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Mutual Learning Exercise (MLE) on Research Integrity

Challenge paper:
Processes and structures

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MLE on Research Integrity: Challenge paper: Processes and structures

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Mutual Learning Exercise on Research Integrity

Challenge paper: Processes and structures

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1 INTRODUCTION

At the Kick-off Meeting of the Mutual Learning Exercise (MLE) on Research Integrity (RI) the 14 participating countries in this MLE (Austria, Bulgaria, Denmark, Estonia, Finland, France, Greece, Ireland, Lithuania, Luxembourg, Moldova, Norway, Spain, and Sweden) presented the basic information about RI framework in their countries. After the discussion sessions, the participating countries agreed on four priority topics for the MLE:

1. Processes and structures for the RI,
2. Incentives for RI,
3. Dialogue and communication about RI, and
4. Training and education for RI.

This Challenge Paper focuses on the first priority topic – ***Processes and Structures*** to promote RI and deal with allegations of research misconduct. The Paper is based on the review of existing relevant literature and documentation, information about RI framework in 14 countries for research integrity (RI) presented at the Kick-off Meeting and consultations with the representatives of the participating countries. The Paper has been developed to help MLE participants prepare for the first Working Meeting in Oslo on the 30th January 2019.

The scope for the Challenge Paper 1 on Processes and Structures is outlined in Section 2. Section 3 presents an overview of the information available from published literature and surveys on the existing landscape for RI in Europe, and Section 4 presents the lessons learned from the consultations with 14 countries participating in the MLE, as well as from ongoing H2020 grants related to RI. The Paper concludes with the main challenges that can be addressed in the First Workshop, with the aim to formulate lessons from existing circumstances in the participating countries that can be applicable in a wider community. The Appendix to the Challenge Paper 1 contains information related RI in for each of the 14 participating countries.

2 SCOPE

This Challenge Paper is based on the review of existing relevant literature and documentation on the topic of RI structures and procedures, as well as the discussions at the MLE Kick-off Meeting in Brussels on the 15th November 2018. After the Kick-off Meeting, the representatives from the 14 countries participating in this MLE were consulted in order to collect relevant data about RI, which would be useful not only to address the processes and structures for RI but also to provide a wider picture for RI in research/academic, public and policy communities.

During the scoping and kick-off meetings, the following themes were identified for the topic of Processes and Structures:

1. Definitions related to RI

One of the important themes that emerged in the discussion includes differences in how RI is defined in practice. The participating countries were interested in exploring differences in normative approach to RI: "good" research vs misconduct, RI vs research ethics, research fraud vs research misconduct, questionable research practices vs detrimental research practices, crime vs ethical breach.

2. Structures for RI

The participating countries identified as one of the central aims for this MLE to compare national and institutional structures among the countries in order to exchange good practices and identify possible directions and suggestions for further development of RI system in their countries. They are also interested in exchanging experiences related to challenges in creating RI bodies, particularly in relation to what expertise is relevant for the members of RI bodies, was well as hot to deal with competing interests of members of these RI bodies. Finally, the problem from the policy and funding viewpoint is how to monitor RI bodies in individual institutions, particularly in countries which do not have top-down organization of the RI framework.

3. Processes and practices

Although this topic includes processes and practices for promoting responsible conduct of research, those will be explored in more depth in other challenge papers, particularly the one related to Training and Education. The primary focus for this theme is exchanging best practices regarding processes for dealing with research misconduct. The important challenge that was identified as potential topics for the discussion are relate to the good practices in implementing RI principles and requirements in real life, so that all stakeholders subscribe to good practices and actually implement them in their work. Another challenge that emerged was the overlap of legal regulation and research integrity and research ethics principles, which often may overlap. Finally, the question of protection of both the whistle-blowers and the accused in allegations of research misconduct was identified as a theme where exchange of good practices would be useful for the participating countries.

4. Resources for RI

As the participating countries are at different stages of developing RI systems, they are interested in sharing best practices and different roads in ensuring sufficient resources for RI framework.

5. Cross-national/cross-institutional/cross-sectoral/cross-disciplinary issues

With a growing importance of multidisciplinary and multinational research, important themes for RI systems in country are related to dealing with RI issues, particularly in research misconduct investigations : a) across national boundaries (when a researcher changes country of residence), b) cross-institutional (when a researcher changes institutions within a single country), c) collaboration across sectors (academia, research, industry), and d) cross-disciplinary differences (where established professional practices may significantly differ, such as authorship practices). The participating countries were particularly interested in exchanging good practices in how to cross different barriers in investigating research misconduct and how to ensure that structures and processes work across different barriers.

6. Emerging issues

The participating countries were also interested in the discussion and sharing of good practices in dealing with emerging issues for RI, such as the application of the General Data Protection Regulation (GDPR) in research, as well as the implications of Open Science

for RI, including Data Management[1] and FAIR principles for data use (findability, accessibility, interoperability and reusability)[2], and Open Access publishing of research[3].

This Challenge Paper will deal in more depth with what is known about definitions, structures, processes and resources for RI, and will put forward the challenges related to collaboration in investigating research misconduct and to emerging issues, such as data management, protection of privacy and open access.

3 LANDSCAPE

Since December 2015, when the Council of the European Union put research integrity for the first time on its agenda and adopted Conclusions recognising "research integrity as the foundation of high quality research and as a prerequisite for achieving excellence in research and innovation in Europe and beyond"[4], research integrity has become an important part of research policy also for research funding organizations but also at national research policy, research and funding bodies.

3.1 Current policies for RI and new initiatives

Currently, we have the revised "European Code of Conduct for Research Integrity"[5] (ECCRI), developed in 2017 by the European Science Foundation (ESF) and All European Academies (ALLEA), as the basic document for RI in Europe, particularly in H2020 programme, where RI is part of contractual obligation (in Article 34 of the Grant Agreement).

Other international organizations have recently addressed RI. For example, World Economic Forum convened a group of young scientists to produce a "Code of Ethics for Researchers"[6] in 2018, which defines important principles related responsible conduct of research: 1) Engage with the public, 2) Pursue the truth, 3) Minimize harm, 4) Engage with decision-makers, 5) Support diversity, 6) Be a mentor, and 7) Be accountable. This Code was criticised as being produced by single stakeholder in research, younger researchers (younger than 40 years of age in this case), whereas the ECCRI was built by diverse stakeholders[7].

In 2017, an international group of diverse stakeholders published The Brussels Declaration on Ethics & Principles for Science & Society Policy-Making[8], calling for cooperation of all stakeholder and setting expectation for all of them in relation to RI.

