Governance of research integrity:
Options for a coordinated approach in Europe

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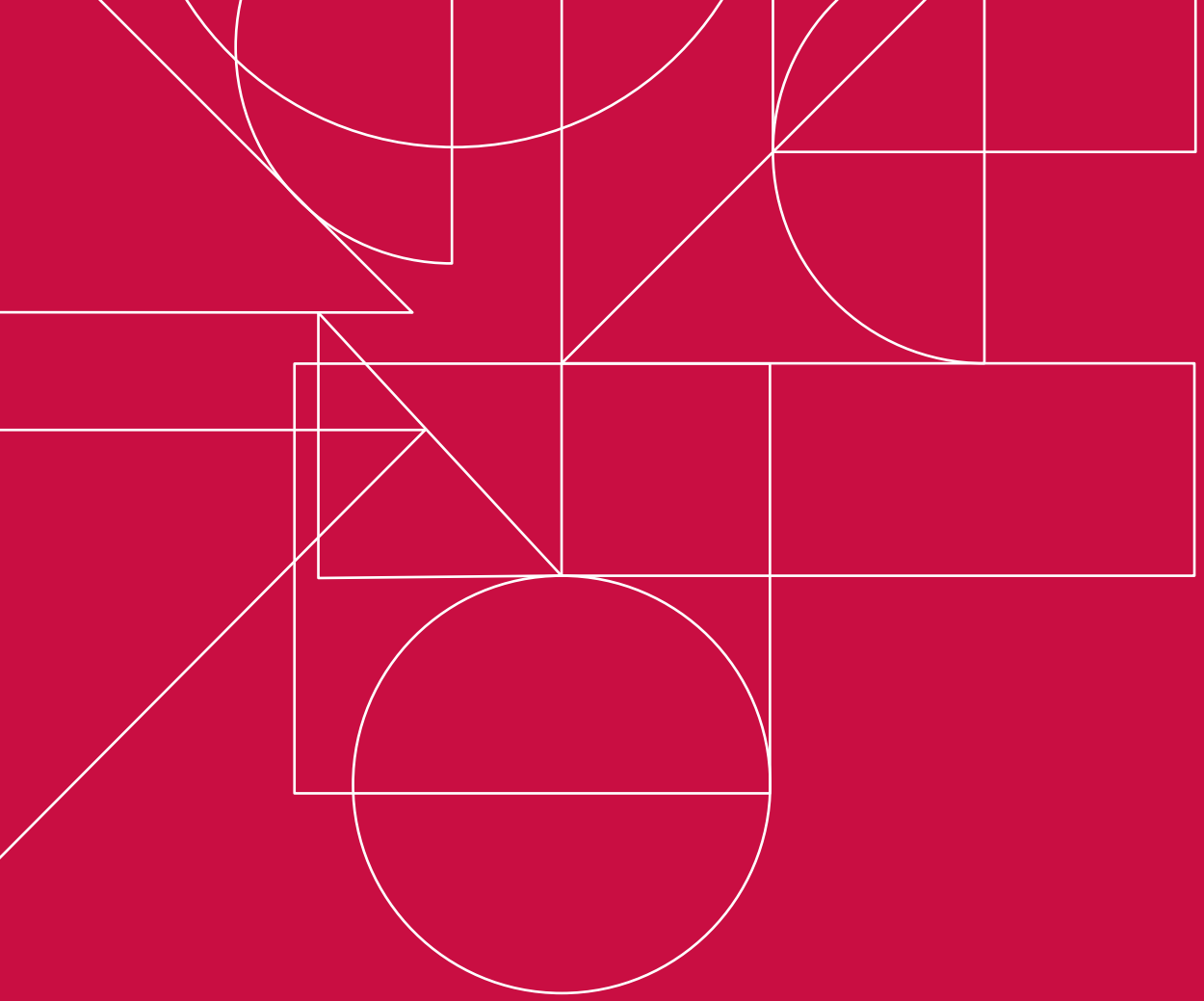

Governance of research integrity: Options for a coordinated approach in Europe

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This report reflects the authors' understanding of the published literature, interview material and workshop discussions. The invited participants in the project assisted the authors in understanding the scope of the issue, provided subject matter expertise and, in some cases, reviewed a draft of this report. The authors are solely responsible for the report and the accuracy of its contents.

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Summary

Governance of research integrity:

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This report is the result of an EMBO project to analyse whether and how a more coordinated approach in Europe would contribute to improving the integrity of research and meeting the challenges of handling cases of research misconduct. We analysed potential functions for a European body, the main ones being *investigatory*, *advisory*, and *oversight*. We also looked at other mechanisms, including the coordination of procedures used by European research performing organizations, funders and publishers. The project included a literature search, and input from an international group of experts through interviews and a workshop organized in partnership with the Organization for Economic Co-operation and Development (OECD) Global Science Forum (GSF).

To ensure trust in scientific knowledge, scientific[1] research must be conducted responsibly and to the highest standards. However, scientific research is not immune from problems: breaches of good practice, accepted norms, regulations and ethical behaviour.

In the past 20 years or so, an increasing number of cases of breaches of good research practice worldwide have been reported and have reached public attention. Most well known cases involve practices considered to be serious misconduct, which are generally identified as fabrication, falsification, or plagiarism (FFP). However, many other less sensational practices often referred to as questionable research practices (QRP) also threaten the quality of research outputs. Evidence from surveys of researchers' practices, and statistics related to problematic images found in scientific papers, shows that the incidence of QRP is high (e.g. Fanelli, 2009; Pulverer, 2015; Bik et al., 2016). To protect the quality, validity and reliability of research results, and public trust in scientific research, all breaches of good research practice must be addressed appropriately.

In Europe in the past ten years or so, there have been efforts at the national and international levels to develop policies to address these breaches. Guidelines, frameworks and structures have been established in many European countries. International initiatives such as the European Network of Research Integrity Offices (ENRIO), the Committee on Publication Ethics (COPE), the Science Europe Working Group on Research Integrity, and the revision of "The European Code of Conduct for Research Integrity" (ALLEA, 2017) indicate a growing awareness of the need to foster, promote and protect research integrity, and react appropriately to its breaches.

Despite these efforts, the research community has been slow to respond. Most universities and research institutes still struggle when confronted with cases of research misconduct, and are often unprepared to respond appropriately. Even where national guidelines on good research practice and research misconduct have been developed, their adoption by universities and research institutions often lags behind. This is due in part to the administrative burden of creating new structures and procedures, in part to an underestimation of the problem, and in part to fear of damaging institutions' reputations. Moreover, the idea persists that self-correction can solve all the problems (Alberts et al., 2015; Anderson, 2018; Gunsalus, 1997; Ioannidis, 2012). The effect is that the level of thoroughness and objectivity of institutional investigations is inconsistent, sometimes investigations are not pursued, and sometimes they do not contribute to correcting the research literature.

The variety of systems developed within European countries and the lack of systems in some countries create a heterogeneity of responses to research misconduct, and obstacles to dealing with research misconduct in particular in international scientific collaborations.

[1]We use the terms "science" and "scientific" with the German meaning of "Wissenschaft", which encompasses the sciences and humanities as a whole.

Summary

Many stakeholders play a role in shaping the environment for research: individual researchers, universities and research performing organizations, scholarly journals and funders, academies, learned societies and governments. Universities and research performing organizations, however, play a crucial role in encouraging high research standards: as employers, because of their educational mission, and as places where research, and research misconduct, happen.

EMBO undertook this analysis as a way of helping the research community take responsibility for and confront these issues.

A European *investigative* body

A European body could be established that would investigate breaches of research integrity on behalf of universities and research institutions, and even funders and scholarly journals. This body would have no legal authority or decision-making power to follow up on its findings, because legal responsibilities would reside with the researchers' employers, i.e., universities or research institutions. This body would focus on analysing the material and data provided by the institutions (e.g. lab notebooks, published articles, images) and producing a summary of its findings, on the basis of which employers would determine the severity of the breach and decide how to follow up.

Advantages

- It would ensure a higher degree of homogeneity and coherence in the handling of investigations in Europe, compared to the current handling at local and national level, because all cases would be treated in a similar way.
- It would develop expertise and professionalize the handling of cases, which currently are mainly handled by *ad hoc*, non-professional committees at the local or national level.
- Because of its independence from local or national interests, it would help ensure objectivity and neutrality, and so mitigate conflicts of interest, which are a significant obstacle to the resolution of cases of research misconduct, in particular at the level of local committees.
- Because of its independence, individuals could report allegations with less fear of retaliation.
- It would be particularly beneficial for institutions that do not have dedicated structures or experience in handling such cases, or that recognize that internal conflicts of interest might hinder their objective handling of an allegation.
- It would be particularly useful in collaborative research projects involving researchers from different institutions, countries or disciplines. Such collaborations are becoming the norm in many fields, but agreements establishing partners' responsibilities are often not formalized. A supranational body could be tasked to take on the responsibility for investigating allegations.
- This body could collect and share information on closed cases and best practices, becoming an important resource for others.

Disadvantages

- Universities and research institutions might be reluctant to expose breaches of research integrity committed by their researchers, for fear of losing reputation and support. They might also not want to delegate investigations of their researchers for fear to lose their autonomy.
- National regulations might limit access to data and materials, preventing an external body from analysing the facts.
- Some countries might not recognise the legitimacy of a supranational body, depending on its status.
- Establishing an international investigative body might discourage institutions from developing policies to address research misconduct, preferring to delegate this responsibility to the international body.

Summary

A European *oversight* body

A European oversight body would not conduct but only review investigations conducted by European institutions to ensure that they followed appropriate procedures. Institutions could request to have their investigations reviewed and certified by this body to restore or maintain trust, or funders could require that their funded institutions have their investigations certified by it.

Advantages

- It would incentivize institutions to conduct investigations according to procedures that have been discussed and agreed-upon internationally; this would help ensure the quality of investigations, and foster more consistency in their handling.
- Its independence from local committees or agencies would limit the risk of conflicts of interest.
- By reviewing investigations from different countries and institutions, it would build expertise on different systems and best practice.

Disadvantages

- It might not be able to require an institution to redo an investigation if it found the original investigation lacking.
- If a new investigation is needed, this would consume resources and delay the conclusion of the investigation process.

A European *advisory* body

A European body could be established to support European universities and research institutions in all issues related to research integrity. It would not have an investigative role, but would support European universities and research institutions in all issues related to research integrity, across all disciplines. Such a body would not substitute for, but would complement existing national and local structures or committees. For example, it could advise institutions about structures and policies to promote research integrity, prevent misconduct, and respond to allegations. It could also maintain a roster of international experts to assist investigation committees, and facilitate communication among different stakeholders.

Advantages

- It would give coherent advice to European institutions and foster homogeneity and consistency in handling investigations of research misconduct in Europe.
- It would be particularly useful for institutions that do not have yet structures in place for handling allegations and investigations of research misconduct.
- Where local or national committees or bodies are in place, it would be able to support them, providing additional advice in specific cases.
- In cases involving collaborations between institutes and countries, it could function as an objective mediator, assisting all parties while they proceed with an investigation.
- It would gain expertise and could function as a focal point for collecting and sharing best practices.
- A permanent body with dedicated staff would be able to provide specialized advice, tailored to the needs of institutions and individuals.

Disadvantages

- It could be perceived as redundant or in competition with existing national advisory agencies and other international organizations that are active in the area of research integrity.

Summary

Implementation

Setting up a new international body *de novo*, with any of the roles above, is a complex operation. One easier option for establishing a European body would be to affiliate it with an existing European research organization with experience in analysing misconduct allegations or advising on research integrity issues; more international non-governmental organizations that are already active in the area of research integrity could be involved. Examples are analysed in details in this report. Its establishment could be tested initially in a single field of research, for example the life sciences, and later expanded to other disciplinary areas. European funders could provide resources to ensure the sustained functioning of the international body.

Part of the early work of an international body would include building a taxonomy of specific research integrity breaches (FFP and QRP), and considering how and whether various international, national, or institutional codes of conduct could be applied. Definitions and working procedures would need to be established and agreed upon among countries: a complex process, as previous efforts by the OECD have shown (OECD Global Science Forum, 2009).

A policy question is for what type of allegations and investigations institutions would turn to the body: only fabrication, falsification and plagiarism (FFP); only questionable research practices (QRP); or both. In some countries, the two types of breaches are differentiated according to who is responsible for investigating them. However, in the view of the authors of this report, all of these practices could be detected by an expert analysis.

Gaps identified

Through the analysis we identified gaps in understanding and addressing responsible conduct of research in Europe, to ensure appropriate responses to research misconduct as well as to maintain researchers' and the public's confidence in the research system.

