings will eventually and inevitably be discovered and rejected, either through the peer review process or replication studies.

### **2.5.1 Peer Review as a Means to Uncover Research Misconduct**

In the eyes of many researchers peer review is the best kind of self-policing available. It is used throughout the research process: to evaluate grant applications, assess the ethical soundness of a proposal and validate the results that emerge as publications. Peer review is, therefore, a cornerstone of quality assurance in research funding allocation and the validation of research outputs. But is it reasonable to also depend on peer review to uncover research misconduct?

A 2013 study sent a fabricated manuscript containing unacceptable errors to over 300 journals where poor review practices were suspected. Alarmingly, the survey found that over half of the journals accepted the manuscript for publication following peer review, even where reviewers had pointed out difficulties with it.<sup>42</sup> An examination of some of the most well-known perpetrators of serious misconduct shows that many had a significant number of fraudulent or questionable publications (a record 170 in the case of Yoshitaka Fujii) that peer review of those publications had failed to detect.<sup>43</sup>

But what can we realistically expect of peer review as a means to uncover research misconduct? The rising number of grant applications submitted to funding agencies, and manuscripts submitted for journal publication each year, puts research administrators and journal editors under increasing pressure to find enough peer reviewers to assess the quality and validity of these applications or manuscripts. As a result, not every peer reviewer may be an expert in the specific methodologies proposed or used nor, in many instances, might they be experienced researchers. Likewise, journals have limited resources to check authorship, conflicts of interest and so on, although technology has made detection of plagiarism more feasible.

Funding agencies and journals recognise these difficulties. For example, there is extensive ongoing work to improve the peer review process for assessing quality parameters in funding applications (see for example the work of the Swedish Research Council<sup>44</sup>), by clarifying guidelines and procedures, offering training for peer review panels, monitoring bias in peer review<sup>45</sup> and so on. However, it is too early to know what the impact of these changes will be in terms of the capacity of peer review of either grant applications or journal manuscripts to uncover research misconduct, and the reality is that peer review would not be capable of identifying much questionable behaviour happening at the level of the laboratory.

### **2.5.2 Replication of Research as a Means to Uncover Research Misconduct**

There has been increasing concern in recent years, in particular within the biomedical research community, about the lack of reproducibility of key research findings. As a result, serious efforts are being made to identify how to improve and optimise this (see for example the 2015 UK report 'Reproducibility and reliability of biomedical research: improving research practice'<sup>46</sup>).

Replication is seen as an important tool in the self-policing armoury, but does it work to uncover

research misconduct? There are certainly a small number of cases where consistent failure to replicate results aroused suspicions of misconduct, but replication difficulties rarely play a primary role in uncovering misconduct.<sup>47</sup> The problem with relying on replication to identify and correct errors, whether intentional or unintentional, is that relatively little research is replicated. Replication studies have few, if any, sponsors, although the pharmaceutical industry is starting to fund some studies.<sup>48</sup> Some methods and findings are difficult, if not impossible, to reproduce (for example natural experiments). There is a growing number of research areas in which the effective repetition of experiments would require so many resources that this will not take place (for example in some areas of physics). Finally, there is little incentive for researchers to undertake replication studies that are not presenting novel ideas since they will be hard to publish.

In a fully self-regulated world, researchers themselves would serve as the front line to preserve integrity and expose wrong-doing. In the Stapel case, this was precisely what happened.<sup>49</sup> However, the results of almost all surveys show that even where a researcher observes an incidence of misconduct in a colleague they often do not report it, knowing perhaps that the fate of whistle-blowers is generally not a happy one. For research institutions, the fear of reputational damage can lead to efforts to minimise evidence of misconduct or sweep cases under the carpet. Therefore, relying wholly on researchers to uncover research misconduct among their colleagues through peer review or replication studies is inadequate, and the whole research system needs to work in concert to address this issue.

## **2.6 What Are the Impacts of Misconduct?**

Research misconduct is not a victimless crime. It has impacts for researchers and research participants, institutions, fields of research and society.