Expectations from the scientific community:

- The integrity of science needs to be clear and the integrity of scientists providing advice must be unimpeachable
- The full range of scientific disciplines should be included; notably, the social sciences can play a key role in improving how the public may react or adapt

[1] European Commission. Guidelines on FAIR Data Management in Horizon 2020. 2016. Avaiable at: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf.
[2] Turning FAIR inot reality. 2018. Available: https://ec.europa.eu/info/sites/info/files/turning_fair_into_reality_1.pdf.
[3] Science Europe. Plan S. Accelerating the transition to full and immediate Open Access to scientific publications. 2018. Available: https://www.scienceeurope.org/wp-content/uploads/2018/09/Plan_S.pdf.

[4] The Council of the European Union. Draft Council conclusions on research integrity. 2015. Availalble: https://data.consilium.europa.eu/doc/document/ST-14201-2015-INIT/en/pdf.
[5] The European Code of Conduct for Research Integrity. 2017. Available: https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf.
[6] World Economic Forum. Young Scientists. Code of Ethics. 2018. Available: http://www3.weforum.org/docs/WEF_Code_of_Ethics.pdf.
[7] Hiney M. Code of conduct for research integrity. Nature 2018;556:436.
[8] The Brussels Declaration. 2017. Available: https://www.sci-com.eu/main/docs/Brussels-Declaration.pdf.

- Scientists must learn to use established communication channels for providing policy advice more effectively and be less aloof and perhaps less arrogant
- Scientists must listen and respond to criticism".

Expectations from the policy-making communities:

- Policy-makers must listen, consult and be held accountable
- Ethical consideration of the impact of policy decisions is crucial
- Policy-makers have to challenge science to deliver on public investment
- Policy-makers should be willing to justify decisions, particularly where they deviate from independent scientific advice
- -Policy-makers should acknowledge the potential for bias and vested interests contrary to the scientific consensus".

Expectations from the public, media, industry and interest groups:

- The public plays a critical role in influencing policy and must be included in the decision-making process
- Industry is an investor in knowledge generation and science and has every right to have its voice heard
- Interest groups similarly have every right to have their voice heard as guardians of the common good or legitimate sectoral interests
- Advice from any source to policy-making must acknowledge possible bias".

3.2 Surveys of RI frameworks in Europe

In response to the growing importance of RI and it incorporation in European and global research policies, many European countries have adopted laws, codes or guidelines to promote research integrity and prevent research misconduct. They also established the national or organizational framework for research integrity, including relevant structures and procedures. However, these policies and structures, as well as the definitions of research integrity and misconduct differ quite varied among European countries.

This Challenge Paper will present the findings of four surveys that explored how different aspects of RI are addressed in different European settings. These surveys were published from 2013 to 2017 and involve different but overlapping country samples. The results of these surveys will be presented chronologically, in order to capture the possible changes in time.

3.2.1 Survey of the Danish Agency for Science, Technology and Innovation (2013)

This survey explored the national systems for handling cases of research misconduct in 15 European countries[9]. The European countries covered by the survey were: Austria, Belgium, Croatia, Denmark, Ireland, Luxembourg, Norway, Poland, Switzerland, Sweden, The Netherlands, and United Kingdom. Three other surveyed countries were Australia, Canada and USA.

The survey showed that there are different definitions of research misconduct. For some countries only falsification, fabrication and plagiarism (FFP) constitute misconduct, but in others the list is longer and includes what is usually called "questionable research

[9] The Danish Agency for Science, Technology and Innovation. National systems for handling cases of research misconduct. 2013. Available: http://www.enrio.eu/wp-content/uploads/2017/03/National_systems_for_handling_cases_on_research_misconduct.pdf.

practices". In some countries' definitions, misconduct needs to include intention, and honest errors and scientific discussions are differentiated from misconduct behaviour. The policies in different countries also take different forms: some are defined by law and are legally binding (such as in Denmark, Norway, and Poland) whereas in others the guidelines/codes are not legally binding documents.

At that time (survey was conducted in 2012), some European countries had national legislation that addressed RI (Croatia, Denmark, Norway, Poland, Sweden and Switzerland). In some of them, the role of research institutions in research misconduct is defined. Furthermore, in all surveyed countries except Luxembourg, investigations of research misconduct cases is the responsibility of the institutions, with varying practices in involving other bodies, such as national RI bodies. Such bodies have different roles, from actually making the decisions and recommendations to having only advisory role; they can also supervise institutional processes.

The members of the RI bodies (or committees – the term used in the survey), are usually established researchers from different research disciplines and are appointed for a term which usually ranges from 2 to 4 years. The committees may have a lawyer as a member to help with the legal matters. Finally, some committees can include outside (foreign) expertise, and one country (Austria), engages only outside experts in their cases.

Regarding the procedures for handling research misconduct cases, the survey identified different practices regarding four steps.

The possibility for taking up cases: The cases (complaints) are usually submitted to a committee by private persons or institutions submitting a complaint, which usually needs to be in a written form. Some committees can initiate cases on their own. After the preliminary investigation, the committee decides whether to proceed with the case, i.e. whether it has the competence to deal with the complaint of whether it falls under their mandate or terms of reference.

The hearing process: Usually takes the form of statements from the parties in a case. These statements are mostly in a written form, but some committees (like in Austria) can have oral hearings too. In some countries this process is regulated by general legislative rules on administrative decisions.

The possibility for appeal: The range is from an appeal at the institutional level (Ireland, UK) to an appeal to an external body (committee) (Belgium, Croatia, Norway, Poland, Netherlands). In some countries, there is no formal appeal system (Austria, Denmark, Luxembourg, Sweden).

The possibility for sanctions: These can be at the level of institutions (range from a warning to disciplinary action or withdrawal of title or internal funding) or funding agencies (ranging from withdrawal of funding to prohibition from submitting funding application). In countries that have national bodies, these usually provide recommendations to the institution which then the institution choose to follow. In some countries, the decision of the national committee has binding power.

The surveyed countries also differ in the confidentiality/transparency of the misconduct investigation. About half of the surveyed countries deal with the cases in confidence and does not make the decision public, whereas the other half keeps the cases are confidential but the decisions are made public (often anonymized).

The protection of whistle-blowers, defined as "persons disclosing information to other person's wrongdoing", also varied, with half of the countries having some protection for them and the others without such protection.

Finally, the respondents in this survey identified benefits and challenges to the system of handling cases of research misconduct:

a) the research institutions are best placed to conduct investigation of misconduct allegations, where the research was done;
b) this calls for institutional mechanisms in place and willingness to handle such cases, which is sometimes not the case;
c) absence of coordinated national policies may result in different outcomes for similar cases at different institutions;
d) the existence of a permanent national independent body for handling research misconduct cases was identified as a positive element, but the lack of authority of such body to make binding decision presents a serious challenge to the success of combating research misconduct in the community.

3.2.2 Survey of RI guidance documents in countries in the European Economic Area (2014)

This survey performed a systematic content analysis of biomedical research integrity guidance documents from the countries in the European Economic Area[10]. The study included 31 target countries and obtained response from 30 countries. The documentation was collected from 19 countries and included 49 guidelines. The countries included in the analysis are not specified but include (according to the references to the documents) Austria, Belgium, Czech Republic, Estonia, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Netherlands, Poland, Spain, Sweden, Switzerland, ND United Kingdom.

