



Promoting Integrity as an Integral Dimension of Excellence in Research

Policy brief for science policy makers and research managers

DOCUMENT DESCRIPTION

Deliverable Number D 5.1

Work Package WP5

Task T 5.1

Type Policy advice for science policy makers and research managers

Version Draft 2

Number of Pages 17

Due Date of Deliverable Month 33, 31/05/2018

Actual Submission Date Month 35, 20/07/2018

Dissemination Level Public

Authors Marten Juurik, Gloria González Fuster, Kadri Simm, Katrin Velbaum, Kristi Lõuk, Mari-Liisa Parder, Margit Sutrop



This project has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No. 665926.

Table of Contents

| | |
|--|----|
| Introduction | 3 |
| Recommendations | 7 |
| How to achieve conceptual clarity? | 7 |
| How to promote research integrity? | 9 |
| Ethical and legal framework of research integrity and misconduct | 11 |
| References | 16 |



Introduction

This policy brief puts forward the main recommendations emanating from the PRINTEGER¹ project for policy makers, science policy advisers and research managers. We will focus on two key questions: firstly, whether the increasing abundance of policy documents, international, national, disciplinary and institutional codes and guidelines creates a problem for research managers and research organisations, and, if so, to what extent approximation on an EU or international level should be a goal. Secondly, how can research integrity be meaningfully promoted in order to effectively lessen the incidence of misconduct.

One of the core observations of the PRINTEGER project is that integrity policy is not only about rules that scientists need to follow, and that research integrity policies should thus shift focus from individual cases of misconduct to organisational responsibilities. In addition, promotion of research integrity requires integration of different neighbouring policies (e.g. data protection, research evaluation), and making them more relevant and meaningful for researchers in their everyday context of doing research.

Addressing the harmonisation potential

One of the first international calls for greater convergence in the context of research integrity came from the World Conference on Research Integrity celebrated in 2007, which put forth the need to "*clarify, harmonise, and publicise standards for best practice and procedures for reporting improper conduct in research*" (Mayer, Steneck, 2007: 2). The 2007 World Conference final report states: "*Harmonisation and collaboration across both disciplines and journals are needed. Obvious parties to be involved or take the initiative are the OECD Global Science Forum, the Interacademy Panel, ICSU, UNESCO and the Association of STM Publishers. Several expressed a willingness to take the initiative that should lead to a general International Code of Conduct*" (ibid: 28).

A decade later, there is still no international code for research integrity, although there exist some regional codes such as the European Code of Conduct for Research Integrity, issued by All European Academies (ALLEA, 2017). Numerous discussions on harmonisation (Boesz & Lloyd, 2008; Resnik, 2009, 2015; Blake et al. 2011; Fieldsend 2011; Li et al., 2015; Urushihara et al., 2017) have highlighted the following

¹ For more information on the PRINTEGER project, see: <https://printeger.eu/>



key points: 1) a need for global policy which would form the basis of possible harmonisation; 2) a need for an international governing body to oversee the harmonising process and implement the policy; 3) a need for an overview of national regulative differences; 4) a need to overcome national differences concerning research.

Those in favour of harmonisation believe that an international policy document (i.e. international standards of research integrity) would solve the initial problem of lacking a common basis for issues related to research integrity. Resnik (2009: 221) proposes several reasons why international standards would additionally be useful: to help solve disputes in cases of international cooperation or when there are no local standards; to encourage the development of local standards, and to foster trust between scientists from different countries.

The question of who should implement the global policy is similarly complicated. Resnik (2009: 221) suggests that such a regulative body should be influential enough to address a large proportion of scientists world-wide, focusing on ethics in all aspects of research, but such a regulating body does not yet exist. However, it could be argued that harmonisation could alternatively be achieved through the work of different organisations and societies, focusing on various ethical issues in distinct fields and regions. There are still many unanswered questions regarding the potential for a harmonised regulatory system: should it be centralised or decentralised, international or interregional; should it use any safe harbour regulations; should it be legally binding; who should have the power to punish infringers?