### **2.6.1 Impacts of Misconduct in the Clinical Research Sphere**

Patients can suffer because treatments they receive are based on faulty or incomplete data. According to Lehman and Loder “a large proportion of evidence from human trials is unreported, and much of what is reported is done so inadequately”.<sup>50</sup> The impact of these practices is that “missing data about adverse events in trials can harm patients, and incomplete data about benefits can lead to futile costs to health systems”. Take, for example, Study 329 on the efficacy of paroxetine, a common antidepressant, in children and adolescents. This was originally reported in the *Journal of the American Academy of Child and Adolescent Psychiatry* in 2001 to be “generally well tolerated and effective” and in 2002 over two million prescriptions for paroxetine were written for children and adolescents in the US.<sup>51</sup> However, a recent review of the evidence in the *British Medical Journal* supports the opposite conclusion in young people, and is the result of the Restoring Invisible and Abandoned Trials initiative, aimed at forcing pharmaceutical companies to release all of their data for independent scientific scrutiny.<sup>52</sup>

Even where a paper reporting a clinical study is eventually retracted, it could have had an impact prior to its retraction, which can take anywhere between 22 and 79 months.<sup>53, 54</sup> This is exemplified by a 2011 systematic review of 788 papers retracted between 2000

and 2010 because of faulty data, which reported 180 primary clinical studies and 851 secondary studies that cited the flawed primary studies.<sup>55</sup> 28,000 subjects were enrolled (and 9,189 patients were treated) in the primary studies and a further 400,000 subjects were enrolled (and 70,501 patients were treated) in the secondary studies.

In addition, on-going access to retracted articles is a problem. A 2011 analysis of the availability of articles retracted from MEDLINE between 1973 and 2010 found that 75% were still available on non-publisher websites, where the retracted status of the paper was not clear.<sup>56</sup> Ideally, the retracted status of a paper should be clear as well as the reasons for that retraction, which in many instances will be honest error.

Finally, retracted clinical studies may have a 'retraction tail', that is they may continue to have an impact on the field beyond their retraction. The retracted study published by Wakefield et al. in the *Lancet* in 1998 suggested a link between vaccination against measles, mumps and rubella (MMR) and the development of autism in children.<sup>57</sup> Despite being discredited, initial media coverage of the 'findings' led to a significant drop in the rate of MMR vaccination of children in many countries and a subsequent rise in the number of measles outbreaks in the UK, US and Canada during the late 2000's and beyond.<sup>58</sup>

### 2.6.2 The Collateral Damage of Misconduct

Obviously, a serious misconduct charge will damage the career and reputation of the guilty researchers. They may lose their jobs, have medical licences or PhD awards revoked, become outcasts in the research community, and in some serious cases receive prison sentences (although this is rare). What may not be so obvious is the collateral damage that misconduct can cause to colleagues and the field of study associated with the guilty researcher(s).

Graduate students supervised by a discredited senior researcher may not be able to count joint publications in their academic CVs, their PhD dissertations may be tainted by fraudulent data provided by their supervisor (for example in the case of Stapel) and their future job prospects may be damaged.<sup>59</sup> There is also a 'retraction penalty' for other authors connected to papers published by the accused prior to a retracted paper, with an average fall-off in their citations by 2.88 per year, rising to 5.39 after five years.<sup>60</sup> Somewhat unfairly, many whistle-blowers experience negative consequences in their personal and professional lives.<sup>61</sup> At best, a whistle-blower may find their work environment uncomfortable, forcing them to seek employment elsewhere. Their institutions may make them into enemies<sup>62</sup> or disgruntled colleagues can blacklist or shun them.<sup>63</sup> Whistle-blower protection also needs to consider the rights of the accused to fair treatment, to know the identity of their accuser(s) and to be protected from false or vexatious accusations. Even where there is legislation to protect the rights of whistle-blowers these regulations don't always work.<sup>64</sup>

Following the retraction of a paper because of misconduct, the field of study may suffer. Articles published in the same intellectual space but with no link to the retracted paper(s) have been shown to experience a 'citation penalty' – a lasting 5-10% decline in their rate of citation – with a positive correlation to the severity of the misconduct that led to the retraction(s).<sup>65</sup> Another

negative impact observed was a decrease in new articles and research funding flow into the field, suggesting that researchers may avoid retraction-afflicted fields lest their reputations suffer through association.