Individual scientists and the scientific community:

1. It appears that a number of researchers do not acknowledge that breaches of research integrity, both serious misconduct and poor research practices, are a serious problem that jeopardizes the quality of scientific outputs and endangers the reputation of science.
2. Scientific rigour may not always be at the top of researchers' priorities.
3. Although some researchers are aware of poor research practices in their organization, they may not feel responsible for addressing them.
4. The desire to protect colleagues and friends can be an obstacle to addressing allegations and conducting investigations properly.
5. Correcting the scientific literature should take priority over establishing guilt. In some cases, this is hindered by researchers not agreeing to correct or retract articles when requested to do so by journals.

Universities and research institutions:

1. Heads of universities and research institutions might not always recognize the importance of developing policies and structures that prepare them to respond to allegations.
2. Procedures for handling allegations of research misconduct may not prioritize the correction of the scientific record, but rather focus on establishing innocence or guilt. Clarifying responsibilities can take a long time, but the scientific data must be corrected as soon as possible to avoid faulty research being used for further studies, or to develop therapies or drugs.
3. Procedures to handle allegations may not include policies on how to protect those who report suspicions, or the accused researchers.

4. Conflicts of interest of members of internal investigative committees may be a significant obstacle to investigations.
5. Not enough attention is paid to assessing and promoting institutional culture (or "climate"), although a good institutional culture is a key factor in fostering research quality and preventing research misconduct and poor research practices.
6. Training in good scientific practices is not generally available for staff at all levels.

General:

1. While nearly all definitions of research misconduct include fabrication, falsification and plagiarism, there is no general agreement about what constitutes questionable or poor research practices. The definitions in different international and national codes do not always align.
2. Policies need to be developed to balance confidentiality and transparency in conducting investigations and communicating results to stakeholders and the public. The pros and cons of different current approaches should be analysed by appropriate experts.
3. Policies about communication between universities and research performing institutions, scholarly journals and funders when handling allegations are not well defined.

Report conclusions

A more coordinated approach to handling investigations of breaches of research integrity in Europe is desirable and would help fight those breaches. International organizations that are already involved in investigating allegations, developing specific guidelines or providing advice for their members could play a role in establishing specific mechanisms, if they were appropriately resourced to expand their current remit. In this report we analysed as examples bodies that could be established by EMBO, the European Commission, COPE, and ESF-Science Connect. Other European groups that have been active in research integrity, such as ENRIO, Science Europe, or All European Academies (ALLEA) could also play a role in the establishment of an international body. The EC and other European funders could provide financial support. However, depending on the role assigned, the implementation of specific mechanisms at an international level could be perceived as limiting research institutions' autonomy or countries' sovereign rights. Solutions limited to a research area—at least to begin with—might be more appropriate.

Chapter 1. Introduction

Research integrity includes "*the use of honest and verifiable methods in proposing, performing, and evaluating research and reporting research results with particular attention to adherence to rules, regulations, guidelines, and commonly accepted professional codes or norms*" (NIH, 2018).

Research results must be trusted in order for researchers to build on the knowledge produced by their colleagues, for policy makers to develop public policies that benefit society, and for industry to turn scientific results into useful products. Moreover, public funding of research depends on the public's trust that research is conducted responsibly.

In the past 20 years or so, an increasing number of cases of breaches of good research practice worldwide have been reported and have reached public attention. Most well known cases involve practices considered to be serious misconduct, which are generally identified as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results" (FFP) (Office of Science and Technology Policy, 2000) (see Box 1). However, other less sensational practices also threaten the quality of scientific results (see Box 2). These are often referred to as questionable research practices (QRP) (Steneck, 2006), unacceptable research practices (ALLEA, 2017) or detrimental research practices (NASEM, 2017). While there is general agreement on the definition of research misconduct as FFP, there are calls to broaden it to include a range of QRP (Bagioli et al., 2019; NASEM, 2017). However, there is no consensus on which QRP should be included in the definition (Resnik, 2009). A different approach to the definition of research misconduct was proposed in 1995 in the US governmental Report of the Commission on Research Integrity (Redman, 2017). The proposal was to focus the definition on three concepts: misappropriation, interference, and misrepresentation. It was never accepted, but it is an example of the potential to define research misconduct differently from the current approach.

The incidence of both types of bad practice, FFP and QRP, is well documented. A meta-analysis of surveys of researchers' practices found that nearly 34 percent of researchers admitted to questionable research practices, and about 72 percent had observed questionable research practices by colleagues. About two percent of researchers admitted to fabricating or falsifying data at least once, but about 14 percent of researchers reported having observed colleagues doing it (Fanelli, 2009). Analyses of scientific papers pre- and post-publication indicate a high incidence of problems with images: for example, problematic images were found in about 20 percent of manuscripts accepted for publication by EMBO Press journals (Pulverer, 2015), and in about four percent of more than 20,000 published biomedical papers analysed by Elisabeth Bik and colleagues (Bik et al., 2016). A prevalent belief is that some problems are contingent on the environment of local institutions, and are therefore better investigated locally. A counter argument to this is that research is an increasingly international endeavour in which international collaborations, international conferences, international journals, funders and databases are connecting researchers from all around the world. The fact that it is possible to start, support, and communicate research conducted in different countries shows that standards, methods, principles and values of research have some common ground. There are some specific topics, such as the perception of conflicts of interest, that might be culturally different, but a sense of what good and bad research and laboratory practices are, is the same across Europe.

Box 1 Fabrication, falsification, plagiarism (FFP) as defined by US Office of Science and Technology Policy

Fabrication is the making up of data or results and recording or reporting them.

Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(Code of Federal Regulations, 2011)

Box 2 Examples of questionable, unacceptable or detrimental research practices (QRP)

- Improper study design; biased selection of methods or controls
- sloppiness in the recording and managing of research data
- data manipulation to obtain statistical significance ("p-hacking"); the use of inappropriate statistical methods
- biased reporting
- impropriety of authorship
- failure to disclose financial and other conflicts of interest
- non-compliance with scholarly journal policies (e.g. multiple submissions, republication)
- failure to report modification of images
- failure to acknowledge other contributors to research results
- inadequate supervision of lab members
- failure to maintain confidentiality as reviewers
- etc.

Aim and scope of this report

EMBO, an international scientific organization promoting quality in the life sciences, undertook this analysis as a way of helping the research community to take responsibility for and confront these issues. The aim was to explore new possibilities for reaching a more coordinated approach to the governance of research integrity in Europe. We used examples mainly from the life sciences, as that is the area of expertise of EMBO.

While we acknowledge that prevention of FFP and QRP is fundamental, in this study we focused on the handling of allegations and investigations which are equally important as a deterrent and to ensure that the research record is corrected, as well as to maintain trust in the research system.

We benefitted from the input of an international group of experts via interviews and participation in a closed workshop. While most of these experts reviewed a draft of this report, the authors are solely responsible for the content and its accuracy. For more details on the methodology used in this project, see Chapter 2.

Systemic factors

The reasons behind breaches of good research practices are diverse, but systemic factors are increasingly being recognized as contributing to this problem (Alberts et al., 2015; Nuffield Council on Bioethics, 2014; NASEM, 2017). For example, publication pressure and a highly competitive environment in academic research play an important role in pushing scientists to engage in bad research practices (Martinson et al., 2005; Fanelli, 2010). Research assessment for career advancement and funding allocation in academia is based often on publication metrics such as the number of articles published by a researcher and the impact factor and other metrics of the journals where the articles are published (Moher et al., 2018). These factors can push researchers to fabricate, to shade the truth, and sometimes to take shortcuts that result in the quick production of data that detract from quality and validity.

Surveys demonstrate the effect of these perverse incentives on researchers. For example, in a survey of medical professors in the Netherlands, the majority of respondents rated publication pressure as "excessive" (Tijdink et al., 2013); a survey of 5,000 biomedical and social science researchers in the US indicated that pervasive competition for research funding was one of the main drivers for researchers' misbehaviour (Martinson et al., 2009). In a survey by the UK Nuffield Council on Bioethics, the majority of respondents suggested that high levels of competition and the pressure to publish might be factors tempting scientists to use lower research and ethical standards (Nuffield Council on Bioethics, 2014).

Community-driven initiatives have been attempting to address these systemic factors: the San Francisco Declaration on Research Assessment (DORA, 2012), the Leiden Manifesto (Hicks et al., 2015) and the Hong Kong Principles for Assessing researchers (Moher et al. 2019) address the widespread abuse of publication metrics. ASAPbio promotes the use of pre-prints in the life sciences to relieve publishing pressure (ASAPbio, 2020); and additional initiatives seek to foster data sharing and reproducibility of research results, such as the Center for Open Science in the US (COS, 2020), and the EQUATOR Network to promote good health research reporting practices (Equator, 2020).

Policy responses: a variety of approaches to RI governance

Despite the relatively high incidence of problematic research practices, the research community has been slow to react, partially because it believed that collective self-governance through peer-review, correction and replication would solve the problem (Alberts et al., 2015; Anderson, 2018; Gunsalus, 1997; Ioannidis 2012).

The US was the first country to develop a structured system to promote good research practice, prevent and handle allegations of research misconduct in federal funded research in the late 1980s. In Europe, Scandinavian countries were the first to develop such systems in the 1990s (Nylenna et al., 1999). Other European countries and institutions followed, developing their own procedures, guidelines, definitions and codes.

The approaches taken are diverse, with the effect that Europe presents a fragmented landscape of systems for research integrity (Bosch, 2010; Hiney 2015). Some countries have structured systems, while others do not provide detailed guidance to their research communities, let alone systematic structures (see Chapter 3 for examples of existing systems). This creates difficulties, in particular for handling allegations that involve international collaborations or collaborations between different institutes in the same country. In these cases, the responsibilities for investigating are often unclear, and the risk that allegations are ignored is high.

Reaction of research organizations

The underlying concept in the existing guidelines and codes is that responsibility for handling allegations of research misconduct and investigations resides primarily with universities and research centres, where the research is conducted and researchers are employed. However, many universities and research centres still have not developed policies and structures to promote research integrity or address its breaches. The consequence is that often institutes and scholarly journals do not deal with allegations: problematic research continues, is published, and can remain uncorrected for a long time. Blogs flagging suspicious research results, such as PubPeer and Retraction Watch, contain many examples of this.

Furthermore, the treatment of allegations and the sanctioning of researchers found guilty of research misconduct are often inconsistent. Committees sometimes reach different conclusions after investigating the same cases (Horbach et al., 2019). Although this may be justified by the fact that different institutions might focus on different aspects of a case, it undermines trust. Conflicts of interest often prevent allegations from being followed up on, as researchers are hesitant to damage their colleagues' careers or their employers' reputations. Procedures to protect witnesses who report problematic practices are uncommon, or not efficient, with the effect that many cases

may not be reported for fear of retaliation. Investigations of collaborative projects involving research groups from different countries are particularly problematic, because the responsibility for each step in a research misconduct investigation may be in dispute.

Efforts toward coordination in Europe and globally

The first attempt to define principles and responsibilities for research integrity with global validity was "The Singapore Statement on Research Integrity" (World Conference on Research Integrity, 2010). In Europe, ESF and All European Academies (ALLEA) published the first version of "The European Code of Conduct for Research Integrity" in 2011 (ESF-ALLEA, 2011), which was updated in 2017 (ALLEA, 2017). The European Network of Research Integrity Offices (ENRIO) was founded in 2008 to promote exchange of information and experience between practitioners in research integrity governance in Europe. Editors of scholarly journals also formed international collaborations, including the International Committee of Medical Journal Editors (ICMJE) and COPE, to develop practical guidelines for editors and authors to foster integrity in scholarly publishing.

In this project EMBO wanted to build upon the previous work done by the international community and to analyse different options to coordinate efforts in Europe, in particular in the handling of research misconduct.

Chapter 2. Methodology

The aim of the study was to analyse and discuss potential structures and other mechanisms to develop an international approach to the governance of research integrity. The study focused on the reaction of institutions to breaches of research integrity. In particular we focused on the situation in Europe, to understand the issues that would need to be dealt with in considering transnational efforts in the European context. We used examples mainly from the life sciences, as that is the area of expertise of EMBO. We started with an analysis of the reaction to research misconduct of research organizations and national agencies to learn their advantages and disadvantages and how a European coordinated approach could help solve them. We limited our analysis to a number of countries that represent a range of approaches taken worldwide.

Use of term "research misconduct"

In this report we use the term research misconduct in a broad sense, to include fabrication, falsification and plagiarism (FFP) as well as a range of practices that have been defined as questionable, unacceptable or detrimental research practices (QRP). We make a distinction between the two sets of practices when necessary.

Literature review

We conducted a literature review of the interventions proposed or tested to develop a coordinated approach to the governance of research integrity and misconduct. This included academic literature, project reports, summaries of international meetings and news articles.

