Recommendations for the Investigation of Research Misconduct

ENRIO Handbook

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The European Network of Research Ethics and Research Integrity

European Commission

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Recommendations for the Investigation of Research Misconduct

By the ENERI consortium in close cooperation with ENRIO

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Preamble

In 2007, the European Network of Research Integrity Offices (ENRIO) was established as an initiative by the UK Research Integrity Office (UKRIO) and persons from half a dozen other European organizations or initiatives handling cases or interested in research integrity (RI). Since then ENRIO has grown as an informal network to about 30 member organizations covering more than 20 European countries.

In 2011, the European Code of Conduct for Research Integrity was developed by All European Academies (ALLEA) and the European Science Foundation (ESF). It was revised in 2017 and offers the research community a framework for self-regulation, leaving the basic responsibility to the research community for formulating the principles of research and defining the criteria for proper research behaviour. ENRIO endorses the basic principles of the European Code of Conduct (CoC).

While the European CoC is focused on research integrity (RI) in a broader sense, this ENRIO Handbook aims to offer further specifics on section 3.2 of the Code "Dealing with Violations and Allegations of Misconduct". The Handbook consists of detailed practical recommendations on how to deal with research misconduct and other unacceptable practices.

Although the intended users of this Handbook and future updates are ENRIO's member organizations, it may also be useful for other organizations in and beyond Europe. However, the Handbook does not intend to offer binding advice for member or non-member organizations of ENRIO on how to deal with research misconduct and how to protect those involved in an investigation. Such advice would be unrealistic due to cultural, social, political, technical and legal differences between (European) countries. Despite these differences, member and non-member organizations of ENRIO may learn from each other and share experience. This has already happened during the ten years ENRIO has existed, during which time the field has evolved. New national (or local) RI-bodies have been established and guidelines and procedures have been developed or revised in different countries. On the European level, research integrity is much more on the agenda compared to 10-15 years ago. This leaves room for soft harmonization which is one of the main purposes of this Handbook.

The fact that research is becoming more and more international or cross-boundary is another reason for soft harmonization. The room for special local rules or guidelines is narrowing down. Soft harmonization could ease the way for dealing with cases involving researchers in different countries and/or institutions.

Nevertheless, in 2019 ENRIO still reflects a diversified European picture. One main divergence is whether the "institutional" responsibility for research integrity and dealing with violation is local, national or shared/divided between different bodies at different levels. Roughly half of the countries within ENRIO have national or local supporting platforms or networks, dealing with research integrity, either offering general advice, training and/or mediation (only). The other half have national committees that deal with research misconduct cases giving non-binding or binding opinions, whereby their scope is nationwide or restricted to affiliated research institutions nationwide only. Furthermore, some national committees are authorized to act either in the first and/or second instance. Other national bodies only have a guiding role. National committees can be either voluntarily or legally based. This is of importance as mandatory public laws generally apply to legally based committees. Publishing of cases, too, may differ: Some national committees publish their cases (e.g. on their websites), some name the involved parties, while others focus strictly on anonymous descriptions. Some publish in the mother language only, while others also publish in English. Finally, national and/or local committees may have their own regulations.

Regarding the protection of those involved in the investigation of research misconduct cases, countries within ENRIO generally offer protection to persons who "blow the whistle". ENRIO has been dealing with this important issue and has planned to publish some recommendations.

As noted, the primary source of inspiration for this Handbook is the European Code of Conduct for Research Integrity (2017). In addition, different national codes of conduct and guidelines etc., reports from the OECD Global Science Forum on "Best Practices for Ensuring Scientific Integrity and Preventing Misconduct" (2007) and "Investigating Research Misconduct Allegations in International Collaborative Research Projects" (2009) have been taken into consideration. Experience and learning from the biannual World Conferences on Research Integrity that have been convened since the first conference in Lisbon, Portugal, in 2007 have also been incorporated. Furthermore, Science Europe has been dealing with research integrity and published several useful reports and pieces of advice within the past years.

Most essential for this Handbook, however, has been the input and knowledge of (the representatives of) ENRIO's member organizations. The Handbook is a kind of consensus document although it also represents different views on different topics etc. It is important to stress that it has no legal status and it is not meant to represent the "official policy" of different European countries.