### **2.6.3 The Financial Costs of Misconduct**

There are direct and indirect financial costs associated with misconduct. A 2014 study of publications retracted because of serious misconduct calculated that their direct cost to the NIH was an average of \$425k per article.<sup>66</sup> The study also estimated that total NIH funding wasted on retracted papers between 1992 and 2012 was \$1.67 billion. Another study that looked at the costs to an institution of investigation of a misconduct case, calculated that the direct cost of investigating a single misconduct case is approximately \$500k, and that the total cost of all allegations reported to ORI in 2009 was about \$110 million.<sup>67</sup>

These estimates do not include the opportunity costs of loss of trust/goodwill by the public and damage to the reputations of laboratories or institutions, nor the indirect costs of unproductive research by other scientists who have based their work on flawed data. Neither do these estimates include the indirect costs to society of misconduct, such as preventable illness or loss of life due to misinformation in the medical literature. An outbreak of measles in Wales in 2012, with 1,200 cases of the potentially fatal disease, was associated with non-vaccination of babies in the late 1990s because of the Wakefield scandal, and cost an estimated £470k.<sup>68</sup>

The European research system is considerably larger and more complex than the US one. The cumulative costs of misconduct for Europe, both direct and indirect, will be pretty astronomical if no effort is made to promote a culture that embraces research integrity and prevents research misconduct and all its attendant negative impacts.

## **3 Efforts to Ensure Research Integrity**

There is broad international agreement on the value and benefit of developing processes and structures that can promote research integrity. These ensure consistency, fairness and transparency in the investigation of misconduct allegations. The challenge for each institution, agency, society or country is to find a considered balance between local responsibility and structures on the one hand, and national research integrity co-ordination and oversight on the other hand.

### **3.1 Promoting Research Integrity and Preventing Misconduct**

One of the principal aims of promotional activities is to enhance awareness of research integrity and good research practice, facilitate information exchange amongst research interest groups (junior and senior researchers, funders, university management, publishers and so on) and prevent problems down the line. Good research practice, in this sense, is researchers' shared understanding about appropriate behaviours in the context of themselves, their colleagues, the laboratory, department and discipline.

### 3.1.1 Training as a Tool for Promotion and Prevention

Training in research integrity is commonly held to be the best available means of preventing misconduct. The approaches taken to training vary widely across institutions and countries and there is no agreement about the most effective approach, about who needs/should receive training, how early this training should begin (at post-graduate level, undergraduate level, or even during school years?) and about the necessary qualifications of trainers.

Offering research integrity training as part of undergraduate and postgraduate education is a common training approach, although the content, intensity and mode of delivery of training vary widely across institutions. In 2014, an informal survey of European Network of Research Integrity Offices (ENRIO) members on educational approaches in 11 countries in Europe, found that training tends to focus largely on rules and procedures, good research practice guidelines and on case studies that throw up ethical concerns and dilemmas. Delivery of training is through lectures, seminars and workshops, textual and on-line tutorials<sup>69</sup> or a blended approach.<sup>70</sup> The groups receiving training are primarily doctoral and post-doctoral researchers, and to a lesser extent senior research staff, teaching staff, quality managers and other administrative staff.

Despite the fragmented nature of training offerings, there is currently no Europe-wide effort, based on empirical evidence, to identify the most effective approaches to the focus, content, delivery modes, timing and frequency of training, such that a harmonised 'European Framework for Research Integrity Training' can be developed and adopted locally. In addition, standardised training for research integrity trainers has not yet been developed, that would allow sharing of good practice amongst practitioners and ensure consistency in the training products delivered at national level. That said, a number of countries in which there is some national co-ordination of training (e.g. Canada, Germany and Austria) have initiated 'train-the-trainer' courses to introduce consistency into research integrity curricula in their country.

### 3.1.2 How Effective is Training in Changing Behaviour?

To date there have been few studies on the short-term effectiveness and longer-term impacts on behaviour change of training in research integrity. However, there is some evidence to suggest that training which focuses on rules and procedures may not be very effective.<sup>71, 72</sup> It has been argued that, instead, training should focus on the fundamental norms that underpin research (see Section 2.1). If internalised at an early stage in a researcher's career, such norms would provide fledgling researchers with a solid ethical framework within which to work.<sup>73</sup>

In the field of ethics training, a 2009 meta-analysis of the effectiveness of different training methods suggested that the most successful programmes were case-based, interactive and practical, with course content that allowed students to examine real-world dilemmas and their behaviour within them.<sup>74</sup> This more realistically reflects the day-to-day practice of research, which has many uncertainties and ethical challenges. Unless these are acknowledged and their sources understood, researchers will not be adequately prepared for the kinds of decisions they have to make on an ongoing basis.<sup>75</sup>



Finally, there is a growing consensus on the need to offer specifically tailored education and support for more experienced researchers and academics, who are very influential in defining acceptable research practice for the next generation of researchers. Good quality mentoring, in combination with training that focuses on norms rather than processes, has the potential to influence behaviour in ways that decrease the likelihood of misconduct.<sup>76</sup>