Two themes emerged as dominant in guidance documents on RI – related to content of RI and to research misconduct. Importance of RI and threats to RI were predominantly addressed in relation to the fist theme. Authors' responsibility is most often addressed, whereas conflicts of interest and data management, particularly the preservation of data.

In relation to research misconduct, the guidance documents most often defined misconduct, including the intention, negligence or deceit in the definition, and often addressed authorship manipulations. They also tried to identify factors contributing to misconduct, primarily competition and personal motivation for success and recognition). In relation to the impact of misconduct, damage to trust between scientists, society and science and of funders was often address in the documents, as well as damage to reputation of science in general, of institutions and projects. In relation to dealing with allegations of misconduct, the documents most often state that institutions should have adequate procedures for dealing with misconduct and that they should have the first responsibility for handling allegations, that procedure should be quick and confidential, and that protecting both the whistle-blower and the accused person (warning also that whistle-blowers can be have dishonest intentions). Finally, many guidance documents emphasized the importance of RI training and RI environment in preventing misconduct.

3.2.3 Survey of RI practices in Science Europe member organisations (2016)

This survey was performed in 2014 and included 27 responses from 33 different organizations that are members of Science Europe (1 response covered 7 individual councils that were all member organizations)[11]: Austria, Belgium (2 organizations) Denmark (2 organizations), Estonia, Finland, France (3 organizations), Germany (3 organizations), Hungary (2 organizations), Ireland, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland, United Kingdom). The survey presents predominantly the experiences from research funding organizations (26 out of 33 responding organizations).

[10] Godecharle S, Nemery B, Dierickx K. Heterogeneity in European research integrity guidance: Relying on values or norms? J Emp Res Hum Res Val 2014;93:79-90.
[11] Science Europe. Research Integrity Practices in Science Europe Member Organisations. 2016. Available: https://www.scienceeurope.org/wp-content/uploads/2016/07/Science-_Europe_Integrity_Survey_Report_July_2016_FINAL.pdf.

The survey address several important topics related to RI, including training, raising awareness, self-assessment, and recommendations on policy and procedures, but here presented are those relevant for the Challenge Paper.

Definition of RI: One third of responding organizations did not have a definition of RI, and many noted that the borderline with the RI and research ethics remains unclear. However, having policies and processes for research ethics is not sufficient to cover RI issues.

RI policy and instruments: Most of the respondents stated that their organization has a specific RI policy.

Legal instruments: About a half of respondents stated that their organizations had to follow one or more legally binding instruments or processes for dealing with misconduct cases, and the half of respondents also had established processes for dealing with allegation of misconduct and more had established some kind of institution, on different levels to deal with misconduct cases. However, the information on these processes is not readily available in the public domain (on the organization's web site). The bodies for investigating misconduct cases are most often external to the responding organization, and are permanent bodies. About half of these bodies have decision making role, and the other half have advisory role in misconduct cases. For investigatory groups formed within the organization that conducts misconduct investigation, the membership is predominantly external to the organization. There was no predominant nature of bodies dealing with misconduct allegations, as they ranged from board of an organisation to an internal body such as an ethics committee or dedicated external bodies.

Mobility in misconduct cases: Only a few of the respondents reported that their organizations had procedures for dealing with allegations against persons that moved before the allegation was made or during the investigation process or after the completion of investigation. Furthermore, few organizations also had processes to check the history of misconduct allegation with previous employers, or required a declaration on previous proven cases of misconduct for a position or grant. No organization had a policy to check with previous employers about any history of allegations of misconduct for new appointments.

Whistle-blowers: Only a few organizations had arrangements for whistle-blowers.

Sanctions: A range of sanctions was reported, from warnings to blocking of grants to withdrawal of academic degrees. In some cases, the sanctions are determined by different bodies that concluded the misconduct cases. Only in a single case there was a sanction for organization that failed to follow RI rules.

Appeal: Less than half of the organizations permitted appeals against administrative decisions on RI cases.

Collaboration: only a few organizations had RI and collaboration in misconduct cases as a part of collaborative agreement with other organizations.

3.2.4 Survey of guidance on RI and misconduct at European universities (2017)

This survey explored what guidance about RI is available at 18 universities from 10 European countries (Belgium, Finland, France, Germany, Italy, Netherlands, Spain, Sweden, Switzerland, United Kingdom), which are members of the League of European Research Universities (LERU).[12] The analysis encompassed 38 documents, which were mostly available online, in the public domain, but for some there was no document in English so it was difficult for the outside community to understand. Most of the analysed

[12] Bonn NA, Godecharle S, Dierickx K. European universities' guidance on research integrity and misconduct: accessibility, approaches, and content. J Emp Res Hum Res Ethics 2017;12:33-44.

documents were in the form of a code of conduct in which they state principles, values standard and/or norms of research and integrity.

Most of the document define fabrication, falsification and plagiarism as research misconduct, and many explicitly state that honest errors are not misconduct, and some included negligence as misconduct. Some documents also described other undesirable practices, such as authorship misuse, duplicate publication and data mismanagement.

The specificity of this survey was that it looked at the surveys in mid-2014 and then again in 2016. The authors noticed that the documents were more available on the web pages and that they were updated for several institutions, with new issues addressed, such as whistle-blower policies etc. Some institutions (examples from UK) started publishing RI annual report or statements on their web-sites. Also, they are also now more often refer to national or international RI guidance, such as the European Charter for Researchers.

The authors concluded that the current guidance documents show a variability of approaches to definitions and policies, but that they should be more transparent and available to the national and international community.

4 LESSONS

The analysis of available research and surveys so far, showed quite a large variety of RI structures and practices in Europe.

This section will present the recent findings from H2020 projects that specifically dealt with research integrity (Table 1). These project provide some guidance related to the questions and challenges identified by the participant countries during the Scoping and Kick-off Workshops, such as the definition of RI vs that of research ethics, the definition of and competencies for research integrity and research ethics experts. The summary of information about RI structures and procedures collected from the 14 countries participating in this MLE will also be presented. Detailed information about RI in 14 countries are presented in the Appendix to this Challenge Paper.

Table 1 H2020 projects related to RI and serving as sources of information for this MLE

Project acronym	Project title	Web-site
PRINTEGER	Promoting Integrity as an Integral Dimension of Excellence in Research	https://printeger.eu/
ENERI	European Network of Research Ethics and Research Integrity	http://eneri.eu/
EnTIRE	Mapping Normative Frameworks for EThics and Integrity of REsearch	http://www.entireconsortium.eu/

4.1 Definition of RI

The **ENERI project** specifically deals with the definitions of research integrity and research ethics.[13] The following is provided to explain research ethics:

"**Research ethics** addresses the application of ethical principles or values to the various issues and fields of research. This includes ethical aspects of the design and conduct of research, the way human participants or animals within research projects are treated, whether research results may be misused for criminal purposes and it refers also on aspects of scientific misconduct"

Research ethics is considered as a more generic concept than research integrity:

"**Research integrity** is recognized as the attitude and habit of the researchers to conduct research according to appropriate ethical, legal and professional frameworks, obligations and standards."