From the perspective of European Union (EU) policy, the possibility to support harmonisation is limited by the boundaries of EU competence, and, inside it, must be guided by the principles of subsidiarity and proportionality.

The analysis within the PRINTEGER project (D 3.4) found that documents and legislation within the EU are marked by disparate definitions, diverging delimitations of scope and varied levels of specificity concerning the concepts of research integrity and misconduct, as well as the relations between them.

The fact that there are differences in national and international policies is not surprising. The more important question might be whether harmonisation is possible, and to what degree. Already in 2007 the Co-ordinating Committee for Facilitating International Research Misconduct Investigations of the OECD Global Science forum raised concerns about harmonisation: *"While a harmonisation of national procedures on research misconduct investigations could be useful, the committee agreed that such a goal was highly unlikely to be achieved, and could even*



be undesirable, due to the diversity of national research systems” (Organisation..., 2007: 6).

The presumption underlying such approaches is that disharmony has negative impact on research. The inventory of more than a hundred key documents (D 2.1) on integrity and misconduct as well as a subsequent conceptual analysis (D 2.3) certified that there is significant diversity in definitions of research integrity and misconduct in Europe. The relationship between research integrity and research misconduct is also understood differently. Some associate research integrity with a positive approach and misconduct with negative approach, seeing misconduct and research integrity as two sides of one coin, while others see research integrity as *“the purse that sometimes contains the coin of scientific misconduct, occasionally in addition to others”* (D 2.4:22). The legal analysis also showed that in some regulatory frameworks scientific misconduct is given prominence, delineating research integrity’s contours negatively (D 2.4:3). The exploration of research integrity in WP II from the perspective of ethics, law, and social sciences illustrated that consensus between various disciplines about the meaning of integrity and misconduct might be unlikely, but discussion can bring more clarity in the interpretation of these terms.

We conclude that although the lack of agreement on the definitions may cause practical problems, it is not necessary to attempt to solve it by a unification of codes or harmonisation of laws. One should rather put more effort into conceptual clarification and scientific discussion on how the concepts of research integrity and misconduct should be understood, interpreted and applied. The conceptual and normative analysis carried out in the PRINTEGER project demonstrated that for the purposes of concept clarification one should decide whether it is justified to broaden the concept of research misconduct to include besides fabrication, falsification and plagiarism (FFP) also questionable research practices (D 2.3, D 2.5). Likewise, one should achieve agreement on whether integrity is a property of research findings, individual researchers, research organisations or research system (D 2.3), as each of these can be promoted differently.

In the deliverables of WP II we have proposed to uncouple the concepts of research integrity and misconduct, and to regard them as separate and independent concepts so that neither is expected to be fully defined by the other. Misconduct and integrity belong to different categories and cannot be opposites: while misconduct may indicate a lack of integrity, lack of misconduct does not necessarily imply integrity (D 2.3:11). Uncoupling the concepts of misconduct and integrity allows us also to see that different measures should be used to promote research integrity, on the one hand, and to prevent misconduct, on the other.



How to promote research integrity and prevent misconduct?

All policies dealing with research integrity need to acknowledge the collective dimension and the economic context of doing science, and go beyond the sole focus on individual responsibility (D 2.5: 17-18). Several deliverables of the PRINTEGER project stressed that it is crucial to provide equal attention to individual, organisational, and structural/institutional aspects. One report suggested that too much attention has been given to individuals compared to institutional or organisational aspects of misconduct, and this has led to scapegoating (D 2.5: 18), or punishing the 'bad apples' in order to attempt to restore the reputation and legitimacy of an organisation (D 2.6: 18). Individual researchers are rarely the only ones to blame as they alone cannot ensure research integrity – the necessary conditions have to be created at the level of the organisation and the system of science at large.

If research misconduct is a result of individual and organisational factors, it is not enough to promote **individual** integrity through education and training: it is also crucial to promote **organisational** integrity (D 2.6: 21). Therefore, it becomes critical to collect information on how research organisations work on a daily basis and analyse organisational behaviour, from governance structures and control systems to responses to cases of misconduct (D 2.6: 18).