### 3.1.3 Creating a Culture of Integrity

The emphases in most research integrity guidelines are on changing individuals. Fanelli et al. have argued that rather than focus on incentives that influence individual behaviours, such as pressure to publish, “efforts to reduce and prevent misconduct might be more effective if focused on promoting research integrity policies, improving mentoring and training, and encouraging transparent communication among researchers”.<sup>77</sup> Koocher and Keith-Spiegel have argued that in a supportive environment, colleagues, supervisors and assistants who work with, near or in the same discipline as researchers contemplating or committing misconduct constitute a powerful and potentially valuable resource to minimise and correct behaviour, especially where the misconduct may not be intentional.<sup>78</sup>

Therefore, the characteristics of the environment in which researchers work may be just as important in determining their behaviour as the training they receive in research integrity. For example, a survey that looked at the impact of industrial funding, work-group size and organisational climate on the productivity and openness of PhD students and postdocs found that positive organisational climate and small work-group size were associated with productivity and positive behaviours.<sup>79</sup> Another study of 102 first year PhD students found that their ability to make good ethical decisions was correlated with prior experience of a number of environmental dimensions.<sup>80</sup>

Martinson et al. have shown that researchers’ perceptions of how fairly they are treated in their work environment (‘organisational justice’) play an important role in fostering, or undermining, positive research behaviours.<sup>81</sup> The authors propose that “in the distribution of institutional rewards, greater attention to the quality of research would foster better scientific conduct than rewards that are based on the number and size of research grants, the ‘glamour’ of one’s topics and findings, or sheer number of publications”.<sup>82</sup>

At present there are no established indicators that allow empirical measurement of the impacts of research integrity initiatives, either in terms of processes, outcomes or perceptions. A recent report from the European Commission attempts to set out a framework within which indicators could be developed.<sup>83</sup> The proposal is to measure the impacts of eight criteria that they considered most important to creating and sustaining a supportive environment for responsible research and innovation, namely: governance; public engagement; gender equality; science education; open access/open science; ethics; sustainability; and social justice. Having such indicators available would help to assess whether, and how, promotional initiatives are enhancing good research practices.

In the US, efforts to assess the strength of existing organisational research climate, target areas of weakness and monitor the impact of changes made to improve these, prompted Martinson et al. to develop a validated Survey of Organisational Research Climate (SORC).<sup>84</sup> This provides a snapshot of seven dimensions of research climate including: ethical leadership; socialisation and communication processes; and policies, procedures, structures and processes to address risks to research integrity.<sup>85</sup> They have argued that establishing such baseline data stimulates and facilitates internal discussions and informs training initiatives and other activities to promote research integrity.

Application of this tool to 2,836 randomly-selected biomedical and social science faculty and postdocs in 251 departments in receipt of NIH funding, found that the SORC was predictive of self-reported research behaviours.<sup>86</sup> Another study of 11,455 faculty, postdocs and PhD students from three research-intensive universities in the US concluded that this instrument could be administered in large university settings across a broad range of fields, department types and individual roles within academic units.<sup>87</sup> It might be helpful for European research organisations that are serious about creating a culture that fosters research integrity to consider adopting a similar tool to establish a baseline within research institutions, identify areas of particular weaknesses and assess their progress towards creating a work environment that enhances rather than hinders positive research behaviours in their staff and students.

### 3.2 International Initiatives to Ensure Research Integrity

Since research is becoming an increasingly international endeavour, it is not surprising that all recent global initiatives have called for harmonised principles and/or agreements. Resnik has argued that existing and well-established standards for the ethical conduct of research are insufficiently broad to cover the many issues encompassed by research integrity and that the time has come to develop appropriate international standards. A proactive and harmonised response internationally to promoting and securing research integrity in national systems offers significant benefits for research and graduate education. There are many reasons why European standards for research integrity are important:

- ▶ In an increasingly collaborative research environment international standards transcend national boundaries and may help to adjudicate and resolve disputes between researchers from different countries by removing sensitive issues and adjudicative powers from local/institutional politics.
- ▶ International standards reassure those with an interest in research (global funding organisations, potential international research collaborators, government, the public, industry, and publishers) that European researchers conform to the highest standards of research practice and that the European research system is equipped to respond in a timely, fair and consistent manner to any misconduct allegations that arise, including where the allegation is made against someone who moves between countries.
- ▶ In the absence of local standards, international standards can foster trust among scientists working in different countries by providing a framework within which researchers can evaluate and agree appropriate conduct.