Thus, RI includes both external and internal forms in relation to a researcher: external in the form of laws/regulations, policies, codes or guidelines that govern researchers in their work, and internal, in the form of internalized norms or desirable practices.

The two fields "combine general ethical reflections, ethics and law as academic disciplines addressing research activities, moral attitudes of researchers, normative policies of stakeholders like sponsors or funding organizations, and various ethical expectations of the civil society". More details are available in recently released ENERI RI&RE manual.[14]

PRINTEGER project analysed how different stakeholders define RI, particularly the difference in how researchers and policy-makers have diverged in their outlook of RI.[15]

[13] ENERI. What is research ethics? Available: http://eneri.eu/what-is-research-ethics/.
[14] ENERI. ENERI Manual. Research integrity and ethics. Available: http://eneri.eu/e-manual/.
[15] PRINTEGER. Deliverable 2.2. Promoting virtue or punishing fraud: mapping contrasting discourses on 'scientific integrity'. Available: https://printeger.eu/wp-content/uploads/2016/10/D2.2.pdf.

While researchers have a rather wide discourse of RI, seeing it as a virtue that should be promoted, the policy makers take a more regulatory tone in their documents, with strict norms and financial concerns. This conceptual divide results in several problems, which need to me kept in mind in discussing RI structures and procedures. One of the problems is that research see RI policies more as an obstruction than as native part of the research community, and approach the policies them ritual but not real compliance. Furthermore, it is then more difficult to harmonize approaches to RI or impose one definition of RI, especially having in view already described diversity of national practices and politics.

4.2 Conducting research misconduct investigations

PRINTEGER project tried to assess the incidence of research misconduct and found that it is very difficult to determine even the registered incidence of scientific misconduct and, more generally, RI breaches.[16] There was very little available data on misconduct cases on the official sites and in the public domain. The need for transparency is challenged by the need for confidentiality and fair procedures.

PRINTEGER project investigated in detail fair procedures in research misconduct investigations.[17] The report includes the discussion on the necessity of procedures on one side, and the necessity of fairness on the other, visibility and transparency, clear limitations of the scope of investigations, access to preliminary evidence, decision on launching an investigation, reporting of misconduct, protection of whistle-blowers, dealing with allegations in "bad faith", rights of the accused, nature of investigating and deciding bodies, publicity and transparency of the procedure, determination of misconduct, sanctions, appeals and communicating the results of an investigation.

Detailed presentation of this report is beyond the scope of this Challenge Paper, but it an important read for all involved in setting up and maintaining an RI framework. The report ends with the conclusion (again) that that the differences in the definition of RI make difficult to have harmonized procedures. However, it argues that, from a legal perspective, the absence of clear definition could be to some extent mitigated by case law or a collection of decisions on research misconduct, so that those decisions could define the common contours of research misconduct and provide a learning opportunity and reflective exercise for the RI system in an organization or a country.

4.3 Definition of research ethics/research integrity expert

Both ENERI and PRINTEGER project dealt with this issue.

ENERI project had a wide stakeholder consultations about what constitutes expertise for RI (and research ethics).[18] As the report was not publicly available at the time of writing this Challenge Paper, the conclusions are presented here in more detail.

The evidence from literature and EU projects indicates that "experience in ethics assessment processes is valued over qualification, and training is advised for all members" and that "specific knowledge/qualification is required for *ethics specialists* and *legal experts*". In regard to certification of this expertise, "procedure and training certification are favoured over personal certification". The expert interviews with 11 participants identified core competencies for RI/RE expertise:

- "Ethical competences (deep knowledge of national and international regulation; cases, awareness of moral dilemmas and ethical deliberation)

[16] PRINTEGER. Deliverable 3.1. Final report on the incidence of misconduct. Available: https://printeger.eu/wp-content/uploads/2015/12/D3.1.2.pdf.
[17] PRINTEGER. Deliverable 3.10. Fair procedures. Available: https://printeger.eu/wp-content/uploads/2018/05/D3.10.pdf.
[18] ENERI. Deliverable 6.1. Summary of empirical programme and preliminary set of indicators for e-database. Not yet available online.

- Integrity competences (deep knowledge of national and international regulation, policy and guidelines)
- Research/science experience [having performed research activities in the past]
- Legal competences
- Ethics assessment/review experience [having performed ethics assessment in the past]
- Integrity assessment/review experience [having performed integrity assessment in the past]"

Table 2 presents the identified desirable skills for RI/RE experts

Table 2 Desired skills for RI/RE experts

Hard skills	Soft skills	Process skills	Emotional skills
Analytical skills	Communicational	Administrative/management	Open-mindedness
Scientific skills	Interpersonal	Turning ideas into recommendations/practice	Independence
Ethical commitment/thinking/abilities	Eye for details	Decision-making	Societal/cultural/health care awareness/impact
Critical thinking	Ability towards deliberation		Personal commitment
Assessment/ review	Peace-making, conflict-resolution		
	Collaboration		

In relation to the certification of expertise, the following recommendation was provided, based on the interviews and a survey of stakeholders:

" … training should only be offered on a voluntary basis and not be made mandatory and that 'any ethics/integrity training' should be accepted as opposed to a certified training by an official body. When defining the type of certification required for the training, a majority would opt for a certification to be received following completion of the course as opposed to requiring certification of the teaching method of the specific course."

4.4 RI country report cards

For the purpose of this MLE, information about the environment for RI was collected for all 14 participating countries. The full information on individual countries is presented in the Appendix to this Challenge Paper in the form of RI Country Report Cards.

The idea of Country Report Cards came from the discussions of different stakeholders during the 4th World Conference on Research Integrity (WCRI) in Rio de Janeiro in 2015. The discussions were held during one of the Conference's Focus Tracks, on Improving Research Systems: the Role of Countries.[19] The participants, who came from different countries (Austria, Brazil, China, Croatia, France, Germany, Ireland, Japan, Kenia, the Netherlands, Norway, Saudi Arabia, Singapore, Slovenia, Switzerland, UK, and USA) discussed the ways how information about RI framework in a country could be organized. The came with the principle of RI Country Report Cards, whose purpose would be to help in benchmarking and then monitoring the development of RI framework in a country; a

[19] Kleinert S, Marušić A. F2 Focus track on improving research systems: the role of countries. Proceedings of the 4th World Conference on Research Integrity. Res Int Peer Rev. 2016;1(Suppl 1): 55-56. Available at: https://researchintegrityjournal.biomedcentral.com/articles/10.1186/s41073-016-0012-9.

tool for comparing good practices and for empowering to develop and strengthen RI; to increase awareness of RI and to encourage research into possible effective ways to strengthen the integrity of the research systems.