While there is an expectation that organisations should do more to promote responsible conduct in research, and reduce the risk of research misconduct, it is less clear **how** this should be done. The survey conducted in the PRINTEGER project (D4.2) pointed out that increasing penalties could help to prevent misconduct in science. However, participants of the focus groups organised by the project recommended that instead of concentrating on individual penalties for perpetrators (axed around individualisation through surveillance, detection, and punishment of individual deviance) policies should foster caring, responsive and responsible research culture (centred on learning organisations, collective and shared responsibility, creation of a climate of deliberation).

The project's analysis showed that attempts to foster integrity should take a more holistic approach, including both principle- and virtue-based approaches and relying on reflection and promotion in addition to compliance (D 2.3, D 2.6). For promotion of integrity on an individual or organisational level, a virtue-based approach can be helpful. If the aim is to set forth clear rules and achieve compliance, then a principle-based approach might be more convenient. Yet there are several reasons why the combined use of both approaches should be considered. As stressed in the legal analysis of research integrity, the emphasis on external control and prevention measures – that are mostly focused on guiding the action of individual researchers –



disregard the context in which knowledge is produced (D 2.5: 18). Motivational aspects, like career advancement and profit, fall outside of the scope of the principle-based approach. Nonetheless, although the virtue-based approach does not cover all the contextual complexities that affect the scientific practices, it still helps to integrate motivational aspects into the ethical discussion about research integrity (D 2.3). Thus, focusing on compliance or promotion of good behaviour only is likely to lead to problematic one-sided attention on either deviant behaviour or the motivational aspects.

Recommendations

The following recommendations and suggestions are based on the findings of the PRINTEGER project, including the inventory of key documents, conceptual and empirical analysis, legal analysis, ethical and legal clarification of integrity and misconduct, survey, focus groups, case studies, and preparation of educational tools. Some of the recommendations for improving integrity in research organisations are also inspired by the Bonn PRINTEGER statement (Forsberg et al, 2018).

How to achieve conceptual clarity?

Lack of clarity has been repeatedly mentioned in discussions about research integrity and misconduct, both within PRINTEGER project and in wider policy and academic discussions. Differences in understanding research integrity have been partly caused by the typically wide scope of the concept (covering methodological, social and personal aspects), differences in academic traditions and disciplines, differences in terminology and difficulties with translation (the same terms having different meanings and connotations in different contexts and languages). Nonetheless, there seems to be some agreement on some of the underlying values beyond research integrity concerns: truth, honesty, transparency, respect, dignity, freedom, autonomy, and responsibility. These abstract similarities might support the belief that harmonisation towards universal definitions is possible and thus feasible. The outcomes of WP II give cause to doubt whether such an aim is realistic in the short or mid-term, while the question of whether it might be desirable is still open.

Based on the findings of PRINTEGER, we propose the following recommendations:

1. **Integrity policy should consist of two pillars: the regulation of misconduct (rule-based) and the encouragement of virtuous behaviour (values and virtues based).**



Some confusion originates from the concepts of *misconduct* and *research integrity*, which are sometimes seen as direct opposites, so that any violation of integrity would be considered misconduct. *Research integrity* can be understood as a much broader concept than the absence of misconduct. The concept of research integrity contains two levels: holding a coherent set of values and living up to these values, while research misconduct focuses only on actions. While one may comply to all rules, one may still not hold the professional values and thus lack research integrity. Many aspects of research integrity are not strictly rule-based, as for example mentoring or being an example for others. Failing to be a good example (which is not the same as being a bad example), should not be considered misconduct. Uncoupling these two concepts is thus helpful in understanding and qualifying many situations.

2. Research integrity policy should address research findings, individual researchers, organisations, and the research system.