- ▶ Well-recognised, clear and coherent international standards can encourage and support the development of local standards that ensure consistency, transparency and fairness in the handling of allegations, protect institutions and individuals, and enable public officials to ensure that public funds invested in research are properly awarded and spent.

Several international organisations that variously represent researchers, research funding organisations, publishers and policy makers, engage with research integrity issues. These organisations tend to prioritise awareness-raising, information exchange and the identification of general principles relevant to good research practice and misconduct investigations. Many have published guidelines relevant to their membership. These include (but are not confined to):

- ▶ OECD Global Science Forum<sup>12</sup>
- ▶ European Science Foundation (ESF)<sup>4</sup>
- ▶ Committee on Publication Ethics (COPE)<sup>90</sup>
- ▶ Council of Science Editors<sup>91</sup>
- ▶ International Council for Science (ICSU)<sup>92</sup>
- ▶ InterAcademy Panel<sup>93</sup>
- ▶ World Commission on the Ethics of Scientific Knowledge and Technology (COMEST)<sup>94</sup>

The European Commission (EC) has a long history of promoting some aspects of ethics in research, but has only recently taken an interest in research integrity per se. Horizon 2020 is the first EU research Framework Programme in which the Rules of Participation explicitly mention research integrity, and the Model Grant Agreement contains a specific article on research integrity (Article 34). Under the Model Grant Agreement a principal investigator can be excluded from applying for Framework Programme funding for up to five years following a proven case of FFP, blatant attempts at duplicate funding or serious undeclared conflicts of interest. The penalty goes up to ten years exclusion if there is a second proven case against that researcher. The Commission funded its first ‘research on research integrity’ co-ordination and support action (PRINTEGER) in 2015, with further funding for a project to calculate the costs of misconduct to be funded in 2016, and the possibility of more ‘research on research integrity’ topics in Horizon 2020 future work programmes. The Commission is also planning to support a European network in this area, and is reviewing Article 34 in order to strengthen it.

### 3.3 National Efforts to Ensure Research Integrity

Research activity may be increasingly international in nature, but the promotion of research integrity and the investigation of allegations of research misconduct will continue to be addressed through national structures. These may apply at the level of the institution, region or country. Typically, the primary responsibility for promoting integrity and handling issues of research misconduct resides with the institution that hosted the research and/or is the employer of the researcher against whom an allegation of misconduct is made, although professional bodies may have a role in, for example, the case of regulated health professionals.

There is currently no agreement across Europe about the best national regulatory frameworks for research integrity. A number of countries do not have any national guidelines to address promotion of integrity and management of research misconduct. Where there are guidelines, a 2012 survey of 15 countries both within and outside Europe found that these vary hugely in approach, and only half of European countries have specific legislation to deal with misconduct.<sup>96</sup>

The 2008, the OECD Global Science Forum identified three generic ways of organising misconduct investigations, namely ad hoc committees, standing committees and dedicated national committees. In reality, countries may have a blend of these arrangements. The ESF Forum on Research Integrity more usefully grouped governance arrangements according to where oversight responsibility lay: in the institution; with regional/national organisations; or through a National Research Integrity Office.<sup>97</sup>

### 3.3.1 Research Integrity Governance at the Level of the Institution

Responsibility for research integrity needs to start in the institutions that are the direct employers or educators of research staff and students. This parallels the institutions' responsibility for financial probity or other forms of personal misbehaviour, which are also matters for the employer. This is the case in most countries, where local institutions undertake investigations of misconduct allegations. These may be done through ad hoc committees of senior researchers, who operate independently or under the aegis of an existing university-based research ethics committee. Some institutions have established standing entities (e.g. offices, committees) linked to institutional procedures to guide their investigations.

Such self-regulation endorses local responsibility and leadership, enhances the visibility of integrity issues at an institutional level and ensures that local knowledge of the circumstances of suspected misconduct can inform appropriate action. However, there are also disadvantages to self-regulation, including:

- ▶ inconsistency of ad hoc processes;
- ▶ lack of an appeals mechanism, in particular with ad hoc arrangements; and
- ▶ the likelihood of personal conflicts of interest.

Perhaps the biggest risk to 'internal' investigative approaches is lack of transparency. Research institutions also face serious conflicts of interest in investigating their own employees. Potential reputational damage to an institution, especially where an allegation involves a 'star' researcher or a research area in which the institution prides itself on excellence, could increase the temptation to hide cases or deal with issues behind closed doors. Therefore, self-policing can work against perceived impartiality and increase the risk of public scepticism about research.