The Focus Track concluded with the proposition of the content for a RI Country Report Card. The idea for this structure came from the quality assessment approach used in health care – the so-called Donabedian approach.[20] In this approach, a system (in this case RI) is evaluated through its **structures** (characteristics of the RI/RE system), **processes** (procedures for ensuring responsible research and procedures for dealing with research misconduct) and **outcomes** (results of RE/RI system).

The discussion of the stakeholders at the 4th WCRI identified the following defining elements of **structures**: the number of researchers and research institutions per population (to capture the demographics of the research community); the amount of spending on research and the distribution of private, public and charity funding; scientific strategy; national bodies and laws relevant for RI/RE; the organizational structure and level of research integrity; number of researchers and others involved in RI/RE; percentage of postdoctoral students who get paid positions and percentage of grant success for applications to national funders (to capture structural elements of the research environment. For **processes**, the following elements were suggested: procedures to disseminate and enforce RE/RI policies, existence and nature of training for RE/RI, evaluation and monitoring of the RE/RI policies and activities, transparency of outcomes of research misconduct allegations, presence and activity of designated RI offices in institutions, procedures for whistle-blowers protection, funding for RE/RI work and research; registration of clinical trials (for biomedical research) and actions to ensure transparency of research (open access). For outcomes for RE+RI, the discussion at the 4th WCRI did not come to a clear conclusion and there were different suggestions, ranging from "the status of research integrity in a country (as measured by an array of indicators)" to "the current efforts on achieving maximum research integrity and a conducive research environment". In the discussions that followed the 4th WCRI, the following elements for **outcomes** were identified: results of research integrity evaluation as a part of institutional quality assessment; research impact assessment and translation of research findings to the community; public's perception of research integrity in their country, rewards for collaborative science and incentives for networks.

This topic continued to be in the focus of WCRI, so the practical application of Country Report Cards were discussed at the 5th WCRI in Amsterdam, May 28-31, 2017. Country Report Cards were presented for 4 countries: USA (by ZH Hammat, formerly from the Office of Research Integrity, ORI),[21] UK (by E. Wager, former president of the Committee of Publication Ethics),[22] Norway (by E. Engh, from the Norwegian National Research Ethics Committees)[23] and Croatia (by A. Marušić, president of the European Association of Science Editors).[24] This exercise for four countries discovered the diversity of approaches to RI globally and in the EU.

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[20] Donabedian A. Evaluating the quality of medical care. Milbank Mem Fund Q. 1966 ;44 Suppl:166-206.

[21] Hammat ZH. Accountability & transparency for research integrity via country report cards: USA. Presentation at the 5th World Conference on Research Integrity, Amsterdam, 28-31 May 2017. Available at: https://wcrif.org/images/2017/documents/3.%20Wednesday%20May%2031,%202017/1.%20Aula/Z.%20Hammatt%20-%20Accountability%20and%20transparency%20for%20research%20integrity%20via%20country%20report%20cards.pdf.

[22] Wager E. Research integrity country report card: UK. Presentation at the 5th World Conference on Research Integrity, Amsterdam, 28-31 May 2017. Available at: https://wcrif.org/images/2017/documents/3.%20Wednesday%20May%2031,%202017/1.%20Aula/E.%20Wager%20-%20Research%20integrity%20report%20card%20for%20the%20UK.pdf.

[23] Engh E. Country report card on research integrity: Norway – a broad approach. Presentation at the 5th World Conference on Research Integrity, Amsterdam, 28-31 May 2017. Available at: https://wcrif.org/images/2017/documents/3.%20Wednesday%20May%2031,%202017/1.%20Aula/E.%20Engh%20-%20Country%20report%20card%20on%20research%20integrity%20-%20Norway%20-%20a%20broad%20approach%20to%20research%20integrity.pdf.

[24] Marušić A. Report card: Croatia. Presentation at the 5th World Conference on Research Integrity, Amsterdam, 28-31 May 2017. Available at: https://wcrif.org/images/2017/documents/3.%20Wednesday%20May%2031,%202017/1.%20Aula/A.%20Marusic%20-%20Accountability%20and%20transparency%20for%20research%20integrity%20via%20country%20report%20cards.pdf.

The principle of RI country report cards was then used to develop the information framework for collecting data on RI for European countries for the ongoing EnTIRE project. The country report cards were piloted and tested on three countries: Netherlands, Spain and Croatia.

The same approach was used to collect the information on RI system in 14 countries participating in this MLE. The country tables were first filled with information available in the public domain (starting from the information at the European Network of Research Integrity Offices – ENRIO).[25] Then the tables were sent to the representatives of the 14 countries, who participated in the MLE Scoping and Kick-off Workshops. The revised tables are presented in the Appendix to this Challenge Paper. For some countries, the legislation changed recently or will be changing in near future, so it was not always possible to obtain most recent information.

The information in the tables is very extensive, and presented here is a very brief summary of the structures and processes. The tables can serve, as they were intended, as a benchmark for the current situation and follow up of the development, and as a comparison and learning tool to improve RI in a country setting.

Table 3 presents a brief summary of the structures and processes in the 14 countries participating in this MLE, according to the information available in the public domain and updated by representatives from participating countries (feedback from a few countries is still pending). Only 5 out of 14 countries did not have a national RI policy (Bulgaria, Greece, Lithuania, Luxembourg, Moldova). Also, only 2 out 14 countries did not have a national body or bodies for RI (Greece, Moldova), and only 3 countries (Bulgaria, Moldova, Lithuania) were not represented in the ENRIO. Finally, most of the countries had a defined procedure for handling misconduct (8 out of 14 countries)

On the other hand, institutions in most of the countries (n=9) did not have specific RI expertise in the form of RI offices or officers although the level of misconduct investigation was institutional (6 countries) or a mixture of institutional and national (8 countries).

Table 3 Basic information about RI structures and processes of MLE participating countries

Country	National RI policy	National body(ies) for RI	RI expertise (officers) in institutions	Member of ENRIO	Misconduct investigation level (institutional, national, other)	Procedure for misconduct investigation defined
Austria	**Yes** (OeAWI Guidelines for Good Scientific Practice)	**Yes** (Austrian Agency for Research Integrity – OeAWI)	**No**	**Yes**	**Institutional and/or national** (OeAWI)	**Yes** (OeAWI Rules of Procedure)
Bulgaria	**No**	**Yes** (Committee on Academic Ethics)	**No**	**No**	**Institutional or national** (Ethics Committees or Committee on Academic Ethics)	**No**
Denmark	**Yes** (Danish Code of Conduct for Research Integrity)	**Yes** (Danish Committee on Research Misconduct – DCRM)	**Yes** (Research Integrity Officers; Special Advisers)	**Yes**	**Institutional and national** (DCRM)	**Yes** (Danish Act on Research Misconduct)
Estonia	**Yes** (Estonian Code of Conduct for	**No**	**No**	**Yes**	**Institutional** (Ethics Committees)	**No**

[25] European Network of Research Integrity Offices. Available at: http://www.enrio.eu/.