The concept of research integrity can be conceptualised on four levels: it can be attributed to research findings, individual researchers, research institutions and other organisations, and the research system as such. On the level of *research findings*, integrity can be understood as wholeness of data, soundness of methodology, reliability, validity, objectivity, transparency, but also as lack of falsification and fabrication. On the level of *individual researchers*, integrity can be understood as adherence to norms and values, upholding the virtues, social responsibility, duty of care and individual accountability; in this context, integrity can be promoted through training, mentoring and aspiration. On the level of *institutions*, attention falls mostly on research organisations, creating support-mechanisms for researchers, offering guidance, adopting policies, improving the work environment and fostering a culture of responsibility and offering advice and support to individual researchers and research leaders, and handling of allegations of misconduct. On the level of the *research system*, we can focus on funding, publishing, education, co-operation with the industry, policy-making and professional associations. It is important to understand that different levels require different methods and approaches to promote integrity.

3. The concept of misconduct and use of strict rules should refer only to the actions and behaviours where there is a very strong consensus among the research community.

It is difficult to argue that research integrity might be promoted effectively without any sanctions. Even though it has been recommended to focus on aspiration, mutual learning, open discussions, restoring trust and over-coming alienation, some



violations may be so severe that they do require sanctions or penalties. However, such consequences should be reserved for clearly delimited cases of misconduct, falling under predictable rules. To avoid uncertainties among researchers and to guarantee fair procedures, undefined questionable research practices should not form a part of sanctioning policies and instead remain open for discussions and debates.

- 4. To achieve relevancy and avoid alienation, researchers should be involved in the policy making process related to research integrity, from defining key concepts to implementation.**

Several deliverables in PRINTEGER (D 2.2, D 2.5, D 2.7, D 4.3) indicate that there is risk of alienation between researchers on the one side and regulators, administrators and policy-makers on the other. Special attention should be given to overcome any possible barriers between these groups, and to avoid purely top-down initiatives that may generate or further deepen distrust.

Any initiative to define matters of research integrity, especially those being sanctioned, should be bottom-up in nature. It is generally open to discussion how to bring it about and who would be responsible, as bottom-up initiatives cannot be forced from the top without deepening the sense of alienation. A possible unwillingness of researchers to participate in research integrity initiatives, however, should be understood in the institutional context of time pressures and distrust, and not be seen as individual shortcomings, e.g. lack of responsibility.

- 5. Even if there might be no need for entirely new regulatory initiatives in policy for research integrity, efforts to coordinate better with other laws and policies are required.**

As part of policy-making, should be considered how any possible new policies on research integrity could be perceived by the research community. There is a fear of overregulation, perceived abundance of information and high formality of documents. To address these concerns, it is important to ensure that new policy documents do not become irrelevant and unused. When possible, pre-existing documents should be updated and fine-tuned to ensure relevancy by addressing new problems and challenges, as well as to keep the amount of policies and sources at a manageable level.

How to promote research integrity?



The PRINTEGER project has identified the need to fully acknowledge both the individual and collective dimensions of doing science (D2.5, D2.6). The significance of institutional and organisational factors which pressure individual scientists should not be underestimated. When assigning responsibilities in this field, a balance between individual and institutional responsibilities should be pursued. Individual researchers may not have the effective means to control all aspects of research, and thus they should not be burdened with obligations that are more appropriate at the level of research institutions.

Based on the findings of PRINTEGER, we propose the following recommendations:

6. On the individual level, more attention shall be given to advisory and aspirational instruments.

Some participants in focus groups (D 4.3) expressed their concerns about a too strong emphasis on sanctions and punishments: they may prevent researchers from being honest and open about their mistakes and hesitations. From the perspective of training, sharing good practices and learning from mistakes and questioning should be encouraged. To further the aim of aspiration, experienced, exemplary and well-respected researchers should be encouraged to take the leading role in promoting integrity.

7. Training should be well thought-through, balancing principle- and virtue-based approaches, and using methods suitable for developing moral reasoning and character.

Instead of lecturing, training sessions should foster open discussions, practice applying principles and standards to real-life situations and make use of interactive and engaging tools. Sharing good practices and educational tools is important as smaller research organisations may lack the necessary resources to develop their own research materials. Well thought-through training will help to overcome alienation and make policies more relevant to researchers. Policy-makers should, in co-operation with researchers, consider whether training in research integrity should be a mandatory condition for academic positions, especially if a researcher has a leading role in a research team or project.