Workshop

A closed workshop was held in the EMBO building in Heidelberg from 23-25 January 2019. The participant list and agenda are contained in Appendix 2. EMBO organized the workshop in partnership with the OECD GSF, which shares a focus on international research issues and a commitment to foster responsible research. The workshop gathered an international group of experts representing a variety of stakeholders: institutional research integrity officers, members of national agencies for research integrity, institutional leaders, researchers, funders, science bloggers, editors, and behavioural scientists. The workshop was closed and held under the Chatham House Rule to allow the participants to work through difficult and sometimes controversial issues thoroughly. The workshop featured introductory talks by several participants to help frame our thinking about the roles of different types of coordinated approaches. Structured discussions were employed to facilitate focused discussion of particular aspects of each proposed mechanism. Participants were asked not to reject any options out of hand because they might not be supportable under current laws or national research integrity regimes, but rather to propose their best policy options to address the gaps identified. We then asked participants to share any specific examples or analyses they had done that could inform our thinking about how realistic any particular policy option might be. Those examples are not discussed in detail in this report, but were helpful in our analyses of where resources might be best used and which coordinated mechanisms would be most or least acceptable to all stakeholders.

Interviews

We also interviewed individuals who were involved in global initiatives to address misconduct, in national bodies to manage research integrity, in setting up new national bodies, and in an existing organization involved in research management. The aim of these interviews was to inform our understanding of the current state of governance of research integrity and to clarify some issues raised in published works.

Contributions

This report reflects the authors' understanding of the published literature, interview material and workshop discussions. The invited participants in the project assisted the authors in understanding the scope of the issue, provided subject matter expertise and, in some cases, reviewed a draft of this report. The authors are solely responsible for the report and the accuracy of its contents.

Chapter 3. Advantages and disadvantages of existing systems

A variety of approaches and systems have been developed worldwide for governing research integrity and addressing misconduct. They differ not only between countries, but also within the same country, and some countries lack any approach or system. The differences are striking in Europe, where systems range from self-regulation with no institutional or national guidelines or structures (although this is increasingly rare); to governance at the level of individual institutions,

based on internal guidelines for good research practices and *ad hoc* or standing committees to handle allegations; all the way to a variety of national approaches in which policies, guidelines and organizations are developed by governments, funding agencies or by independent groups of universities, research institutes and funders (ESF, 2008; ESF Member Organisation Forum, 2010; ENRIO, 2019). In some cases, two or more of these systems are present at the same time.

Before analysing the options for a coordinated European approach to handling allegations of research misconduct, we looked at existing systems in a number of countries, both in and outside of Europe, to identify their advantages and disadvantages, common issues, and gaps that a centralized structure could help fill, considering the European context. In particular, we looked at the situation in Austria, Belgium, Canada, Denmark, Germany, Portugal, and the US, because they provide a good representation of the different systems used worldwide.

Governance at the level of single institutions

When no national codes and guidelines exist, such as in Portugal, some institutes have developed their own internal guidelines, polices and structures to address allegations of research misconduct and to implement measures to foster good research practices. These local structures are typically developed as a reaction to the first allegation of misconduct involving a prominent researcher at the institute (Bouter, 2020). As a workshop participant described, when institutes are unprepared, the first reaction to such cases is often denial of the allegation. External pressure, usually by the media, then might force the institution to look into the allegation and proceed. An *ad hoc* panel of internal experts is convened, sometimes in a hurry, to conduct an investigation (Horbach et al., 2019). This panel reports to the leadership of the institute and might suggest an action to be taken. The leadership, usually the director, takes the final decision. Such an *ad hoc* reaction may result in an inaccurate and non-transparent process, and may lead to inconsistent conclusions from one case to another. Fear of breaching confidentiality might preclude clear explanations of how a final decision was taken. This may jeopardize the local community's trust in the institutional leadership.

Advantages

One advantage of governance at the level of single institutes is that local committees and responsible officials have direct access to relevant people, data and other material to assess the validity of allegations and conduct investigations, and are familiar with local structures. The local institution employs the researchers, so it is mainly responsible for eventual sanctions (ENRIO, 2019; ESF Member Organisation Forum, 2010). Moreover, the process of receiving allegations and conducting investigations alerts institutes to possible internal problems, weaknesses and lack of policies. This provides the opportunity to look for solutions. The first experience might lead the institutes to formulate guidelines, develop structures such as investigation committees, appoint a responsible individual or group to receive allegations of research misconduct, and sometimes to organize training, usually for PhD students.

Disadvantages

A major concern relates to the composition of local investigative committees. These committees typically include senior and established researchers with subject matter expertise who are employed by the institutes. This may create real or perceived conflicts of interest, as committee members might want to protect their colleagues and friends, or the reputation of their institutes. Moreover, senior institutional representatives external to the committee might interfere with an investigation to protect the reputation of the institute.

Generally, the members of institutional committees lack relevant investigational expertise or skills, such as interview techniques or knowledge of how to collect, review and interpret evidence to make a research misconduct finding (Horbach

et al., 2019). Outstanding researchers with excellent scientific and peer review skills are not necessarily good investigators in cases of alleged research misconduct, and they seldom handle enough cases to develop expertise. Training in the relevant skills is not, or only partially, available. A legal advisor is sometimes involved, but this is not a rule in all institutes.

Institutional investigative committees are also very homogeneous. For example, younger researchers are usually not represented, which may create a risk of bias toward protecting the interests of established researchers, may make other researchers distrust the system, and may discourage them from reporting concerns or problems internally. The extended use of online blogs such as PubPeer (2020), where potential problems can be flagged anonymously, might be seen as an effect of this mistrust. The voluntary nature of committee work is another concern. Members of investigative committees usually have to add this work to their other duties as researchers, heads of labs, teachers, and members of other committees, and so they may not have sufficient time to dedicate to this delicate task. This slows down responses to allegations and investigations, and endangers their quality.

Another disadvantage of governance at the level of single institutes is the lack of external incentives to respond to allegations in cases where there is no media pressure. The responsibility to follow up on an allegation resides solely with the leadership of the institute and depends entirely on its willingness to start a usually unpleasant process related to an employee. Conflicts of interest and fear of potential reputational damage might also play a role here. Furthermore, individuals reporting a potential problem are often not supported by any structure or framework, which might discourage in particular more junior scientists, who fear negative consequences for their careers.

If no formal procedures or guidelines are developed, responses to allegations will be *ad hoc* and likely without good preparation (ESF Member Organisation Forum, 2010). In the absence of a formal commitment to address allegations, the risk is high that research misconduct is never discovered, reported or investigated. The lack of investigations in countries or institutes with no frameworks of any sort might be due to a lack of attention to research integrity issues (Bosch, 2010).

A further limit of governance at the level of single institutes is a lack of transparency in reporting on closed investigations. Institutions often do not publish reports, even when funders or national agencies mandate that they do so. A 2018 survey by the UK Parliament found that, although the 2012 "UK Concordat to Support Research Integrity" (Universities UK et al., 2012[2]) requires it, only a quarter of universities had published a report of cases dealt with in their annual report (House of Commons, Science and Technology Committee, 2018). Also, most institutional reports are not standardized: the information they contain is limited and does not always clarify the issues at stake or how a decision was taken (Gunsalus et al., 2018). A study of four reports of institutional investigations graded all of them as inadequate (Grey et al., 2019). This may be because the primary aim of institutional investigation reports is to document the evidence for findings of research misconduct, and may not always reflect all the processes used during an investigation.

National frameworks

A variety of national frameworks exist, in which policies, codes and or guidelines have been developed by national funding agencies, such as in the US, Canada and Germany; by governments, such as in Denmark, Finland and Norway; by national academies, such as in Belgium; or by representative bodies, such as in Ireland, or by independent bodies such as in Austria and the UK. In some cases, these systems are supported by relevant laws, as in the US, Denmark and Norway. National advisory bodies have been created in some countries with the aim of advising institutions on research integrity issues, such as the Agency for Research Integrity (OeAWI) in Austria. In some cases, national bodies are responsible for investigating allegations of research misconduct, such as the the Commission for Research Integrity in Austria, and in other countries national

[2]The Concordat was revised in 2019.

bodies review institutions' concluded investigations, such as in Canada, Finland and US. We looked at the advantages and disadvantages of each type of national framework in a subset of the countries mentioned above.

USA: A national legal framework and oversight bodies

The first national bodies in the world were established in the US in the late 1980s: the Office of Research Integrity (ORI) in the Department of Health and Human Services (DHHS), and the National Science Foundation (NSF) Office of Inspector General (OIG). Their mandate, based on federal law, is to ensure the integrity of the funded research in their jurisdiction, for ORI in Public Health Service (PHS)-funded research in the health and biomedical sciences, which includes National Institutes of Health (NIH)-funded research, and for NSF OIG in the non-medical fields of science and engineering. ORI and NSF OIG provide policy guidance to institutions, and require that institutions have policies and procedures to address allegations, as well as training for their staff about research integrity. While the responsibility for addressing allegations and conducting investigations resides primarily with the institution where the research is conducted, both ORI and NSF OIG oversee and review investigations conducted by institutions and make independent findings for the US government, which are made public. However, NSF OIG can also perform investigations itself, if necessary or required by an institution, while ORI does not have this authority. Both bodies only handle cases of FFP, while universities are in charge of handling cases of QRP. However, ORI has a more restrictive view of what constitutes plagiarism than NSF OIG, and, for example, does not handle allegations of plagiarism of ideas against former collaborators (NASEM, 2017).

The 2017 NASEM report "Fostering Integrity in Research" suggests the establishment of an independent national advisory body in the US that would work across disciplines to enable the development of a coherent and unified approach to research integrity challenges. At the time the recommendation was made, structures to deal with breaches of research integrity, including governmental bodies, had already been in place for over 20 years. Indeed, NASEM had already recommended establishing an advisory body in its 1992 report, "Responsible Science: Ensuring the Integrity of the Research Process" (NASEM, 1992), but no action had followed.

Canada: A national framework and a national oversight body

Canada's national framework, the "Tri-Agency Framework: Responsible Conduct of Research" (RCR Framework) (2016) was developed by the country's three major federal funding agencies. It describes policies and requirements for researchers, institutions, and the agencies themselves related to applying for and managing agency funds, performing research and disseminating results. It also describes the processes that institutions and agencies must follow in the event of an allegation of a breach of an agency policy, and it requires that each institute has related policies and procedures that meet the minimum requirements of the RCR Framework. For example, each institutional investigation committee must include at least one member external to the institution. Institutions must also promote responsible conduct of research. Funding agencies retain broad authority to compel institutions to act, and/or to act on their own initiative through the Secretariat on Responsible Conduct of Research (SRCR) and the Panel on Responsible Conduct of Research (PRCR), which reviews institutional investigation reports. The Panel meets on a regular basis to review institutional investigation reports and to discuss emerging policy issues. The Panel is composed of a mix of research administrators and experts from various research disciplines. The goal of the Panel's review is to ensure that institutions have followed up on allegations of breaches in accordance with the Agencies' requirements. The Panel also determines whether there has been a breach of the RCR Framework based on the findings of the institutional investigation reports and recommends recourse to the Agencies, if warranted. The Agencies can impose recourses in addition to any sanctions imposed by institutions, includ-

ing the ineligibility for, or termination of, Agency funding. As well, the Agencies can take action against institutions that fail to properly investigate allegations. The RCR Framework covers all research areas, from health sciences to natural sciences and engineering, to social sciences and humanities. Breaches of Agency policies include both FFP and QRPs.

Austria: A national advisory body and a national investigative body

Austria's framework, the "Guidelines for Good Scientific Practice," was developed by the country's Agency for Research Integrity (OeAWI), an independent non-profit association established in 2008 by more than 40 universities, research institutions and funding agencies. OeAWI has an advisory role and trains on good research practice and research integrity. Public universities must be members of OeAWI, and must have internal structures to deal with breaches of research integrity. The framework uses a broad definition of research misconduct that includes both FFP and a wide range of QRP. Member institutions support the Agency via a fee calculated according to their size. An independent investigatory body, the Commission for Research Integrity, investigates allegations of research misconduct as defined by OeAWI. The Commission is composed of researchers from different fields of expertise, who are non-Austrian citizens to guarantee independence from the Austrian research system. The Commission recommends follow-up measures to affected institutions, which solely decide whether and how to follow up on them.

Germany: National advisory and investigative bodies

In Germany, the German Research Foundation (DFG), the country's major funding agency, has played an important role in creating a culture of research integrity. Its white paper, "Recommendations for Safeguarding Good Scientific Practice" (DFG, 1998/2013), led the research community to formulate a comprehensive system of self-regulation that found a general consensus. To be able to receive DFG funding, all universities and non-university research institutions in Germany had to adopt the recommendations, in particular they must establish internal structures to deal with breaches of research integrity and to investigate allegations of misconduct (FFP). The newly approved DFG code of conduct, "Guidelines for Safeguarding Good Research Practice" (DFG, 2019) has now replaced the recommendations. The DFG also has its own Committee of Inquiry on Allegations of Scientific Misconduct, composed of eight members from different disciplines, which investigates allegations of research misconduct related to its funded research and reviews institutional investigations. Independent from the DFG, a national committee, the German Research Ombudsman, can also receive allegations and has an advisory role in cases requiring conflict conciliation and mediation. The German Research Ombudsman has four members who are German academics nominated by the DFG, and who serve for a four-year term on a voluntary basis. Usually at least one committee member is a legal expert. The development of the unusual decentralized system in Germany is due to the scale of the German academic system, which includes more than 700 institutions, as well as to Germany's federal structure in which each region (*Land*) regulates its academic institutions, and to the emphasis on freedom and independence of universities in the German constitution.