	Research Integrity)					
Finland	**Yes** (TENK Guidelines on Research Integrity)	**Yes** (Finish National Board on Research Integrity - TENK)	**Yes** (Research Integrity Advisors by TENK)	**Yes**	**Institutional or/and national** (TENK)	**Yes** (TENK Guidelines)
France	**Yes** (French National Charter for Research Integrity)	**Yes** (French Office for Scientific Integrity – OFIS)	**Yes** (Research Integrity Officers)	**Yes**	**Institutional** (Ethics Committees, RI Officers, Boards)	**Yes**
Greece	**No**	**No**	**No**	**Yes**	**Institutional** (Ethics Committees)	**No**
Ireland	**Yes** (National Policy Statement on Ensuring Research Integrity)	**Yes** (National Forum for Research Integrity)	**No**	**Yes**	**Institutional** (Ethics Committees)	**Yes** (Guidelines of the National Forum for Research Integrity)
Lithuania	**No**	**Yes** (Office of the Ombudsman for Academic Ethics)	**Yes** (Ombudsman for Academic Ethics and Procedures)	**No**	**Institutional** (Research Ethics Committees)	**No**
Luxembourg	**No**	**Yes** (Luxembourg Agency for Research Integrity – LARI)	**Yes** (LARI Coaches)	**Yes**	**Institutional and national** (LARI)	**Yes** (LARI National Commission for Research Integrity – Rules of Procedure)
Moldova	**No**	**No**	**No**	**No**	**Institutional** (Ethics Committees or Commissions)	**No**
Norway	**Yes** (Act on Ethics and Integrity in Research)	**Yes** (The National Commission for the Investigation of Research Misconduct - GRU)	**No**	**Yes**	**Institutional or national** (GRU)	**Yes** (At the institutional level in accordance with the Research Ethics Act, Public Administration Act, Freedom of Information Act, and Archives Act)
Spain	**Yes** (Code of Good Scientific Practice; National Statement on Scientific Integrity)	**Yes** (Ethics Committee of the Spanish National Research Council - CSIC)	**No**	**Yes**	**Institutional or/and national** (Deontological Commissions, Ethics Committees, Justice System)	**Yes** (At the institutional level, e.g. CSIC Workflow Chart)
Sweden	**Yes** (Good Research Practice by Swedish Research Council)	**Yes** (Group on Research Misconduct at Ethical Review Appeal Board)	**No**	**Yes**	**Institutional or/and national** (Appointed Board at the universities; Group on Research Misconduct at Ethical Review Appeal Board)	**Yes** (At the institutional level; e.g. at the higher education institutions in accordance with Guidelines for universities and colleges in the handling of

						questions of scientific dishonesty)

Table 4 presents the bodies/institutions that produced policies and guidelines for RI. As for other elements of the RI framework, there is a diversity of practices and bodies that produce RI guidance. The documents are produced mostly at the level of the institutions where research is performed.

Table 4 Origin of the guidelines and policies for RI

Country	Published by Ministries	Laws	National Bio-Ethical Committees listed by WHO	National RI Governance Frameworks	Academies of Sciences - a member of All European Academies	National Research Organisations (examples)
Austria			**Austrian Bioethics Commission** issues only recommendations and opinions regarding the ethical point of view on all social, natural scientific and legal issues.	**Austrian Agency for Research Integrity (OeAWI)** -Guidelines for Good Scientific Practice -Guidelines on the Issue of Dual Use -Rules of Procedure for Research Misconduct	**Austrian Academy of Sciences** was involved in the establishment of the OeAWI. Has a member at the Permanent Working Group of Intellectual Property Rights and Science Education Group at ALLEA.	**University of Graz** -Principles of Good Scientific Practice **Graz University of Technology** -Guidelines for Securing Good Scientific Practice **University of Vienna and Medical University of Vienna** -Guidelines for Good Scientific Practice **University of Linz** -Guidelines for Ensuring Good Scientific Practice **University of Klagenfurt** -Ombudsman Guidelines for Good Scientific Practice -Code of Conduct for Good Academic Practice
Bulgaria	**Ministry of Health** -The Rules of Good Clinical Practice	The Act for the Development of the Academic Staff in the Republic of Bulgaria	**Not listed by WHO**		**Bulgarian Academy of Sciences (BAS)** -Rules of Procedure of the Academic Ethics Committee at Assembly of Academicians and Corresponding Members **The Institute for the Study of Societies and Knowledge at the BAS** -Code of Ethics	**University of Sofia** -Code of Ethics for Good Academic Practice **The University of National and World Economy** -Code of Ethics -Rules of Procedure of the Commission for Academic Ethics **Medical University Sofia** -Rules of the Ethics Committee of the Scientific Research **Burgas Free University** -Rules of Conduct Burgas Free University **Institute for the Bulgarian Language** -Ethical Guidelines for Publication **Medical University Pleven** -Code of Ethics of the Scientist **Bulgarian Sociological Association** -Code of Ethics
Denmark	**Ministry of Higher Education and Science** -The Danish Code of Conduct for Research Integrity	**The Danish Parliament** -Research Misconduct Act -Research Council Act -Act on Research Ethics Review of Health Research Projects	**The Danish Council of Ethics** issues statements and recommendations regarding different health issues and dilemmas (e.g. genome testing, use of antibiotics, health data and biological	**The Danish Committee on Scientific Dishonesty (today Danish Committee on Research Misconduct)** -Guidelines for Good Scientific Practice **The Danish Social Science Research Council** -Guidelines for Research Ethics in Social Sciences	**The Royal Danish Academy of Sciences and Letters** -Member of the Science Education Working Group	**University of Aarhus** -Policy for responsible conduct of research -Codes of practice -Standards for Responsible Conduct of Research Health -Principles on Responsible Scientific Conduct at Health -Principles on Responsible Scientific Conduct at Aarhus Business School -Supplemental Standards of Responsible Conduct of Research at Aarhus BSS **University of Copenhagen** -Rules on Good Scientific Practice -Booklet – Practical advice regarding good scientific practice