Individual institutions are unlikely to build breadth and depth of experience in investigating misconduct and will lose time when an allegation occurs, since investigations will be starting from a low knowledge base. There is also a lost opportunity for common learning or accumulation

and sharing of experience. Furthermore, lack of stable and transparent procedures and clearly stated support may make it difficult to whistle-blow, or may discourage people from coming forward with concerns against colleagues or more senior researchers in their institution.

In the absence of national legislation or central oversight, some European countries have adopted a Concordat model (e.g. UK<sup>98</sup>, Denmark<sup>99</sup>, Ireland<sup>100</sup>), National Charter (e.g. France<sup>101</sup>) or Memorandum (e.g. Germany<sup>102</sup>) to which all stakeholders sign up, that sets out commitments and a framework within which they can develop their own policies and processes in a consistent manner. Funding agencies, in particular, have been very influential in driving the development of National Codes or Conduct (see ENRIO list<sup>103</sup>) that set out expectations of good research practice and processes for managing allegations of research misconduct within research performing institutions, thus providing a significant degree of national harmonisation.

### **3.3.2 Research Integrity Oversight by National Agencies and Independent Bodies**

National oversight or advisory functions for the promotion and protection of research integrity have emerged in recent years. In the UK, an independent advisory body (UK Research Integrity Office<sup>104</sup>) is funded by a broad stakeholder group of government departments, universities, funding agencies, learned societies, charities, and a variety of other organisations. The Austrian Agency for Research Integrity<sup>105</sup> is also supported by universities, funding agencies and the Academy of Sciences. Neither the UK nor Austrian offices are regulatory bodies. They work to harmonise and co-ordinate processes and guidelines across institutions and provide consistent advice, guidance and support. In addition, the Austrian Agency provides impartial investigations via an independent Commission for Research Integrity.

Titus and Bosch argue that research integrity needs to be linked to the funding of research.<sup>106</sup> This is, in fact, happening to a greater or lesser extent. Most funding agencies now include specific clauses on research integrity in their grant conditions and set standards of good research practice/investigative procedures for the organisations that they fund. Some agencies have adopted a more robust approach to oversight. For example, the DFG has put an independent Ombudsman for Science Office<sup>107</sup> in place to provide assistance to all German researchers with questions about good research practice and research misconduct, regardless of any connection to the DFG.

In Canada, the three federal funding agencies — the Social Sciences and Humanities Research Council (SSHRC), the Natural Sciences and Engineering Research Council (NSERC), and the Canadian Institutes of Health Research (CIHR), also known as the Tri-Agencies — collaborate closely on issues of research integrity. They require each host institution to comply with a Memorandum of Understanding outlining their responsibilities and the standards to which they must adhere.<sup>108</sup> In the US, all funding agencies have responsibility for research misconduct. They provide policy guidance and technical assistance to research institutions and perform a review and oversight function of those cases referred to them by institutions. They may also carry out investigations themselves if asked by an institution, or where they are not satisfied with how an

allegation is being handled locally. The major players in this area are the OIG<sup>109</sup> and the ORI<sup>110</sup>, who are responsible for the research integrity of health and biomedical research funded by the NSF, and the NIH, respectively.

The risks inherent in institutional self-regulation can be countered by such approaches. Regional or national oversight can also facilitate a higher appeals mechanism (by accused, accuser or institution) and lessen the opportunities to hide proven cases. For smaller funding agencies, the difficulty with taking on this oversight responsibility is that they may not have the resources or expertise necessary to monitor compliance with their recommended procedures. In addition, this approach does not provide coverage of both public and commercial activity, and will be limited to the discipline that the funding agency supports.

Similar difficulties may also arise when oversight is provided by professional associations and learned societies, even in systems such as the one in the Netherlands where the Dutch National Board for Research Integrity (LOWI) has a broad coverage of research integrity governance in the country. The reality is that regardless of who provides oversight, responsibility for implementation will still reside locally, with the attendant challenges and risks described in the previous section.

### **3.3.3 National Research Integrity Offices/Commissions**

Properly constituted and independent National Research Integrity Offices with statutory powers can resolve many of the issues with self-regulation and/or oversight by research funding agencies, professional associations and learned societies. National Research Integrity Offices can provide consistent advice, support and guidelines across both the public and private research sectors. They can offer true independence for investigations, and equality in access and treatment of cases, making conflicts of interest less likely. Importantly, National Research Integrity Offices can reach professional competence, and the authority for good research practice and investigations is clear to everyone. Such offices facilitate international co-operation and learning, and provide opportunities to establish links with other National Research Integrity Offices internationally, for example through the ENRIO<sup>111</sup>.