Denmark: A national code and an investigative body

The Danish system for research integrity is established by a law, the "Act on Research Misconduct etc." (2017), which also regulates the handling of its breaches. A national code, the "Danish Code of Conduct for Research Integrity" (2014), provides a common framework to be implemented across all areas of research at all universities and research centres. The Danish Agency for Science and Higher Education, under the Ministry of Higher Education and Science, is responsible for promoting research integrity nationally. The Danish Committee for Research Misconduct, established by the same Ministry, is responsible for handling breaches of research integrity, in close collabora-

tion with the affected universities and research centres. According to the law, the committee decides only whether an allegation relates to misconduct (FFP) or to a questionable research practice (QRP). The committee handles cases of FFP, while institutes are responsible for investigating allegations of QRP. Institutional investigations are reported to the national Committee and published in brief in an annual report. The committee consists of a chairman and eight to ten academic members representing a broad range of academic disciplines. For each academic member, there is an alternate who joins the Committee in case of absence or when otherwise relevant. The academic members and alternates are recognized researchers who are appointed by the Danish Minister for Higher Education and Science following an open call and in consultation with the Independent Research Fund Denmark. The Chairman is a high court judge and is appointed by the Minister following a nomination from the Danish courts.

Belgium: A national code and a regional oversight body[3]

The Belgian system is a hybrid of the systems described so far. There is no national regulation or directive on how to handle breaches of research integrity. A national "Code of Ethics for Scientific Research in Belgium" was produced by the Royal Flemish Academy of Belgium for Science and the Arts (KVAB) (2009) and other national academies with the support of the Federal Public Planning Service Science Policy (BELSPO). A regional body, the Flemish Committee for Research Integrity (VCWI), was established in 2013 within KVAB. It can give a second opinion on cases already handled by university committees. All Flemish universities and many other Belgian research institutions have adopted the national code. It does not specify or recommend procedures for dealing with misconduct, so individual institutions have developed their own. For example, Ghent University set up a Committee for Research Integrity, which investigates allegations of research misconduct, determines whether there has been a breach of integrity, and suggests a response to the university rector. It includes a chairperson, a secretary, a legal advisor, and a pool of about 10 professors of the university; no external members are involved. The Committee receives 10 to 15 allegations per year, not all of which lead to a formal investigation; some cases, such as authorship disputes, are handled as informal mediation processes. Cases should be closed within six months of the receipt of the allegation, but in practice many cases last up to one year, which is allowed by the procedural code upon justification. In all Flemish universities, policy advisors are appointed to develop policies that foster research integrity and ethics, often as a part-time remit. In many cases, they are also responsible for the implementation and evaluation of those policies.

Observations

Advantages of national bodies

In general, the main advantage of nationally coordinated bodies over local committees is that they are distant from local interests. This lends a higher degree of impartiality to their advice, investigation and oversight of cases. Moreover, national bodies give consistent advice or follow consistent procedures, and thus give coherence to the national approach to research integrity and its misconduct.

National investigative bodies, such as the Commission for Research Integrity in Austria, present a number of advantages over institutional investigative committees. They facilitate consistency and transparency in the handling of allegations, as the same procedures are followed nationwide. They also ensure a higher level of accountability, because the responsibilities for investigations are clear. They are composed of members external to the affected institutes, which limits conflicts of interest and fosters confidence, in particular for junior researchers who might fear negative consequences on their careers if they report problems locally. Their members usually include legal experts, lawyers or judges, which helps in the

[3]At the time of completing this report, a Commission Supérieure pour l'Intégrité Scientifique (CSIS) for the Walloon French-speaking part of Belguim was about to be launched.

professional conduct of investigations. National investigative bodies also handle more cases than local committees, so their members gather experience and develop expertise. The ongoing communication between the national committee and the institutes is seen as facilitating good research practice.

National oversight bodies, such as the Panel on Responsible Conduct of Research (PRCR) in Canada, can strengthen the quality of investigations by ensuring that institutions conduct their investigations according to given guidelines. They also promote a higher degree of accountability, as institutions often have to submit reports about their closed investigations. In the UK, which has a national advisory body, the UK Research Integrity Office (UKRIO), the House of Commons Science and Technology Committee recommended that an independent national research integrity committee be established to "independently verify whether a research institution has followed appropriate processes to investigate misconduct," to eliminate the perception "that investigations are not concluded properly in order to avoid embarrassment" (House of Commons Science and Technology Committee, 2018).

National advisory bodies, such as OeAWI in Austria, offer consistent advice about procedures to handle allegations and investigations, and about preventive measures, such as training, incentives and rewards; this gives a coherent approach to fostering research integrity and addressing misconduct in institutes within countries. They also collect and publish annual reports of closed cases by country, which can help institutions learn how to handle new cases (see also ENRIO, 2019).

Disadvantages of national bodies

National investigative bodies might be slower in processing investigations than local committees, as their members are located in different institutions and do not meet regularly. In particular in countries with a large scientific community, they might become overwhelmed by the number of cases to investigate. A concern was expressed about the danger of retaliation against individuals choosing to report to a national body rather than to a local committee, once the identity of the individual reporting is known.

Some *national oversight bodies* do not have the authority to overturn the result of an institutional investigation they disagree with, such as ORI in the US.

National bodies established by funders, within legal frameworks, funded by voluntary fees

National bodies can be established by different agents: governmental or other funders, voluntary networks of institutes, universities, academies, or independent non-governmental organizations or groups. National bodies organized by funders have a high degree of authority because they can link funding to compliance with their policies, incentivizing institutes to comply (ENRIO, 2019; ESF, 2000). However, some potential problems have been recognized, for example that conflicts of interest might affect their investigations, as funders might want to protect their grantees or fear reputational damage. National bodies established within legal frameworks, such as those in the US and Denmark, also have a high degree of authority. However, the American system presents the disadvantage that academic disputes may turn into legal ones; this complicates and slows down investigations, and implies costs, because lawyers need to be involved. Together with some scholarly journals' lack of engagement, this might impede or prevent the correction of the research literature, which is an important objective of investigating misconduct in research. Finally, independent national bodies funded by voluntary membership fees, such as OeAWI, may have budget problems.

Difficulties in cross-boundary allegations and investigations

A limitation of all systems, local and national, is the difficulty in cooperating successfully with other countries when allegations involve international research groups or researchers moving

from one country to another. The variety of existing procedures in Europe often makes it difficult to define responsibilities and even to identify the appropriate interlocutor. Because research is increasingly international, this limitation is becoming even more problematic. Many international research projects still do not have formal agreements governing partners' responsibilities, although international guidelines on how to handle cases of misconduct and on how to ensure integrity in international research collaboration have been developed, such as the OECD GSF guidelines, "Investigating Research Misconduct Allegations in International Collaborative Research Projects: A Practical Guide" (OECD Global Science Forum, 2009), and the Montréal Statement on Research Integrity in Cross-Boundary Research Collaborations (World Conference on Research Integrity, 2013). Navigating through the different systems, identifying and contacting the responsible officials, is often problematic also for editors of international journals (Wager et al., 2017).

Limits in the definition of misconduct and questionable research practices

A further aspect of most of these systems, both local and national, is that the research practices considered serious misconduct and to be investigated formally are mostly limited to FFP. Canada and Austria are exceptions, as their respective national investigative committees handle both FFP and a range of QRP. As discussed in Chapter 1, increasing evidence indicates that the incidence of QRP is much higher than FFP, affecting the quality and integrity of research. Most systems reflect this distinction in the separation of responsibilities for handling allegations: the national committee reviews or investigates allegations of FFP, while local institutes deal with QRP. However, as discussed above, local committees may be hampered by conflicts of interest, lack of investigative expertise, limited experience, time constraints and bias. For this reason, many experts are calling for the inclusion of a wider range of poor practices in the definition of misconduct (e.g. Bagioli et al., 2019; NASEM, 2017). A commonly accepted list and description of questionable practices in different research disciplines is also lacking (see Box 1 for examples).

Confidentiality and transparency

Another problem common to all governance systems relates to finding the right balance between confidentiality and transparency. When should a national body or an institutional committee contact a journal, a funder, or another institution, and what kind of information should be given, at what stage? When should a journal contact an institution or a funder? Should the results of an investigation be communicated internally and to the press, with what level of confidentiality? These questions are still open, and there is a need to develop policies on communication in handling allegations, and to analyse their effects.

Chapter 4. An international body: Potential advantages and disadvantages

After having identified the advantages and disadvantages of systems used in different countries, we moved on to analyse whether and how a coordinated approach at the European level could help fill the gaps.

Since the early 2000s, proposals have been made in Europe and internationally to coordinate policies to enhance research integrity and fight misconduct. The research community has embraced self-regulation as a means of fostering the principles of

research integrity and dealing with misconduct. Proposals have been made, and partially implemented, to create clearinghouses and websites that collect information on national policies and structures. However, the establishment of an international or European agency or body for research integrity has not been attempted, mainly because of concerns about national and institutional sovereignty.

In this chapter, we analyse different options for an international body: what roles and scope it could have and how it could be implemented to achieve a more coordinated approach to handling research misconduct at the European level.

4.1 Structural options: Intergovernmental and non-governmental organizations

Before comparing the different options for the structure of an international body for research integrity and misconduct, we analysed the advantages and disadvantages of different kinds of international organizations, to learn how a European body for research integrity could be structured. We looked at intergovernmental and non-governmental organizations.

An intergovernmental organization (IGO)

Intergovernmental organizations are based on formal collaborations between governments that commit to work together toward a common goal. They are established by treaties or other legally binding contracts. They are financed through contributions of the government members, and can have different scopes, aims, and structures. Examples of this kind of organization are the OECD, the United Nations Educational, Scientific and Cultural Organization (UNESCO); the European Organization for Nuclear Research (CERN), and the European Molecular Biology Conference (EMBC), the funding body of EMBO.

IGOs present a number of advantages over other international collaborations: they facilitate international exchange of ideas and best practices; they are sustainable, because financial support is regulated by treaty; and the support of signatory governments confers authority and legitimacy. At the same time, these organizations also present disadvantages. Establishing an intergovernmental organization requires writing and ratifying a treaty, a process that can last years or even decades; their governance can become complicated, especially if many states are involved; and they may be inflexible, as governments tend to resist change.

A simpler method to establish a European body for research integrity and misconduct, instead of creating a new IGO, would be to add a new structure or activity to an existing IGO with a similar scope. This would not require signing a new treaty, therefore it could be achieved sooner and more easily. However, such a structure might lack autonomy, having to align its mission with that of the parent organization. Conflicts of interest between the organizations might arise. For example, if an existing international agency funding a specific research area were to take on the role of investigating breaches of research integrity committed by its grantees, it might wish to downplay the gravity of the breaches to defend the reputation of its scientific area or that of its funding schemes.

Intergovernmental organizations with a research scope that could be considered for a new role to foster research integrity are the OECD GSF, for all disciplines; and discipline-specific organizations such as CERN; EMBC; the European Southern Observatory (ESO); and the European Space Agency (ESA). In Chapter 5 we analyse EMBO as an example of an international scientific organization that could assume such a role.

A non-governmental organization (NGO)

A non-governmental organization can be structured as a collaboration at the national or international level. NGOs are independent of governments and usually non-profit, with different missions, e.g. educational, humanitarian, environmental, human rights, or scientific. Generally easier to

establish than IGOs, NGOs can be founded on different kinds of agreements, from a memorandum of understanding to a formal contract. They can be based in one country, distributed in different countries, or constitute an informal member network with no headquarters. Their members can be individuals or groups, including universities and research centres, funders, and journals. Examples of international organizations with a research scope that might be useful to consider for hosting an international body focused on research integrity are the International Science Council (ISC), COPE, Science Europe, PubPeer, the World Conferences on Research Integrity, and ENRIO. See Chapter 5 for an analysis of the pros and cons of associating a new structure to an international non-governmental scientific organization.

However, NGOs can present disadvantages, depending on how they are structured. They are no less prone to conflicts of interest than organizations built on other principles: for example, they might provide information and analysis on issues in which they have a vested interest. An example of this is the involvement of patients' organizations in the technology assessment of medicines and treatments manufactured by companies that also fund the organizations (Mandeville et al., 2019); another example would be an organization that opposes genetically modified (GM) food funding studies on the effects of GM feed on animal health. The legitimacy of an NGO might be questioned, in particular if it is structured as an informal network. Financial sustainability is also a challenge, with the country hosting the organization often bearing most of its costs. Funding may come from member fees, but it might be problematic to collect fees or to increase them when necessary.