			material, genetic modification).			-Code of Good Scientific Practice in Research Collaborations with External Partners -Code for Authorship -Code for public sector services **Roskilde University** -Rules on Good Scientific Practice **Technical University of Denmark** -Code of Conduct for Research Integrity -Guidelines for handling suspicions regarding research misconduct and breaches of responsible research -Capacity at DTU -The policy of the Retention of Primary materials and Data -Principles for Good Scientific Practice **Copenhagen Business School** -The concept for CBS' procedure for violation of the Code of Academic Conduct
Estonia	**Ministry of Education and Research** (in cooperation with Estonian research institutions, Academy of Sciences, and Research Council) -Estonian Code of Conduct for Research Integrity		**Estonian Council of Bioethics** -Handbook of Codes of Conduct -Code of Conduct for Research Integrity -Codes of Conduct: Values, Norms and Ethical Dilemmas	**Estonian Research Council** has compiled an integrated document of European Research Integrity Codes and Guidelines and had an important role in developing Estonian Code of Conduct for Research Integrity.	**Estonian Academy of Sciences** -Member of the Science and Ethics Working group which worked on the development of the European Code of Conduct -In 2002 developed Code of Ethics of Estonian Scientist (outdated)	**The University of Tartu Centre for Ethics** -Handbook of Codes of Conduct -Code of Conduct for Research Integrity -Codes of Conduct: Values, Norms and Ethical Dilemmas
Finland	**Ministry of Social Affairs and Health** -Medical Research Act		**National Advisory Board on Research Ethics** -Guidelines on Research Integrity; Responsible conduct of research and procedures for handling allegations of misconduct in Finland -Ethical principles of research in the humanities and social and behavioural sciences -Supervision of doctoral dissertations and their review process in Finland with a special emphasis on	**Finnish Social Science Data Archive** -Data Management Guidelines **Committee for Public Information (TJNK)** -Bold communication, responsible influence. Science communication recommendations	**The Council of the Finnish Academies** -Member of the Science and Ethics Working group which worked on the development of the European Code of Conduct for Research Integrity -Member of the Science Education Working group	**Universities of Applied Sciences** -Ethical Recommendations for Thesis Writing at Universities of Applied Sciences **University of Helsinki** -Research Data Policy **University of Aalto** -Code of Conduct -Research Data Management Policy -Open Access Principles **University of Turku** -Research Data Guide -Data Policy -Publication Policy -Open Research Policy **University of Tampere** -Open Science and Research Policy **University of Lapland** • Open Science Policy **LUT University** • Research Data Policy • Checklist for Open access Publishing and Data Management

			research integrity - Recommend ations to universities by the Finnish Advisory Board on Research Integrity and Universities Finland UNIFI -Agreeing on authorship. - Recommend ations for research publications			
France	**Ministry of Education and Science** -The policy of Scientific Integrity within Research Operators -French Charter for Research Integrity -Order on Council of Deontology		**The National Consultativ e Ethics Committee for Health and Life Sciences** publishes advisory opinions.	**French Office for Research Integrity (OFIS)** -Roadmap for Scientific Integrity 2020	**Academy of Sciences** -Member of the Science Ethics Working Group and Science Education Working Group **Académie des Inscriptions et Belles-Lettre**	**Inserm** -Signature of Scientific Publications: Good Practices **French National Research Agency** -Charter of ethics and scientific integrity **National Center for Scientific Research (COMETS) and Conference of the University Presidents** -Integrity and responsibility in research practices **National Center for Scientific Research** -Scientific Integrity Guidelines **COMETS** -Ethical reflection on plagiarism in scientific research **French Agricultural Research Centre for International Development (CIRAD**) -Code of Ethics **Vademecum** -Scientific Integrity policy
Greece			**Hellenic National Bioethics Commissio n** publishes recommenda tions and opinions. -Reflections On Contempora ry Issues, Opinions and Reports 2008-2013	**EARTHnet** works on the promotion of research ethics and research integrity and on raising awareness on issues regarding RE and RI. **The Network of Responsible Conduct of Research in Greece (RCR-Greece)**	**Academy of Athens** -Member of the Science Ethics Working Group -Office of Experimental Physics - Scientists and Society: Needs and Responsibilities (Professor Loucas G. Christophorou)	**University of Aegean** -Code of Conduct **Aristotle University of Thessaloniki** -Code of Conduct in Research **University of Crete** -Code of Ethics **University of Macedonia** -Code of Conduct **University of Thessaly** -Ethics Code **Athens University of Applied Sciences** -Code of Ethics **Technological Educational Institute of Crete** -Code of Ethics
Ireland			**Irish Council for Bioethics** -Data Protection Policy	**The National Forum on Research Integrity** position papers -Research Integrity Officer Role and Reporting Structure -The interface between Research Integrity and Research Ethics -Guidelines for the Investigation of Misconduct in Research	**Royal Irish Academy** -Member of the Science Ethics Working Group -Member of the Truth, Trust, and Expertise Working Group -Worked on the development of the National Policy Statement on Ensuring Research Integrity in Ireland	**Irish Universities Association (IUA)** in collaboration with **Health Research Board (HRB), Royal Irish Academy (RIA), Science Foundation Ireland (SFI), Institutes of Technology Ireland (IoTI) , Higher Education Authority (HEA), Dublin Institute of Technology (DIT), Enterprise Ireland (EI), Teagasc, Irish Research Council (IRC), Royal College of Surgeons in Ireland (RCSI), and Quality and Qualifications Ireland (QQI)**

						-National Policy Statement on Ensuring Research Integrity in Ireland **Health Research Board** -Policy on disclosure of conflict of interest -Policy on data protection and health information -Policy on alleged misconduct in research -Policy on Open Access to research -Guidelines for host institutions dealing with alleged misconduct in research **Irish Research Council** -Dignity in the Conduct of Research -Open Access Policy **Royal College of Surgeons** -Checklist for supervisor report -SOPs for research students -SOPs research and children
Lithuania			**Lithuanian Bioethics Committee** issues recommendations related to bioethics.	**Office of Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania** **University Rectors' Conference** -Publication ethics guidelines (under development) **Lithuanian Research Council** -Ethical behaviour of researchers -the Description of the Procedure for the Examination of Notifications Related to Infringements of Ethics of Research Activities at the Research Council -Guidelines on Open Access to Scientific Publications and Data	**Lithuanian Academy of Sciences** -Charter of the Lithuanian Academy of Sciences	**Kaunas University of Technology** -Code of Academic Ethics (General principles of academic ethics; Standards of ethics for researchers)
Luxembourg			**National Ethics Commission (CNE)** prepares opinions that are communicated to the Government by the Ministry of Higher Education and Research and are available to the public.	**Luxembourg Agency for Research Integrity (LARI)** -10 Tips for Robust and Ethical Research oach Handbook	**Luxembourg is not a member.**	**University of Luxembourg** -Research Ethics Guidelines **University of Luxembourg** -Policy on Ethics in Research **Luxembourg National Research Fund (FNR)** -Research Integrity Guidelines -Ethics Charter and Code of Conduct for Research Assessment -Policy on Open Access
Moldova			**Not listed by WHO**	**The National Authority for Integrity** is handling only cases of public servants and head of institutes.	**The Academy of Sciences of Moldova** coordinates scientific and innovation activity and serves as a scientific consultant of the public authorities	