8. Organisations should be encouraged to foster a research integrity culture, for instance, by making integrity policy part of research evaluation, accreditation, or certification criteria.

Promoting research integrity strives toward a culture of responsibility, honesty, open discussions and trust. Although individual scientists and their actions and values do



make up the research culture, it is the institutions and the formal leaders who have the main opportunities and responsibilities to influence different aspects of the culture and work environment. In addition, more senior scientists with greater scientific responsibility should acknowledge their exemplary roles, and strive to be good role-models for their colleagues, especially for junior researchers.

As a general rule, there are no national policies that completely ensure that organisations actually implement different research integrity provisions like offering guidance or training in an efficient manner. There should be a broader discussion of whether and how organisations that do not support young researchers with proper mentoring, that fail to be transparent, or that neglect to handle misconduct cases should be held accountable.

9. Research managers at universities and large research organisations should consider research integrity when designing research evaluation and assessment schemes.

To promote research integrity, organisations should implement wise incentive management and quality assurance procedures. Since strong incentives related to too narrow set of performance indicators (H-indexes or publication points) may be counter-productive to research integrity, organisations should consider a broader set of performance indicators and various assessment methods.

There should be a systematic focus on researchers' well-being within research organisations in order to cultivate a positive work environment, coupled with monitoring of research conduct and processes by peers and management. In addition, building down hierarchies and lessening the structural differences between junior and senior researchers and investment into identity building can help all researchers associate themselves with the goals and values of the organisation. This should contribute to overcome the perceived formality of policies, projecting research integrity as something relevant and important.

Ethical and legal framework of research integrity and misconduct

There is no universally agreed upon definition of research misconduct, although falsification, fabrication and plagiarism are commonly considered forms of scientific misconduct. There is also no consensus on whether misconduct should include other offences against research integrity. This is due to a lack of agreed definitions but also due to differences of opinion on whether certain activities should be categorised as misconduct, questionable practice, bad/sloppy/useless science, etc. Whereas the challenge of integrity lies in the complexity of the concept itself, the problems with



misconduct pertain to different judgements regarding the wrongfulness of certain acts. In PRINTEGER focus groups, these differences of judgement were mostly attributed to disciplinary, cultural and contextual aspects. (D 4.3)

In policy documents, this is sometimes reflected in differentiating between more and less serious forms of violations of research integrity where the more serious violations are considered to be sanctionable (D 3.4) However, there seem to be substantial differences concerning terminology, categorisation and sanctionability. In addition to conceptual matters, there are disparities concerning the way in which misconduct is regulated: how it is reported, documented and sanctioned, how cases are being handled and by whom, and which procedures are in place to protect the parties of allegations. Conceptual differences add up to legal uncertainty which may have unwanted consequences for implementing fair procedures in investigating allegations of misconduct.

The issue of misconduct thus poses a challenge for ethical and legal frameworks and their interactions, as the wrongdoings of scientists can be handled by either legal frameworks, ethical frameworks, or by both in some combination. For instance, some actions that could be considered research misconduct – abuse of animals in scientific experiments, failure to respect the rights of the research subjects in clinical trials, misuse of personal data – may also be regulated by legally binding instruments on national or European level. This potential over-lapping between legal and ethical frameworks is to some extent inevitable and should be addressed during policy-making.

Based on the findings of PRINTEGER we propose the following recommendations:

10. Research integrity should be promoted with the support of a holistic ethical framework.

Despite the complicated relation between legal and ethical frameworks for research integrity, a holistic, clear and workable ethical framework can still be envisioned. On the most fundamental level, such framework should mirror the values of good science and the virtues of a good researcher. This could form a normative basis upon which all relevant principles, standards, rules and procedures should rely. On the next level, such framework should present principles of research integrity which are derived from the fundamental values and offer guidance to researchers. On the next, more precise level, there should be standards which propose specific rules or criteria which are derived from the principles and which could be easily followed, without the need to translate abstract principles into everyday situations. Lastly, such framework should specify which actions would be sanctionable and put forth procedures for



handling such cases, which need nevertheless to be fully compatible with relevant legal requirements.