In conclusion, to establish a European body dedicated to ensuring integrity in research, it would be easier to create a new NGO or to affiliate a new body with an existing international organization, than to establish a new intergovernmental organization. In either case a potential risk of conflict of missions would need to be taken into account.

4.2 Potential role: Investigatory, oversight, advisory, platform for information exchange

We analysed four possible roles for a European body: investigative, oversight, advisory, and an internet platform for information exchange.

Stipulations

For the effective functioning of any pan-European body, we stipulated that: it be granted sufficient authority over institutions; that its operating procedures be agreed upon by all their members; and that it receives sustained and substantial resources.

Investigative role

As discussed in the previous chapter, some countries (e.g. Denmark or Austria) have established independent national bodies responsible for investigating research misconduct. Other countries, such as the US or Canada, have structures within governmental funding agencies to oversee the investigations conducted by institutes. A supranational or international body with the mission of investigating research misconduct does not exist. There are a number of international groups, private companies and individual researchers that provide services to institutions before or during investigations (Abbott, 2019), but these services mainly entail analysing images in published articles or plagiarism detection.

An internationally coordinated body could be established in Europe to investigate research misconduct on behalf of universities and research performing organizations, and also potentially for funders and journals. This body's responsibility would be solely to establish the facts and report them to the institutions. Because there is no international law on research misconduct, institutions would retain authority to decide possible sanctions or other reactions in response to the findings of the international investigative body. This body could analyse materials and data provided

by institutions (e.g. lab notebooks, published articles, images) and produce a summary of its findings, on the basis of which the institutions would decide how to follow up.

Advantages

An international body would bring homogeneity and coherence to the handling of allegations in Europe, because it would follow standard, agreed procedures. Currently, the variety of systems used, or their absence, leads to inconsistency in the treatment of alleged cases and undermines trust in the processes used. The principles stated in "The European Code of Conduct for Research Integrity" (ALLEA, 2017) could form the basis for the functioning of this body.

An international investigative body would be particularly helpful in cases where misconduct is alleged in international research collaborations, and when accused researchers move between different institutes and countries. Collaborative and international research has become the norm, but the responsibilities for investigating allegations of misconduct are rarely stated in the contracts establishing collaborations, if such contracts exist at all. A supranational body could be tasked to take on that responsibility. Such a body would be particularly helpful for institutions with no experience or mechanisms in place to deal with investigations. A number of cases in the past have demonstrated that *ad hoc* reactions do not always lead to good results, so rather than investing efforts in developing new procedures, institutions with no experience could instead turn to this body for assistance in investigations.

A substantial advantage of a centralized investigative body is that it would be independent of the affected institutions, and thus able to work objectively; this would lower the risk of conflicts of interest compared to local and national investigative committees. Its independence would also engender trust, so that individual researchers could report allegations without fearing retaliation and negative repercussions for their careers.

A centralized institution with professional staff would develop broad expertise from dealing with many cases. It would also be able to collate information about different cases, which, if they were allowed to be made public, would be an important resource for institutions. As noted in Chapter 3, this contrasts with local committees, which often lack experience and professionalism.

Disadvantages

Challenges to the establishment of a supranational body with an investigative role were also identified. Institutions are often reluctant to expose internal problems related to their employees, for fear of reputational damage or losing autonomy and support. The scrutiny of an international body might attract public attention, so institutions might not want one involved in their investigations. A common argument against outsourcing investigations to an external body is that problems should be dealt with locally, because local institutes have direct access to data and materials and are familiar with local structures and habits. Another possible disadvantage is that a centralized body would lack familiarity with internal procedures of individual institutions, which might slow down or hinder investigations. In some countries, institutes might be prevented by law from providing access to researchers' data, in particular as the General Data Protection Regulation applies to all EC member states; this would preclude an external investigative body from analysing all relevant data.

Another possible if unintended consequence of a central body is that it would deprive institutions of a learning experience. Being confronted with allegations can be an opportunity to rethink or revise policies, procedures and structures, such as institutional policies on authorship, conflicts of interest, supervising, and infrastructures and policies for data sharing. Delegating the investigative process to an external body might prevent problems from being revealed to the institutional leaders. Moreover, local institutions may be tempted not to expend efforts to address misconduct, but instead abdicate their responsibilities to the centralized body. However, these concerns

could be mitigated if the institutes were open to working with the centralized body to understand and correct institutional weaknesses.

A further concern is that such a body could not handle the volume of cases, and therefore could not complete investigations in a timely manner. The problem of capacity was highlighted in some examples of centralized systems at the national level, in particular in large countries like the US, but also in countries with smaller research communities, like Canada or Austria.

Policy questions

One policy question is what this central body would investigate: only cases of FFP, or also cases of QRP (for examples of QRP see Box 2, page 2). As discussed in Chapter 1, all research misconduct detracts from the quality of research, and QRP are much more prevalent than FFP. Yet, in most cases only FFP is investigated formally. Whether an international body could be tasked with handling all kinds of breaches of good research practices, or only a subset of them, would need to be discussed.

A further policy question relates to which procedures an international investigatory body would follow. Procedures differ substantively in different countries, and reaching consensus would be difficult. The principles stated in "The European Code of Conduct for Research Integrity" (ALLEA, 2017) or a similar statement of principles could form the basis for the functioning of this body. It might be useful, however, for a new body to devise its own principles: to ask, in the current research landscape, what is the best working procedure that respects the potentially conflicting interests of all parties involved?

Oversight role

Another possible role for an international body is to review investigations conducted by institutions to ensure that they follow appropriate procedures. Canada's SRCR and PRCR have such a role, reviewing institutes' reports on their investigations to ensure that breaches of research integrity are followed up according to federal agency requirements; the ORI in the US reviews institutional investigations of research misconduct in Public Health Service (PHS)-funded research. Institutions could request to have their investigations reviewed and certified by this body to restore or maintain trust; or funders and governments could require that institutions use it to ensure that investigations are conducted according to their recommendations or policies.

Advantages

An international body with an oversight role would help ensure the quality of investigations, and might provide an incentive for institutions to conduct good investigations or advance their efforts. Independence from local committees or agencies would reduce the risk of conflicts of interest. At the same time, this body would be seen as respecting the principle of universities' self-regulation more than an investigative body, by leaving the responsibility for investigating to local institutions. By reviewing investigations from different countries and institutions, an international oversight body would develop expertise on different systems and best practice.

Disadvantages

A potential challenge would be to make an institution re-investigate a complaint if it found the original investigation lacking. Investigations are time consuming, and institutions would be reluctant to start a process anew. This would prolong the time needed to conclude investigations. A European oversight body would have to define which procedures institutions should follow in conducting investigations. One option could be to ensure that investigations were conducted according to the procedures of the country where the institute is located, if they exist.

Advisory role

A European body could be established to support institutions in their investigations, advising on all phases from when an allegation is received to communicating the results of the investigation. Such a structure has been proposed as a way to promote international standards of research integrity.

A European advisory body would not substitute for existing national and local structures or committees, but would complement them; it could function as a focal point to collect and share best practices, and when requested, advise on national and international regulations. It could give practical advice on which institutional structures and policies could be implemented in response to allegations, keep a list of international experts who could be involved in investigation committees, or facilitate the communication between different stakeholders. As presented in Chapter 3, a number of countries have national advisory bodies, but there is no international advisory body.

Advantages

A central advisory body at the European level would facilitate consistency and coherence in the handling of research misconduct allegations. Its independence from local committees would confer objectivity, reducing the risk of conflicts of interest. Such a body would likely be accepted more easily by institutions than an international investigative body, because it would not interfere with countries' sovereignty or institutions' authority over their employees. It also would not clash with national regulations, such as the regulation of data sharing. Moreover, a central body would be able to gain more expertise than national or local advisory bodies, in particular on how to handle concerns or allegations in international collaborations or when a researcher moves between countries. Finally, it would facilitate interaction and sharing of best practice among national structures.

Disadvantages

A possible disadvantage of an international advisory body is that it could lead to duplication of effort if a national agency already exists, and problems could arise if both bodies were asked for assistance and gave conflicting advice. Moreover, a central body to advise institutions in different countries could be easily overwhelmed by a high number of requests, a similar concern raised in relation to an international investigative body. See Chapter 4.4 for a discussion of funding options.

Platform for information exchange

An internet platform to collect and disseminate information on guidelines, codes and definitions, procedures and best practice, and closed cases across Europe would be a useful resource to help promote a more coordinated international approach to research integrity. Such platforms are sometimes called clearinghouses. A number of platforms of this type exist. For example, at national level, the ORI website includes a list of closed misconduct cases in the US, as well as information on policies and guidelines, among others. In Europe, the ENRIO (2020) website is an example of an online information resource on how integrity and misconduct are handled in European countries. The Embassy of Good Science (2019) was launched within the EC-funded EnTIRE project. Although currently not focused specifically on investigations of research misconduct, it uses a Wiki approach to engage the research community in mapping laws, policies and guidelines; highlighting relevant cases, educational materials and best practices; capturing the outputs of other relevant EU projects; and supporting the development of training materials on research integrity and ethics.

An example of a global platform for exchanging information, in an area not related to research integrity, is the Clearing-House Mechanism of the Convention on Biological Diversity (2020), which was created to facilitate implementation of the Nagoya Protocol on Access and Benefit-Sharing.

Advantages

An international internet platform would be useful, in particular for countries and institutions with limited knowledge or experience. By engaging the research community, it might encourage and support research integrity, while raising awareness of existing problems.

Disadvantages

A website platform lacks any authority to effect change. It would not provide confidential advice about specific situations. As well, such platforms need to be updated and maintained regularly to ensure that the content is coherent and of high quality.

4.3 Potential domain: Scientific organizations, law enforcement organizations, labour organizations

We analysed three sectors in which a European body could be made functional, to understand in which domain one would be most effective: international scientific organizations, law enforcement, and labour. In principle, such a body could exist in any of these domains, allowing those seeking advice or redress to approach their preferred sector.

International scientific organizations

Existing international scientific organizations would seem to be well placed either to provide an advisory or investigative role directly, or to host and support a quasi-independent organization. Examples of such international scientific organizations are EMBO, ESA, the European Physical Society, or CERN.

The main advantages of an international scientific organization taking on an investigative, advisory or oversight role in research integrity issues would be access to subject matter experts through its membership, knowledge of the research system, and a complementary mission. Being trusted by researchers and the public would give it the authority to take on these roles. Because of its political support, an intergovernmental scientific organization would be more authoritative than a non-governmental organization. Finally, an international scientific organization by definition would facilitate international and cross-institutional information sharing.

Among the concerns expressed about scientific organizations, in particular if taking on an investigative role, is that fear of negative publicity could hamper their objectivity in investigations, especially because members of such organizations are often established researchers. Moreover, many scientific organizations serve specific disciplines, so their remit would be limited to a specific area, while challenges to research integrity are present in all areas.

Initially a single-discipline specific organization could take the lead in its field, and in a second phase other subjects might be included within its remit, or other discipline-specific organizations could take on an equivalent role for their disciplines.

Law enforcement organizations

The singular advantage of existing international law enforcement organizations such as Interpol or the European Court of Justice is their experience with investigations. If the only remit of a supranational body is to provide thorough analysis and annotation for non-expert use, then the investigative arms of law enforcement could be utilized.

However, the optics of a police body investigating misconduct in research would likely undermine trust in the research system, as it could imply that all breaches of research integrity are crimes and should be prosecuted in the legal system. As presented in the previous section, one of the disadvantages of systems with a legal framework is that they push scientific issues into legal disputes, complicating the process and preventing a fast correction of the scientific record. Depending on the nature of the agency, it could be difficult for a law-focused agency to understand the underlying scientific issues and how research is

carried out. Thus, only agencies already knowledgeable about the subject area would be able to conduct such investigations. Alternatively, if this option were seen as otherwise useful, agencies could hire subject matter experts.

Labour organizations

A different way to approach oversight is to think of research misconduct as a labour policy issue. After concerns about the research record, the next significant concern is how misconduct may destroy careers or professional reputations. How to sanction misconduct in the workplace generally has been extensively discussed (Keränen, 2006). The underlying tension between protecting the employee in question, protecting other employees, and protecting the institution remains unresolved. Discussions on this would need to be extended to take into account the specifics of research misconduct.

One obvious forum both for these discussions and potentially for the placement of a supranational body to advise on or investigate research misconduct is the International Labour Organization (ILO), an agency of the United Nations that sets labour standards and develops policies and programmes promoting decent work. ILO produces reports and runs a database about labour laws, standards, policies and statistics. An advantage of labour organizations is that they are generally respected and listened to by governments, and they seek to protect all employees.

However, a labour organization might focus on the human, personnel aspect (the employee), rather than on the research issue (research output) that needs to be corrected. Furthermore, labour organizations may be perceived as siding with employees and being adversarial to management.