The disadvantages of establishing such offices relate to institutions' perceptions and behaviours. Institutions may become defensive about perceived loss of autonomy and interference by a national authority, especially if the resourcing and location of the National Research Integrity Office is seen to be politically influenced. There is also a risk that institutions could abdicate their responsibility for promoting good research practice to the National Research Integrity Office. In the resource-limited research environments still prevalent in many European countries, the costs of establishing and maintaining a fully functioning office may also be a consideration.

Only a small number of European countries have established independent National Research Integrity Offices, and these vary in size and remit. The Scandinavian countries were among the first to develop national research integrity structures with statutory backing. The Danish Committee on Scientific Dishonesty was established in 1992 and investigates allegations of

misconduct at a national level. Norway established the National Commission for the Investigation of Scientific Misconduct in 2007. Primary responsibility for preventing and handling allegations of research misconduct still rests with Norwegian research institutions. However, they may redirect an investigation to the Commission if, for example, a case is deemed particularly complicated, has received considerable public attention or involves possible conflicts of interest. The Commission can also start investigations on its own initiative and investigate cases abroad, if researchers employed by a Norwegian institution have conducted the research or if significant funding originated in Norway.

### **3.4 The Role of Publication Practices in Promoting Research Integrity**

Editors and peer review journals play an important role in responding to research misconduct and creating an environment that encourages honest and open reporting of research. They are often the first people outside the host institution(s) to encounter the results of research and to raise concerns about a paper. Journals have the power to set standards as to what will and should be published in the first place.

#### **3.4.1 Ethical Standards in Publication**

Journal editors have long been very active in promoting ethical standards and behaviours in peer review publication. The Committee on Publication Ethics (COPE)<sup>112</sup> was established in 1997 and provides a forum for editors and publishers of peer-reviewed journals to discuss all aspects of publication ethics and offer advice to editors on how to handle cases of research and publication misconduct. COPE has developed excellent guidelines on good publication practice and other on-line resources for both editors and researchers. Over 500 cases discussed by COPE since its inception are now available in a searchable database that provides an excellent resource not just for journal editors but also for those providing publication ethics training to researchers.

#### **3.4.2 Publishing Policies on Reporting of Research Results**

A 2008 systematic review of registered randomised controlled trials found substantial evidence of both publication bias and outcomes reporting bias.<sup>114</sup> The review concluded that studies that report positive or significant results are more likely to be published than studies that report negative or statistically non-significant results, and that statistically significant outcomes are more likely to be fully reported. Through their publication policies, journals can proactively drive changes in the way research is reported. To do this, they need to develop policies to publish not only both positive and negative results, but both statistically significant and statistically non-significant ones.<sup>115</sup> This would address distortion of research data reporting<sup>116</sup> and could also incentivise researchers to do more replication studies.

Publishers could also require all studies to be registered and all research protocols to be published, especially where those relate to health research.<sup>117</sup> This is certainly not the case at the moment and non-publication of results is common. For example, a study of 585 registered trials on ClinicalTrials.gov found that 29% of the trials had not published their results, and that these trials had an estimated total enrolment of 299,763 participants.<sup>118</sup> Therefore, participants were

exposed to the risks of clinical trial participation without the societal benefits that accompany the publication of trial results. The CONSORT (CONsolidated Standards of Reporting Trials) 2010 Guideline is a good example of an initiative focused on alleviating the problems arising from inadequate reporting of randomised controlled trials.<sup>119</sup> The aim of the Guideline is to enable readers to understand a trial's design, conduct, analysis and interpretation, and to assess the validity of its results.

Bouter argues that making the data files on which a publication is based available to everyone would help to weed out reporting bias.<sup>120</sup> He also noted that it would facilitate systematic reviews by providing easier access to currently-unpublished research that contains statistically non-significant findings. Therefore, policies on study registration, wide availability of journal reports, full study reports, and participant-level datasets need to be endorsed and enforced by journals, funders, research ethics committees, regulators and legislators. As an incentive for researchers to comply with these requirements, academic institutions and funders could adopt performance metrics that recognise and reward full dissemination of research and reuse of original datasets by external researchers.