Within such a framework, numerous policy documents with somewhat different aims and content may still fit together by fulfilling different functions and relating to different levels of the ethical framework. For instance, declarative documents listing shared values relate to the first level, whereas more specific documents listing authorship criteria would relate to third level. However, based on the analysis of existing policy documents in PRINTEGER deliverable 3.4 it seems that currently policies lack specific rules and consequences regarding research integrity. Thus, in the future more attention could be given to the third and fourth levels.

11. Research integrity policy should propose a clear, specific and supportive framework for handling misconduct.

The main focus of an ethical framework should be to support and offer valuable advice to researchers, not to punish and sanction. *Clarity* also means that all researchers should have sufficient information about misconduct, how it is handled, how to report it, how the interests of all the parties are protected, how to appeal it and about other procedural questions. Clarity also means that the handling of misconduct cases should be transparent and that organisations should collect and publish information relating to allegations of research misconduct in an orderly manner.

Specificity means that sanctions should be imposed only in clear, foreseeable and well-defined cases of misconduct. Whenever sanctions are imposed, due regard should be given to the degree of violation and subjective intentionality. Also, researchers should have the right to make honest mistakes and the opportunity to learn from them.

Supportiveness means that all researchers should have the opportunity to ask for advice in case of doubt or when allegations are filed against them. Imposed sanctions should strive towards proportionality, consistency and predictability. Even if sanctions are imposed, the researcher should have an option for future rehabilitation.

Research organisations should foresee a position of ombudsman or equivalent figure to advise the organisation and its members alike. On the individual level, the ombudsman could also advise researchers and offer guidance relating to different policies as well as offering help in complex situations. On the level of the organisation, it can have a supportive role by reviewing policies and procedures of the organisation and suggesting how to improve them. It should be discussed whether the position of



ombudsman should always maintain full confidentiality when possible misconduct cases are discussed, as this would mean another step towards supportiveness (D 4.2)

Another level of normative framework should be about prevention and guidance, not punishment or, even worse, scapegoating individual researchers. To further support learning from identified cases of misconduct, organisations should be encouraged to publish and share handled misconduct cases, annual reports, opinions or conclusions of investigative authorities and other material which could be used as an informative and educational material in the research community.

12. Clarify applicable data use rules, and their relation to research integrity.

Research integrity instruments in Europe encapsulate different approaches towards law, including data protection law. While sometimes research integrity is framed as something different from respecting applicable laws, in other cases normative instruments on research integrity explicitly stress the need for researchers to comply with relevant legal obligations. As changes in scholarly practices are leading to a continuous growth in the processing of personal data, in particular of data available online (for instance by applying so-called Big Data analytics to social media information), the need for researchers to use such data in compliance with relevant data protection standards becomes more important than ever.

The currently applicable General Data Protection Regulation (GDPR)² aims to support the processing of data for scientific purposes, notably by referring to the fact that individuals should be allowed to give consent to the processing of their personal data *'in certain areas of scientific research when in keeping with recognised ethical standards for scientific research'*.³ This, however, triggers the question of how to identify such *'recognised ethical standards'*, and which concrete safeguards (if any) these actually foresee for guaranteeing a required level of data protection. The GDPR itself establishes that processing for scientific purposes *'shall be subject to appropriate safeguards'*, ensuring *'that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation'*,⁴ but it also allows for both European Union (EU) and national law to provide

²Regulation (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 L 119, 4.5.2016, p. 1–88.

³See Recital 33 of the General Data Protection Regulation (GDPR).

⁴Article 89(1) of the GDPR.



derogations to a series of rights, under certain conditions.⁵ All in all, in many cases – and especially in European and international collaborations – it might be difficult for researchers to actually know which data protection requirements apply, and how to operationalise them in practice.