4.4 Options for funding

We briefly looked at how an international organization could be funded, and identified the options discussed below. For all options, the funding should be preferably substantial and sustained.

Governmental fees

This would apply to the funding of an intergovernmental organization. The fee could be based on the number of researchers in a country, or the country's GDP or other economic indicators. An advantage of this system would be that fees would be defined in the treaty or contracts establishing the organization and need not be renegotiated every year. A disadvantage of this system, should it use the number of researchers in a country rather than GDP, might be that it would significantly disadvantage low- and middle-income countries with poorly paid researchers.

Member fees

In this model, each member pays a fee. The NASEM report "Fostering Integrity in Research" (NASEM, 2017) suggests that fees for the recommended Research Integrity Advisory Board in the US should be proportional to the size of the institutes. A disadvantage of this method could be that institutions might be slow to pay their contributions, and would be reluctant to increase them, so it would be difficult to increase the available budget if needed. Considerable thought would need to go into how fees are calculated so as not to disadvantage institutions in lower income countries.

User fees

A fee is paid for each service provided. A disadvantage of this business model is that institutions with a tight budget might not be willing to invest in this kind of service. Moreover, a fixed budget for staff and basic infrastructure would be needed.

Seed money

Another option would be to start with seed money from a philanthropic organization for a limited period of time (e.g. five years), evaluate the efficacy of the project, and if judged positively, move to a more sustainable kind of organization, e.g. an international organization financed by member fees.

Financial support by the European Commission

The advantage of financial support from the EC is that funding would be sustainable, and possibly substantial. Moreover, fees would not need to be renegotiated frequently. Among the disadvantages is that the EC would require approval of all Member States, a lengthy and difficult process; moreover, it is possible that only research projects funded by the EC could make use of this structure.

Chapter 5. Options for implementing specific mechanisms

Having examined different bodies to improve coordination in promoting research integrity and fighting research misconduct in Europe, we considered several options for implementation. We analysed the potential advantages and disadvantages of different agents that could take on the task of establishing each body.

We focused on the agent because its identity may influence how the task is carried out, whether the implementation is an improvement from the current situation, and how acceptable the agent is to stakeholders — researchers, institutions, governments and society. Specifically, we looked at four options:

- An international body established by a European scientific organization
- An international body established by a European funder, or a group of funders
- An international body established by an NGO
- An international body established by a private entity

All the agents that we considered as examples would need substantial funding to be able to take on any new role, would need to be granted enough authority to be able to carry out their task, and strong governance and transparency would need to be part of a solution to concerns about conflict of interest.

5.1 An international body established by a European scientific organization

As we discussed in Chapter 4.1, establishing a new intergovernmental organization is a lengthy process; it would be easier to affiliate a new body with an existing international organization.

There are a number of international scientific organizations in Europe, focused on different disciplines, such as EMBO, EMBL, CERN, or ESO.

EMBO

To understand the advantages and disadvantages of a European scientific organization taking on a role in investigating, advising or overseeing

institutions' efforts to address allegations of research misconduct, we examined EMBO as an example. EMBO is an organization of more than 1800 elected leading researchers. EMBO promotes excellence in the life sciences in Europe and beyond by supporting researchers at all stages of their careers, stimulating the exchange of scientific information, and helping build a research environment where scientists can achieve their best work. It is funded by an intergovernmental organization (EMBC) comprising 30 Member States. The EMBO secretariat is based in Heidelberg, Germany, and comprises about 30 full-time staff members.

EMBO has its own procedures to evaluate allegations of research misconduct by its members, grantees and awardees. Allegations from any source, including from anonymous individuals or administrative officials in institutions, are first considered by the EMBO Director. Well-founded allegations are evaluated by an *ad hoc* committee, composed of EMBO members and assisted by EMBO staff. Not having direct access to data and other information held at researchers' institutes, EMBO bases its evaluations on the information received in grant and award applications and membership nominations, and publicly available information.

EMBO has in-house expertise in analysing allegations also through the work of the staff at EMBO Press, which publishes five scientific journals. EMBO Press has its own revenues and it is not funded by EMBC. Concerns and allegations related to EMBO Press journals are handled by EMBO Press editors and a data integrity analyst, who have access to the images and data that authors submit with their manuscripts.

Through its science policy staff, EMBO has been engaging its scientific community through the delivery of workshops on research integrity in research institutes in EMBC Member States. These are discussion sessions on a range of research integrity issues, including on researchers' and institutional responsibilities, cases of misconduct, conflicts of interest, emerging policy issues in data management and scientific publishing, and on the supervision of lab members. These workshops are organized in close collaboration with EMBO Members.

Advantages

- EMBO has direct access to a wide pool of active researchers in the life sciences—its members—to draw on their subject matter expertise and knowledge of the research enterprise.
- EMBO is an established organization that is respected and trusted by the life science community.
- EMBO is supported by a non-governmental organization (EMBC), and would therefore have legitimacy and authority to act in all its 30 Member States.
- As an international organization, by definition EMBO would facilitate international and cross-institutional sharing of information.

EMBO has a dedicated and functioning secretariat, although additional staff and resources would be required to be able to take on any new role.

All these aspects of EMBO would streamline the investigation process if EMBO would take on an **investigative role**, and would facilitate overseeing and reviewing institutional investigations if EMBO would take on an **oversight role**.

In particular, in the role of an **investigative body**, knowledge exchange between EMBO Press staff and EMBO staff could happen. This would be useful in the initial stage of the establishment of an international body. Subsequently, the investigations carried out by EMBO and EMBO Press would have to remain clearly separated to maintain confidentiality.

As an **advisory body**, EMBO could provide expertise both on specific scientific issues in dispute, and in general about research integrity, drawing on the experience and knowledge of its members and its staff.

Disadvantages

- EMBO is focused on the life sciences, so its remit would be limited to this scientific area.
- EMBO might be seen as representing the interests of its members and its scientific area, the life sciences, and therefore not neutral. This would particularly be problematic in an **investigatory** or **oversight** role.

As mentioned above, the current capacity of the EMBO secretariat would need to be increased to support the organization carrying out these new tasks. Moreover, the involvement of EMBO Members in the EMBO activities is voluntary, and they might not be able to take on additional tasks.

5.2 An international body established by a European funder or a group of funders

Private and public funding agencies are powerful players in the research enterprise. They enable the wide range of research carried out worldwide and shape the research system by attaching conditions to grants and adopting appropriate internal policies. They can also have a powerful role in fostering good research practice and fighting misconduct. In Chapter 3, we analysed examples of national bodies established by national funders to investigate research misconduct in their funded research projects and to review investigations carried out by institutions. Other national funders require or encourage grantees' institutes to develop policies and structures to handle investigations. Funders have the authority to ensure that their mandates and requirements are followed because they can impose sanctions on researchers and institutions who do not comply.

However, it is unlikely that one single national funding agency or international funding programme, such as the Human Frontier Science Program or the European Commission's Marie Skłodowska-Curie Actions, would be able to set up a European investigative body. It would lack the political mandate, and would have authority only over the researchers and institutions it funds. Potential bias towards protecting their own grantees would also be an issue. Rather than an individual funder, a network or group of funders could take on the role of establishing a European body for research integrity and misconduct.

We considered the EC as an example of a European funder that could take on the role of establishing a European body for research integrity and misconduct.

The European Commission (EC)

The European Commission, through the EU Framework Programmes for Research and Innovation, is the largest public funder of research in Europe, and the only one encompassing all disciplines. The current EU framework programme, Horizon 2020, has a budget of about 77 billion euros, including more than 13 billion euros for the European Research Council (EC, 2020). The upcoming framework programme, Horizon Europe, has a proposed budget of nearly 100 billion euros.

Horizon 2020 addresses research integrity through the Horizon 2020 Regulation, the Horizon 2020 Grant Agreement and the Budgetary Regulation. The strong focus on the prevention of breaches of ethical principles in research complements the internal procedures on addressing "fraud and irregularities", including the establishment of panels of experts on research misconduct that review cases that arise during Horizon 2020 project implementation. This process is in addition or in parallel to whatever actions the beneficiaries' institution must undertake. "The European Code of Conduct for Research Integrity" (ALLEA, 2017) has been adopted as the reference document for all EC-funded research projects.

Within Horizon 2020 the EC has funded many different projects under the Science with and for Society (SwafS) programme to prevent misconduct in research, foster sharing of best practice between European countries, develop guidelines and standard operating procedures, and develop training in research integrity. The ERC has also had

a strategy for detecting and addressing research misconduct since 2012. A Standing Committee on Conflict of Interests, Scientific Misconduct and Ethical Issues (CoIME) is responsible for developing guidelines and investigating misconduct related to ERC grants if an allegation is brought directly to the attention of the ERC. In this case, CoIME assesses the allegation and communicates its opinion to the ERC Executive Agency Director, who takes the final decision. In Horizon 2020, possible follow-up actions include excluding a proposal from evaluation, suspending or terminating grants, recovering the budget or requesting that measures be taken by host institutions.

Advantages

- The EC has political mandate to act in its 27 members states.
- The EC would have authority over many national research institutions receiving its funding.
- The EC has stable resources.
- The EC has access to a large pool of international experts in all research areas.

Any structure established by the EC, whether with an **investigatory**, **oversight** or **advisory role** would benefit from these aspects.

Disadvantages

- The EC has authority only over its direct funding, which covers five percent of all European publicly funded research, so most research in Europe would not benefit from it.
- The governance of an intergovernmental organization can become complicated, especially if many states are involved; and such an organization may be inflexible, as governments tend to resist change.
- Member states are unlikely to give up sovereignty rights on ethics and research integrity, so an **investigatory body** set up by the EC will not be able to carry out its function.

An **advisory body** set up by the EC, with no investigatory or legal power, but focused on giving advice to governments, institutions, and potentially individual researchers, would be more easily accepted by countries and institutions than an investigatory or an oversight body, as it would not interfere with countries' sovereignty rights or institutes' autonomy. It could advise not only institutions receiving EC funding, but all institutions in Europe.

Rather than establishing its own **internet platform** for research integrity and to fight research misconduct, the EC is funding The Embassy of Good Science (2019), launched within the Horizon2020-funded EnTIRE project. Its aim is to engage the research community in mapping laws, policies and guidelines; highlighting relevant cases, educational materials and best practices; and supporting the development of training materials on research integrity and ethics.

5.3 An international body established by an international NGO

As discussed in Chapter 4, there are a number of international non-governmental organizations (NGOs) in Europe that are active in fostering research integrity. To understand the potential advantages and disadvantages of an international NGO establishing a body for research integrity and misconduct, we used the Committee on Publication Ethics (COPE) and ESF-Science Connect as examples.

The Committee on Publication Ethics (COPE)

Established in 1997, COPE is a multi-disciplinary, international non-profit organization based in the UK with more than 12,000 members worldwide. COPE's mission is to define best practice in scholarly publication ethics and to assist its members to achieve it. Its members are mainly scholarly journal editors and publishers, who support the organization through member fees. Member journals worldwide have adopted COPE's guidelines on how to address a variety of ethical issues, from dealing with plagiarism, to defining conflicts of

interest, and retracting published articles. Through its website, COPE also provides resources, case studies, and information for journal editors. The COPE team includes seven employees and freelancers who support the activity of the organization.

Advantages

- COPE has experience in analysing misconduct and bad practices in relation to research publishing in all fields of research, so it would be able to assume an **investigatory or oversight role**.
- Recently, COPE has committed to enlarge its membership beyond journals and editors to include academic institutions (COPE, 2019), so it could expand its remit as **investigatory, oversight or advisory body** to include them too.
- COPE has a degree of authority in the research integrity community, and is mentioned in a number of reports and articles as a good example of international collaboration in research integrity (NASEM, 2017; Resnik, 2009).
- The COPE website already contains resources, which could be expanded to include more information and guidance for institutions to become an **international clearinghouse or exchange of information platform**.

Disadvantages

- In particular in an investigatory role, COPE might be viewed as representing scholarly journals' interests and therefore as not being objective.
- COPE does not have direct access to researchers or institutions, and lacks the authority to demand data or other information that would be necessary for an investigative role.
- At least at the time being, its remit is limited to journals.

The current capacity of the COPE team secretariat would need to be increased to support the it carrying out any new task. A further concern is that most COPE committee members are volunteers; they might not be able to take on additional tasks at present.

The European Science Foundation (ESF)

ESF is a non-profit association of 10 research organizations that is committed to promote quality in research in Europe. It was created in 1974 as a coordinating body for the main European funding agencies and research performing organizations across all research disciplines. ESF played an important advisory role through its early work on research integrity and scientific misconduct (ESF 2000, ESF 2008, ESF-ALLEA 2011, ESF-ORI, 2007, ESF Member Organisation Forum, 2010. With its restructuring in 2016, ESF has assumed a new direction and role, and closed its research support activities. Its expert division "Science Connect", created in 2017, provides support services including management of European projects, evaluation of research grants, and evaluation of scientific institutes. ESF-Science Connect has a network of 300,000 international scientific experts from all disciplines who act as evaluators of grant proposals and take part in other peer review activities on behalf of the organization's partners. Their work is supported by a team of 32 individuals, who work from a secretariat based in Strasbourg, France. ESF-Science Connect is also hosting five scientific platforms, which consist of scientific committees or operational offices set by research institutions without the need to create a legal structure. As an example, ESF-Science Connect hosts and operates the office of the cOAlition S initiative aimed at making all research publications Open Access.