### 3.4.3 The Challenges of Data Management in Research

Requiring researchers to make the raw data supporting their journal publications discoverable and accessible has many benefits: for other researchers seeking to build on the work; for institutions seeking to respond to the mandates of policy makers and regulators; and for funding agencies seeking to improve transparency and ensure wider impact of the research that they fund. Discoverable studies and data also facilitate the validation of that data, making manipulation less likely to go undetected.<sup>121</sup>

The quality and reliability of the available research data will be entirely dependent on the capacity of researchers and their institutions to manage, curate and preserve potentially very large or complex data sets. A recent study by Jahnke and Asher on humanities and social science researchers in the US found a multitude of barriers to adequate data management.<sup>122</sup> These included: a lack of formal training in data management practices; lack of awareness about the importance of long-term data preservation; low priority given to long-term data curation in the face of immediate work demands; and lack of availability of effective collaboration tools or online spaces to support the volume of data generated and provide appropriate privacy and access controls. Slowness to implement institution-wide policies for research data management, primarily due to lack of expertise and resources within the institution, has also been identified as a challenge.<sup>123</sup>

The European Commission's ambitions with regards to management, preservation and access to research data are articulated in a 2010 report, to support their Digital Agenda.<sup>124</sup> The report extols the virtues of openly-available and trustworthy data, but recognises that appropriate infrastructures to achieve this will require significant investment, training, and innovation. There are also considerable legal and regulatory barriers to be overcome, if Europe is to move to a truly open data environment. These have been the subjects of a number of Science Europe



publications, for example: the legal regulations under which text and data mining practices fall, the issues arising from increasing use of licensing by publishers and the implications of amendments to the European Union (EU) Copyright Directive<sup>125</sup>; and the implications of the EC General Data Protection Regulation for medical and health research in Europe as they relate to the use and transfer of patient data.<sup>126, 127</sup>

#### 3.4.4 Moving to Open Access Publication

The move to make peer review journal papers openly and freely available through Open Access (OA) has been one of the most significant and positive developments in publishing in recent years. OA can be achieved through fully OA journals such as PLoS<sup>128</sup>, subscription-based journals that make papers available free online after a certain period, or via authors posting manuscripts of articles they have published in subscription journals available in open web repositories, often hosted by university libraries.

OA has the potential to reduce misconduct in research.<sup>129</sup> It creates a more transparent and open system that allows researchers to share research findings and reach a much larger audience compared to traditional subscription-based journals. The ambition of many funding agencies across Europe (including the European Commission and Science Europe members<sup>130, 131, 132</sup>) is to have a fully OA system of publication in the coming years. The NIH already requires OA availability of results from the research projects that they fund and many European funding agencies are moving to mandatory OA policies. Therefore, academic publishers will need to take into account OA in their business strategies and copyright policies and become partners in the OA endeavour.

Achieving a complete move to OA for all research publications supported by European public research investment is not just the responsibility of funding agencies and publishers but will also require political commitment and influence. In parallel, there is a need for standards to be developed for the content of protocols and full study reports, processes for deposition of data files on which a publication is based and for data sharing practices. Current European Open Data initiatives, supported by the European Commission, Science Europe and others, will help to advance this ambition.

## 4 Conclusions

This briefing paper: looked at how research integrity and misconduct are understood; considered the impacts of misconduct; explored the perverse incentives experienced by researchers that may tax even the most honest; and examined the different models and structures currently in place in Europe and elsewhere for promoting good research practice. It is clear from this exploration that the further assurance of research integrity in Europe and the prevention and handling of research misconduct will require efforts by many actors, including individual researchers, research performing organisations, research funders, publishers and national governments.

While research misconduct is certainly not new and may extend back through the history of science, the first mass media reports of serious misconduct date to the 1950s. Despite this, Europe and other regions are still debating what can be done about it. In Europe, the European Science Foundation first raised the issue in 2000 but received little encouragement or support to develop its recommendations. In 2007, the OECD issued its seminal guidelines and many more have followed in the last decade. The challenge now is for European governments, funding agencies and research institutions to follow through on their commitment to research integrity with tangible actions. No one actor can feasibly address all of these actions. Rather, a collaborative effort by all concerned will be required. The inclusion of research integrity as a priority in the Science Europe Roadmap<sup>133</sup> is an important step that puts research integrity firmly on the agenda of its Member Organisations. Addressing research integrity has the potential to increase the quality of research in the European research ecosystem, thereby increasing its overall effectiveness and impact into the future.

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