Lack of respect of data protection obligations in the context of research, nevertheless, can lead not only to contestable research practices, but also to the massive collection of highly sensitive data which can potentially be used afterwards for highly problematic purposes, as was recently illustrated by the ‘Facebook / Cambridge Analytica scandal’.

In this context, cooperation between academic institutions and data protection authorities would be instrumental to help throwing light on – and refining – the necessary data protection requirements. Moreover, research integrity normative frameworks should make clear whether failure to respect data protection requirements shall be regarded as scientific misconduct, and, if so, when.

⁵May be foreseen derogations from the rights referred to in Articles 15 [right of access by the data subject], 16 [right to rectification], 18 [right to restriction of processing], and 21 [right to object] of the GDPR in so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes – see Article 89(1) of the GDPR.



References

Blake, V.; Joffe, S.; Kodish, E. (2011) Harmonization of Ethics Policies in Pediatric Research. *Journal of Law, Medicine & Ethics*. Vol. 39 (1), pp. 70-78. DOI: 10.1111/j.1748-720X.2011.00551.x

Boesz, C.; Lloyd, N. (2008). Collaborations: Investigating international misconduct. *Nature*, Vol. 452 (7188), pp. 686-687

Dove, E., S.; Knoppers, B., M.; Zawati, M., H. (2014) Towards an ethics safe harbor for global biomedical research. *Journal of Law and the Biosciences*. Vol. 1 (1), pp. 3-51; Publisher: Oxford University Press

Fieldsend, D. (2011) Unity in diversity: Can there ever be a true European consensus in bioethics? *Human Reproduction and Genetic Ethics*, ISSN: 1028-7825, Vol. 17 (2), pp. 222-34; Publisher: Equinox Publishing Ltd

Forsberg, EM., Anthun, F.O., Bailey, S. et al. (2018) Working with Research Integrity – Guidance for Research Performing Organisations: The Bonn PRINTEGER Statement. *Science and Engineering Ethics*. <https://doi.org/10.1007/s11948-018-0034-4>

González Fuster, G., Gutwirth, S. (2018). *Codes and legislation*. PRINTEGER. Available at: <https://PRINTEGER.eu/wp-content/uploads/2018/04/D3.4.pdf> [Accessed 19.05.2018]

Li, R; Barnes, M; Aldinger, C., E; Bierer, B., E. (2015) Global Clinical Trials: Ethics, Harmonization and Commitments to Transparency. *Harvard Public Health Review*, Vol. 5 - Global Health, pp. 1-7

Mayer, T., and Steneck, N. (2007) Final Report to ESF and ORI. First World Conference on Research Integrity: Fostering Responsible Research. Available at: http://eurosfaire.prd.fr/7pc/doc/1205751016_wc_research_integrity_final_report.pdf Accessed May 22, 2018

Organisation for Economic Co-Operation and Development Global Science Forum. Co-ordinating Committee for Facilitating International Research Misconduct Investigations. Final Report. (2007) Available from: <https://www.oecd.org/sti/sci-tech/42713295.pdf> Accessed 20 May, 2018

Resnik, D., B. (2009) International Standards for Research. Integrity: An Idea Whose Time has Come? *Accountability in Research*, Vol. 16 (4), pp. 218-228, DOI:10.1080/08989620903065350



Resnik, D., B.; Rasmussen, L., M. & Kissling, G., E. (2015) An International Study of Research Misconduct Policies. *Accountability in Research*, Vol. 22, pp. 249–266 DOI: 10.1080/08989621.2014.958218

The European Code of Conduct for Research Integrity. Revised Edition (2017). ALLEA - All European Academies, Berlin 2017. <http://www.allea.org/publications/joint-publications/european-code-conduct-research-integrity/>

Urushihara, H.; Parmenter, L.; Tashiro, S.; Matsui, K.; Dreyer, N. (2017) Bridge the gap: The need for harmonized regulatory and ethical standards for postmarketing observational studies. *Pharmacoepidemiology and Drug Safety*, ISSN: 1099-1557; Vol. 26 (11), pp. 1299-1306