Advantages

- ESF-Science Connect can draw on the expertise of its broad network of international scientific experts from all disciplines, who could be involved in

evaluating or reviewing research misconduct allegations for institutions.

- ESF-Science Connect could draw on its previous work carried out in the area of research integrity and advise institutions on how to handle allegations and investigations.
- ESF has an operational secretariat that could support any new task taken up.

Disadvantages

- ESF's business model, through a "hosting platform" approach, EC funding, partnerships and member organizations' fees might lack clarity about the ownership of the activities carried out.
- Previous ESF members who took part in its research integrity activities are not involved in ESF-Science Connect, so the organization would need to regain the confidence of some stakeholders in this area.

5.4 An international body established by a private entity

A number of consultancies, such as Image Data Integrity or the services provided by Elisabeth Bik in the USA, and Resis (Research Integrity Solutions) in Italy, provide paid services to universities or funders for image and statistics checking and detection of plagiarism in published and unpublished papers. Institutes have employed these companies to assist in individual misconduct cases, and more recently, to screen their researchers' manuscripts before they are submitted to journals (Abbott, 2019). In principle, any such firm could be tasked with an investigative role and become a central service provider to institutions wishing to have allegations against their researchers evaluated and investigated.

Advantages

- These consultancies have full-time staff who are experts in and dedicated to analysing reports of scientific projects, so they might work better and faster than an *ad hoc* local committee.

Disadvantages

- The for-profit nature of these firms is a concern, in particular the idea of turning the investigation of research misconduct into a business.
- Institutions that are unwilling to investigate their own researchers would not want to invest money into hiring such firms.
- Institutions that would like to use these firms' services might not have the resources, the consequence being that these firms help only willing and wealthy institutions.
- The service provided by these companies is limited to checking images, plagiarism and statistics in publications. However, institutions also need support with conducting interviews, sequestering material and reporting findings, among other tasks.
- Finally, the trustworthiness of private companies would need to be established by all parties involved in their use.

Chapter 6. Other mechanisms: Coordination of procedures

A more coordinated approach to the handling of allegations of breaches of research integrity in Europe also could be reached by other mechanisms than the creation of an international body, such as:

- The coordination of procedures used by research performing organizations across European countries
- The coordination of procedures used by funders across European countries
- The coordination of procedures used by publishers

Coordination of procedures used by research performing organizations across European countries

As noted in Chapter 1, the idea of coordinating the approaches to foster research integrity and prevent misconduct in European institutions dates back to the early 2000s (ESF, 2000; ALLEA et al., 2003). However, concerns about sovereignty rights and "each nation's unique legal and administrative systems" (Boesz and Lloyd, 2008) derailed attempts to develop one set of procedures or guidelines that could be used in different countries. Rather, efforts were then focused on identifying a set of general principles to guide countries in developing their own policies and structures for the governance of research misconduct (Boesz and Lloyd, 2008), and resulted in "The European Code of Conduct for Research Integrity" (ESF-ALLEA, 2011; ALLEA, 2017). The heterogeneity of approaches and procedures used in European countries is a reflection of this (see Chapter 3).

This situation is not likely to change. However, we carried out our analysis to identify the pros and cons of developing a homogeneous system with common procedures in Europe. This might be helpful for countries or situations where governance structures are just developing.

The advantages of developing a single European system are obvious. Similar cases would be handled consistently all over Europe, bringing fairness to the handling of cases; transparency in the process would be ensured; and conflicts of interest would be reduced, as standard and agreed upon procedures would have to be followed. Moreover, the handling of cases involving international research groups, or researchers moving across different countries, would be much better facilitated.

The major difficulty in developing a homogeneous system across European countries would be determining which approach and procedures should become the standard. An option would be to produce new ones, but that would be redundant, as a large number of guidelines have been produced already. Which actor would decide on and enforce the adoption of standard procedures would have to be discussed and agreed on by all stakeholders involved.

Finally, the point was made that for coordinated procedures and guidelines to be implemented effectively, they would have to be associated with a central agency or a structure with staff available to directly advise those responsible for their implementation.

Checklists for members of investigation committees

Rather than coordinate all procedures for dealing with breaches of research integrity, international checklists could be produced for members of investigation committees, to ensure that at least all appropriate steps in an investigation have been followed. A limited number of these lists have been produced (Gunsalus et al., 2018; APRIN, 2018; ENRIO, 2019).

The advantage of such checklists is that they would ensure thorough investigations and facilitate investigation committees' working according to agreed upon steps and principles. Although that is not the only component of a complete procedure to deal with allegations, checklists would improve an important aspect of handling allegations of misconduct. However, awareness of the existence of such lists and their use needs to be fostered.

Coordination of procedures used by funders across European countries

Public and private funders impact research and researchers' careers, not only by enabling research to take place, but also because their goals and selection procedures determine what kind of research is conducted. By attaching conditions to grants, funders have the power to change institutes' and researchers' behaviour.

An increasing number of European funders have been using their influence to address directly the topic of research misconduct. For example, the German Research Foundation, Wellcome Trust and Health Research Board Ireland, require or encourage grantees' institutes to develop policies, structures or procedures to handle allegations of research misconduct. To increase awareness of the values and rules of responsible conduct of research, EMBO requires its Long-Term Fellows and Young Investigators to take training in responsible conduct of research, and provides them with an online course that can be used to meet the training requirement. More funders could follow and expand this set of requirements.

Coordinating requirements across funders would incentivize all institutes to act on breaches of research integrity, as funding would be linked to compliance, and it would make institutions' responses more coherent. Moreover, the establishment of procedures would likely become standard.

At the same time, the scientific community might perceive funders' mandates as a further bureaucratic burden and limiting scientific freedom, so institutes might be resistant to comply with them. Because funders do not want to burden an already stretched research community by imposing new requirements, they might not want to monitor compliance, and so no effect of this approach might be seen. And even if a funder would want to monitor compliance, depending on the size of the funder, this would be a burdensome task. Science Foundation Ireland is one example of a funder that is auditing institutes' policies (SFI, 2017).

Funders could also coordinate their internal procedures and policies, i.e., procedures to deal with breaches of research misconduct committed by researchers they fund. However, some funders might not be willing to investigate their own researchers, out of fear of damaging their own reputation or damaging the grantee's career or because of lack of resources internally. And in general, different funders have different goals, so they might be unwilling or unable to coordinate their policies with funders that have different goals.

Coordination of procedures used by publishers

Publishers and journal editors work at the end of the research process: they receive the results of a research project that has been approved by a funder, sometimes by institutional and funders' ethical committees, and that has been conducted and then summarized in narrative form by a researcher or group of researchers. It is mostly at the end stage of the research process, either after an article has been published or during the review process, that irresponsible research practices or misconduct are detected. Journal editors have thus assumed an important role in understanding what happened, as well in making sure that research results are corrected or eliminated from the research record.

Coordinating procedures that journals have developed to deal with suspected or proven research integrity breaches would contribute to a more coordinated approach internationally. A number of guidelines and recommendations have been developed to deal with problems detected in manuscripts or published articles. Many jour-

nals and a number of funders have adopted COPE guidelines for editors, peer reviewers and researchers, which address a variety of ethical issues. The ICMJE developed "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" to help authors, editors, and others involved in peer review and biomedical publishing create and distribute accurate, clear and reproducible, unbiased medical journal articles (ICMJE, 2019). The recommendations are widely used by editors of different journals, and could be adopted even more widely.

These are excellent examples of coordination of efforts, which could be expanded to include more publishers.

EMBO and colleagues have analysed the communication between journals and research institutes (Wager et al., 2017). A similar effort is needed to analyse the benefits of more coordination in communication between journals and funders. Currently, journals rarely communicate with funders about breaches of research integrity. Sharing this information might help funders to judge more carefully whether a researcher should be funded, or whether funding should be stopped for a research project that has proven faulty. However, such communication should happen only if misconduct is proven, or a paper has been retracted because of misconduct, and a funder was acknowledged in the paper. Communication should not happen merely on the basis of an allegation, as otherwise a funder's decision might be taken before the facts have been established.

Chapter 7. Conclusions

The approaches and systems to foster research integrity and address misconduct adopted in individual European countries are heterogeneous, and some countries still do not have any systems. This diversity creates incoherence in the treatment of cases, and obstructs the handling of allegations involving international research projects or researchers moving between countries. An effect of this is that the correction of the published research literature is hindered.

With this project EMBO wanted to analyse whether the establishment of a European body with four potential functions might contribute to improving the integrity of research and to meeting the challenge of handling cases of research misconduct. The aim is to provide information and contribute to protecting the quality, validity and reliability of research results, and the public's trust in research.

A European investigative body

A European body with an investigative role would ensure a higher degree of coherence, objectivity and professionality in the handling of investigations, than those currently done mainly with institutional *ad hoc* committees. In particular, it would facilitate inquiries and investigations in cases involving international collaborations. However, the implementation of a body at a supranational level could be perceived as limiting research institutions' autonomy or countries' sovereign rights.

A European oversight body

A European oversight body could be tasked to review investigations conducted by European institutions to ensure that they followed appropriate procedures. Receiving the approval of such a body might incentivize institutions to advance their investigative efforts. It would be seen as respecting

the principle of universities' self-regulation more than an investigative body, by leaving the responsibility for investigating to local institutions. At the same time, repeating an original investigation that was found lacking would be difficult and prolong the time needed to conclude investigations.

A European advisory body

A European advisory body, with no investigative role, could support European universities and research performing institutions in all issues related to research integrity and misconduct. It could give practical advice on which institutional structures and policies could be implemented in response to allegations, keep a list of international experts who could be involved in investigation committees, or facilitate communication between different stakeholders. It would not substitute for existing local or national structures or committees, but complement them. A possible disadvantage of an international advisory body is that it could lead to duplication of effort if a national agency already exists, and problems could arise if both bodies were asked for assistance and gave conflicting advice.

A platform for information exchange

An internet platform, sometimes also called a clearinghouse, is useful to find information on guidelines, codes and definitions, procedures and best practice, but it cannot give direct and individualized support for a specific investigation. Such platforms exist already in Europe, so the development of a new one would be redundant.

Implementation

A number of international groups or non-governmental organizations that are already involved and engaged in fostering research integrity could play a role in establishing specific mechanisms. Examples include EMBO, the Committee on Publication Ethics (COPE), the European Commission (EC), the European Network of Research Integrity Offices (ENRIO), ESF-Science Connect, Science Europe and All European Academies (ALLEA). However, this additional activity would be resource intensive and, in many cases, would sit outside the current remit of these organizations, so might not be attractive to them.

European funders, including the EC can influence institutes' and researchers' behaviour through their policies and award conditions. They already play an important role in encouraging and mandating good practices among their grantees and host institutions. In the future, they could play a role in the establishment of a pan-European mechanism for research integrity by providing funding for it and mandating that institutions make use of it.

Open issues related to European mechanisms

The analysis uncovered some issues that would have to be addressed to establish a European mechanism.

- The definition of research misconduct varies in the existing systems in Europe. A taxonomy of specific research integrity breaches, whether fabrication, falsification and plagiarism (FFP) or questionable research practices (QRP) would need to be established to be used as reference by a central mechanism.
- The widely used definition of misconduct as FFP is limited and does not include a range of highly problematic practices, such as sloppiness in the recording and managing of research data; the use of inappropriate statistical methods; failure to report modification of images in publications; failure to supervise lab members; failure to acknowledge contributors to research results; failure to disclose conflicts of interest, and many more. A broadening of the definition would be necessary.
- How various codes of conduct, whether European, national, or institutional, could be applied would need to be considered.
- Working procedures would need to be established and agreed upon among countries.

› Whether a European body would cover all disciplines, or it whether separate bodies would be needed for the different disciplines would have to be discussed.

Gaps identified

Through the analysis we identified gaps that need to be addressed in understanding and addressing responsible conduct of research in Europe, to ensure appropriate responses to research misconduct as well as to maintain researchers' and the public's confidence in the research system.

Individual scientists and the scientific community:

1. It appears that a number of researchers do not acknowledge that breaches of research integrity, both serious misconduct and poor research practices, are a serious problem that jeopardizes the quality of scientific outputs and endangers the reputation of science.
2. Scientific rigour may not always be at the top of researchers' priorities.
3. Although some researchers are aware of poor research practices in their organization, they may not feel responsible for addressing them.
4. The desire to protect colleagues and friends can be an obstacle to addressing allegations and conducting investigations properly.
5. Correcting the scientific literature should take priority over establishing guilt. In some cases, this is hindered by researchers not agreeing to correct or retract articles when requested to do so by journals.