					of the Republic of Moldova.	
Norway		The Act on Ethics and Integrity in Research The Act on Medical and Health Research (Health Research Act)	**The National Committee for Research Ethics (NEM)** -Guidelines for research on persons with impaired informed consent capacity -Guidelines for the inclusion of women in medical research -General guidelines for research ethics	**The National Commission for the Investigation of Research Misconduct (GRU)** **The National Committee for Research Ethics in the Social Sciences and the Humanities (NESH)** -Ethical Guidelines for Internet Research -Guidelines for research ethics on human remains -Guidelines for Research Ethics in the Social Sciences, Humanities, Law and Theology **The Norwegian National Committee for Research Ethics in Science and Technology (NENT)** -Ethical guidelines for science and technology -Research ethics checklist	**Norwegian Academy of Science and Letters** -Member of the Science Ethics Working Group -Member of the Working Group of Intellectual Property Rights -Member of the Science Education Working Group	**University of Oslo** -Ethical guidelines -Ethical guidelines for supervisors -10 commandments for ethical practice in research **University of Bergen** -Ethical guidelines for relations between supervisors and students or candidates at the University of Bergen **The Arctic University of Norway** -Guidelines for Research Ethics **Oslo Metropolitan University** -Ethical Guidelines for Research -Ethical Guidelines for Supervision
Spain		The Law on Biomedical Research	**The Bioethics Committee of Spain** -Recommendations of the Spanish Bioethics Committee for the impulse and implementation of Good Scientific Practice in Spain	**The Spanish National ResearchCouncil** -Code of Good Scientific Practices -Manual of Conflicts of Interest -National Statement on Scientific Integrity	**Spanish Royal Academy of Sciences** -Member of the Core Group of Science Education Working Group **Royal Academy of Sciences and Arts of Barcelona** -Member of Science Ethics Working Group	**University of Barcelona** -Agreement on Openness
Sweden	**Ministry of Education** -Proposal for promoting good practice and managing misconduct in research	The Act concerning the Ethical Review of Research Involving Humans	**Swedish National Council on Medical Ethics** is an advisory board to the Swedish government and parliament on ethical issues raised by scientific and technological advances in biomedicine.	**The Ethical Review Appeal Board - Expert Group on Research Misconduct** **Swedish Research Council** -Good Research Practice	**Royal Swedish Academy of Letters, History and Antiquities** -Member of the Science Ethics Working Group -Member at the Truth, Trust, and Expertise Workin Group **The Royal Swedish Academy of Sciences** -Member of the Core Group of Science Education Working Group	**University of Uppsala** -Research ethics and good research practice at Uppsala University **Karolinska Institute** -Guidelines for planning, conducting and documenting experimental research -Guidelines for planning, conducting and documenting clinical and epidemiological research

5 CHALLENGES

The challenges identified during the Scoping and Kick-off Workshops related to RI structures and processes were the following:

1. Challenges related to the variations in RI frameworks in different countries
2. Challenges related to definitions of RI vs research ethics and definitions of misconduct vs responsible research
3. Challenges related to the expertise and competing interests of members of the RI bodies
4. Challenges related to monitoring of institutional bodies
5. Challenges related to implementation of RI principles in real life
6. Challenges related to the procedures for dealing with research misconduct
7. Challenges relate to resources for RI structures and processes
8. Challenges related to resources for RI structures and processes
9. Challenges related to cross-national/cross-institutiona/cross-sectoral/cross-disciplinary issues
10. Challenges related to emerging issues in RI, such as the consequences of Open Science and General Data Protection Regulation to RI structures and processes.

Some of the above challenges have been addressed or are being addressed by H2020 projects related to research integrity. Also, some of the above challenges may not be relevant for all countries participating in the MLE. Therefore the specific challenges for the first country visit related to the Challenge Topic 1, may focus on the procedures for investigating research misconduct cases. In the situation where the mobility of researchers is increasing, sharing experiences and looking for the possibilities to collaborate on research misconduct cases.

5.1 Challenges related to implementation of principles and requirements in practice and transparency of the process

The questions related to these challenges include:

Q1: How to translate national policies to the national level?

Q2: How to monitor RI procedures at different institutions and ensure that they are harmonized and consistent within a single country?

Q3: What is the acceptable level of transparency before, during and after misconduct procedure?

Q4: Should the findings of research misconduct investigation be made public and with what level of anonymization?

Q5: How to communicate the finding of misconduct investigation to relevant bodies, such as funding organizations and journals?

5.2 Challenges related to mobility of researchers and collaboration of institutions/structures on research misconduct investigation

The challenges here relate to mobility both among institutions in a single country or between countries:

Q1: How to deal with allegations of misconduct for persons that have already moved from the institution when the allegation is made?

Q2: What to do when the person being investigated moves to another institution?

Q3: What to do with misconduct investigation that are concluded but the person being investigated moves?

Q4: Should institutions check for the history of misconduct allegations with previous employers for newly recruited personnel?

Q5: Should applicants for new positions or grants or the institutions they come from be required to provide a declaration on research integrity?

5.3 Challenges related to whistle-blowers

It has been suggested that the term "whistle-blower" is replaced by the term "witness" in order to remove the negative connotation of the word.[26] However, the term "whistle-blower" is commonly used, for example in the newest EU proposal for the protection of whistle-blowers.[27]

The questions that arise in relation to this issue are:

Q1: What are good practices in protecting a whistle-blower?

Q2: How to provide support to whistle-blowers before or at the early stages of misconduct investigation?

Q3: How to protect persons who are either whistle-blowers or innocent associates, such as PhD students?

5.4 Challenges related to sanctions and appeals

Research misconduct investigation results in sanctions. In some countries, appeals can be made to such decisions. There are many open questions related to these issues:

Q1: What are possible sanctions?

Q2: Which sanctions work, do the make a difference?

Q3: Can and should institutions be sanctioned, not only individual?

Q4: How should an appeal process be organized? Should it be possible?

[26] Science Europe. Workshop Report. Advancing research integrity practices and policies: from recommendation to implementation. Brussels, 22 February 2017. Available: https://www.scienceeurope.org/wp-content/uploads/2017/05/WS_Report_Integrity_Practices_Policies.pdf.

[27] European Commission. Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, 23 April 2018. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52018PC0218.

6 Annex: Research Integrity Country Report Cards

RI Country Report Cards were created to provide information framework for country visits and discussions of challenge papers. The information for the cards was fist collected by the expert writing the Challenge Paper 1 based on the publicly available information, and then updated by the representatives of the countries (as indicated in the title of the table for each country). The cards for the countries for which feedback was not received by the deadline for the Challenge Paper 1 are based only on the publicly available information.

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