Universities and research institutions:

1. Heads of universities and research institutions might not always recognize the importance of developing policies and structures that prepare them to respond to allegations.
2. Procedures for handling allegations of research misconduct may not prioritize the correction of the scientific record, but rather focus on establishing innocence or guilt. Clarifying responsibilities can take a long time, but the scientific data must be corrected as soon as possible to avoid faulty research being used for further studies, or to develop therapies or drugs.
3. Procedures to handle allegations may not include policies on how to protect those who report suspicions, or the accused researchers.
4. Conflicts of interest of members of internal investigative committees may be a significant obstacle to investigations.
5. Not enough attention is paid to assessing and promoting institutional culture ("climate"), although good institutional culture is a key factor in fostering research quality and preventing research misconduct and poor research practices.
6. Training in good scientific practices is not generally available for staff at all levels.

General:

1. While nearly all definitions of research misconduct include fabrication, falsification and plagiarism, there is no general agreement about what constitutes questionable or poor research practices. The definitions in different international and national codes do not always align.
2. Policies need to be developed to balance confidentiality and transparency in conducting investigations and communicating their results to stakeholders and the public. The pros and cons of different current approaches should be analysed by appropriate experts.
3. Policies about communications between universities and research performing institutions, scholarly journals and funders when handling allegations are not well defined.

Acronyms

ALLEA All European Academies

CERN European Organization for Nuclear Research

COPE Committee on Publication Ethics

DFG German Research Foundation

EC European Commission

EMBC European Molecular Biology Conference

EMBL European Molecular Biology Laboratory

EMBO European Molecular Biology Organization

ENRIO European Network of Research Integrity Offices

ERC European Research Council

ESA European Space Agency

ESF European Science Foundation

ESO European Southern Observatory

FFP Fabrication, Falsification and Plagiarism

GSF Global Science Forum

ICMJE International Committee of Medical Journal Editors

KNAW Royal Netherlands Academy of Arts and Sciences

KVAB Royal Flemish Academy of Belgium for Science and the Arts

NIH National Institutes of Health

NSF National Science Foundation

NWO Netherlands Organisation for Scientific Research

OeAWI Agency for Research Integrity (Austria)

OECD Organisation for Economic Co-operation and Development

ORI Office of Research Integrity

PHS Public Health Service

PRCR Panel on Responsible Conduct of Research

QRP Questionable Research Practices

RCR Responsible Conduct of Research

RI Research Integrity

SRCR Secretariat on Responsible Conduct of Research

UNESCO United Nations Educational, Scientific and Cultural Organization

VCWI Flemish Committee for Scientific Integrity

VSNU Association of Universities in The Netherlands

WCRI World Conference on Research Integrity

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Appendices

Appendix 1 Biographies and institutional information

Sandra Bendiscioli

Senior Policy Officer, Science Policy Programme, EMBO

Alessandra (Sandra) Bendiscioli is a Senior Science Policy Officer at EMBO. She analyses policy implications in research integrity, scientific publishing, peer review and gender issues in science. She monitors developments in European research policies for the EMBO community. The main focus of her work is research integrity and in particular the systemic factors and policies that influence how researchers carry out their work. She was primarily responsible for the development of a series of workshops on responsible conduct of research, and presents these regularly for the EMBO community and more widely. She holds a masters' degree in Foreign Languages, Literature and Linguistics from the University of Pavia in Italy. After a period of research in Applied Linguistics at the University of Heidelberg in Germany, in 2001 she joined EMBO in the Science and Society Programme, where she was responsible for the organization of events to promote public understanding of science and foster discussions on the ethical aspects of scientific research. She joined the EMBO Science Policy Programme in 2011.

Michele S. Garfinkel

Head, Science Policy Programme, EMBO

Michele Garfinkel is Head of the Science Policy Programme at EMBO. Her major areas of policy research are biotechnology, responsible conduct of research, and scientific publishing. Previously she was a policy analyst at the J. Craig Venter Institute. Her research there focused on identifying emerging societal concerns associated with new discoveries in genomics, particularly synthetic biology. She was a research fellow at the Center for Science, Policy and Outcomes at Columbia University, and earlier was a research associate at AAAS. Michele holds a Ph.D. in Microbiology from the University of Washington, an A.B. from the University of California (Berkeley), and an M.A. in Science, Technology, and Public Policy from the George Washington University. She is an elected Fellow of the AAAS.

Institutional information

About EMBO

EMBO is an international organization of more than 1800 leading researchers that promotes excellence in the life sciences in Europe and beyond. Its major goals are to support talented researchers at all stages of their careers, stimulate the exchange of scientific information, and help build a research environment where scientists can achieve their best work. EMBO helps young scientists to advance their research, promote their international reputations and ensure their mobility. EMBO Courses, workshops, conferences and scientific journals disseminate the latest research and offer training in techniques to maintain high standards of excellence in research practice. EMBO helps to shape science and research policy by seeking input and feedback from its community and by following closely the trends in science. EMBO is funded by an intergovernmental organization, the European Molecular Biology Conference (EMBC), which comprises 30 Member States (embc.embo.org).

Appendix 2 Workshop and interview information

Governance of research integrity: Options for a coordinated approach

Workshop convened by EMBO in partnership with the OECD Global Science Forum

WORKSHOP AGENDA – EMBO, HEIDELBERG, 23 – 25 JANUARY 2019

DAY ONE, Wednesday, 23 January 2019

18.00 – 21.30	**Working dinner at the ISG Hotel** Moderators: **Sandra Bendiscioli**, Science Policy Officer, EMBO **Michele Garfinkel**, Head, Science Policy Programme, EMBO › **Welcome;** Introductions; Ground rules; Statement of work for the group

DAY TWO, Thursday, 24 January 2019

OPENING TALK

9.00 – 9.30	**Research Integrity: Issues and Options** Moderator: **Sandra Bendiscioli**, Science Policy Officer, EMBO › **Carthage Smith**, Lead Co-ordinator, Global Science Forum, Organisation for Economic Co-Operation and Development, France

SESSION I

9.30 – 11.00	**Examples of *successful elements* and *gaps* of *central systems* at *national level*** Moderator: **Sandra Bendiscioli**, Science Policy Programme, EMBO › **Nicole Föger**, Austrian Agency for Research Integrity, AT › **Kathrine Bjerregaard Nielsen**, Technical University of Denmark, DK › **Stephan Rixen**, The German Research Ombudsman, DE › **Susan J Garfinkel**, Ohio State University, USA › Discussion
11.00 – 11.30	**Coffee Break**

SESSION II

11.30–13.00 **Examples of *successful elements* and *gaps* of *non-centralised systems* (funders, universities, research centres, journals' perspectives)**
Moderator: **Carthage Smith**, Lead Co-ordinator, Global Science Forum, Organisation for Economic Co-Operation and Development, France

- **Isidoros Karatzas**, DG Research and Innovation, European Commission, BE
- **Claudio Sunkel**, Institute of Molecular Cellular Biology, PT
- **Stefanie Van der Burght**, Ghent University, BE
- **Bernd Pulverer**, EMBO Press
- Discussion

13.00–14.00 **Lunch**

SESSION III

14.00–15.30 **International effort: a coordinated structure?**
Moderator: **Michele Garfinkel**, Head, Science Policy Programme, EMBO

- **Maria Leptin**, Director, EMBO
  The experience of an international scientific organization
- Structured discussion

15.30–16.00 **Coffee Break**

SESSION IV

16.00–17.30 **Expanding options: what other systems, measures or procedures would work?**
Moderator: **Sandra Bendiscioli**, Science Policy Officer, EMBO

- Structured discussion

19.00–21.30 **Non-Working Dinner**

DAY THREE, Thursday, 25 January 2019

SESSION V

9.00 – 10.30	**Structured discussion of all options: existing systems, coordinated structure, and others** Moderator: **Michele Garfinkel**, Head, Science Policy Programme, EMBO
10.30 – 11.00	**Coffee Break**

SESSION VI

11.00 – 12.30	**Portfolio discussion: apply options to real life scenarios** Moderator: **Sandra Bendiscioli**, Science Policy Officer, EMBO
12.30 – 13.30	**Lunch**

SESSION VII

13.30 – 14.30	**Revisit and revise options** Moderator: **Michele Garfinkel**, Head, Science Policy Programme, EMBO

SESSION VIII

14.30 – 15.15	**Outputs, and outcomes - Next steps** **Sandra Bendiscioli,** Science Policy Officer, EMBO
15.15 – 15.30	**Sandra Bendiscioli, Michele Garfinkel, Carthage Smith** › Concluding remarks and farewell
15.30	**Workshop Ends**

Participant list

Governance of research integrity: Options for a coordinated approach

EMBO, Heidelberg, Germany
23–25 January 2019

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Interviewees

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Emerita Research Director,
CNRS, France, and
Member of the European Group on Ethics in Science and New Technologies,
European Commission

Nicholas H. Steneck
Professor Emeritus of History of Science,
University of Michigan, USA

Jean-Claude Worms
Former Chief Executive,
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Susan Zimmermann
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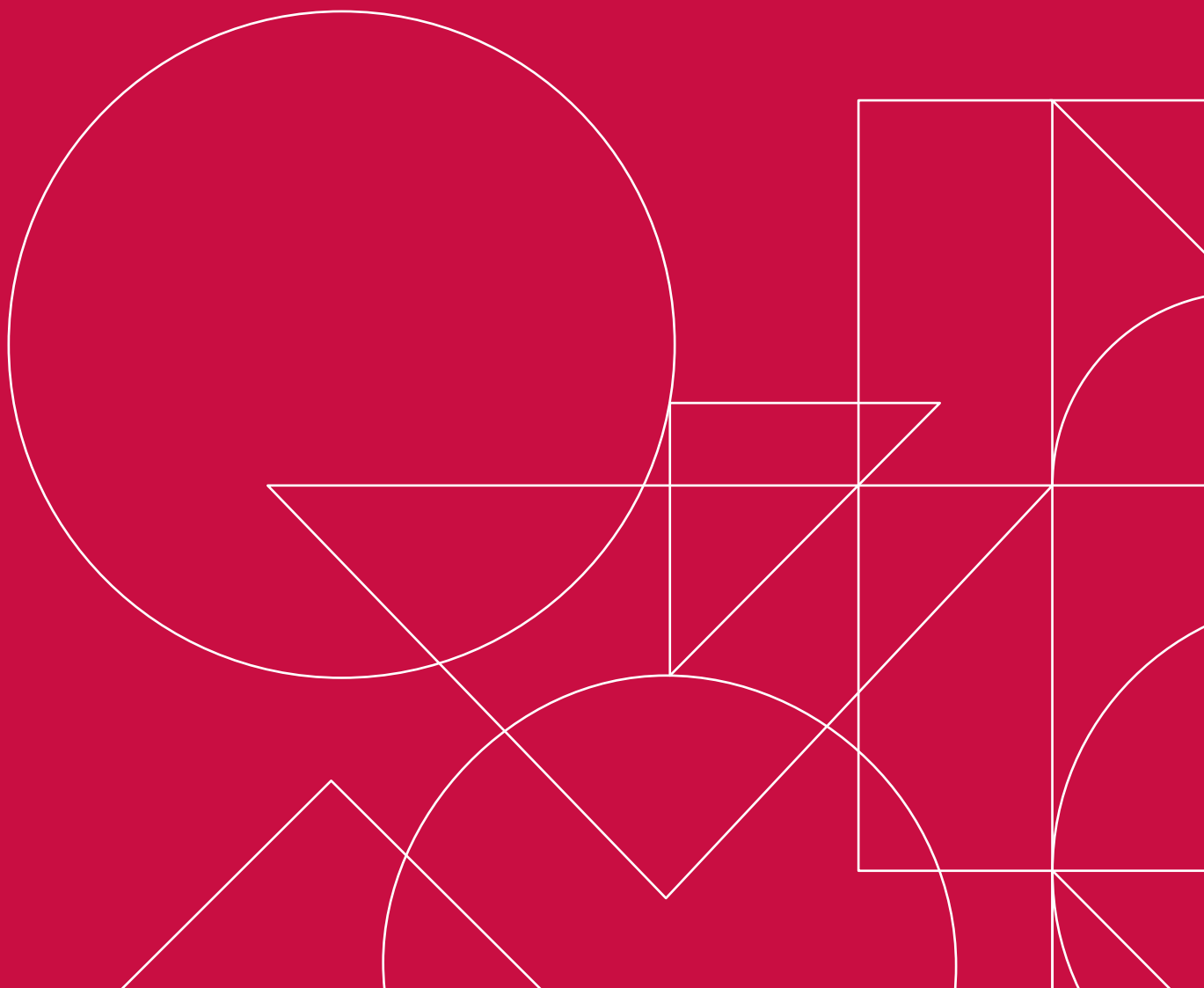

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