What follows is a set of recommendations or things to consider regarding how to deal with research misconduct and how to protect those involved in the investigation based on

experiences and lessons learned by member organizations within ENRIO, allowing for local or national differences in its implementation.

As a living document, this Handbook will need revision over time to remain aligned with future developments within European countries and across the field of research integrity.

ENRIO appreciates any feedback or suggestions for improvement.

March 2019

> **A prompt and effective response to suspicions of breaches of responsible conduct of research is required in order to maintain general confidence in research, including the scientific community's own confidence in research and the public's perception of the trustworthiness of research.**
>
> The Danish Code of Conduct for Research Integrity, July 2015, 22
> (see also European Code of Conduct).

1
Code of Conduct (Guidelines)

Each European country, research institution and researcher should adhere to the European Code of Conduct (CoC) for Research Integrity.

A national addendum to the European CoC or more detailed and specific national, local and/or field specific guidelines/codes of conduct is a benefit and is therefore recommended.

Such local/national guidelines/codes of conduct should be actively communicated, easily accessible and evaluated/revised regularly.

2
Definition of research misconduct and other unacceptable/irresponsible practices

A description or definition of research misconduct and unacceptable practices should be included in national or local guidelines/codes of conduct. If not, specific descriptions or definitions should be outlined in other relevant documents, e.g. in legislation, agreements, policies and procedures.

The question of mental state (mens rea) or level of intent should be addressed. Is there a minimum level of intent, e.g. intentionally or by (gross) negligence? A clear standard, or burden of proof, should specify what is required to demonstrate different levels of intent, along with examples of supporting evidence to prove various levels of intent. However, there also needs to be room for honest errors and sincere difference of opinions as part of academic freedom.

There is no uniform European definition of research misconduct or unacceptable practices although the European CoC provides some guidance here.

Some countries (or institutions) have a clear definition of research misconduct (e.g. Fabrication, Falsification and Plagiarism known as FFP) while others have a more "moral" description. It is rarer to have clear descriptions of minor breaches of good scientific/ research practice or unacceptable/irresponsible research practices although this is important and very beneficial. As definitions of unacceptable/irresponsible research practices are highly dependent on the scientific field or academic discipline in question, the respective national or international associations may be consulted when guidelines are being specified more in detail.

3

Setting up or improving a Research Integrity (RI) system

There is no one model or system that fits all circumstances. The picture is diverse across Europe. Some systems are legally based while others rely on voluntary adherence or lack a (uniform) national or local (institutional) structure for RI.

> *A uniform and robust system for dealing with research misconduct (including major and minor breaches of good scientific/research practice) should be adopted in each European country. Main responsibility could be mainly local or mainly national. Governmental agencies, national funding bodies, private foundations, research institutions etc. could all have a leading role. However, division of responsibility should be clear.*[1]
>
> *The needed resources for such pivotal systems should be made available.*
>
> *Matters regarding the system and procedures etc. should be transparent and must comply (be consistent) with national law or regulation.*
>
> *Every institution/body (e.g. national, cross sectoral or local institution), responsible for investigating possible research misconduct must have clearly stated written procedures. They should be consistent with national law or regulations and the European CoC. The procedures should be available in the relevant national language(s) as well as in English.*

[1] To make it simple we are using the terms local vs. national. However, the levels of governance in different countries are quite different. You will find countries with a) no (formal) structures, b) responsibility at individual institutions, c) thematic divisions of responsibility, d) responsibility at regional or national level (i.e. funding agencies, professional bodies), e) local responsibility with national oversight (or just "national" guidance), f) national office or national standing committee with sole responsibility for investigating serious breaches/research misconduct while institutions may be responsible for dealing with minor breaches.

Rules and procedures for handling investigations should be described and implemented accordingly.

The procedures should be easily accessible and made public. They should be disseminated continuously to all those who belong to and join the institutional research community (university students and faculty members, research collaborators, visitors etc.).

Matters regarding research integrity, misconduct or other misbehaviours should primarily be handled within the research community and/or institutional bodies set up specifically for the scientific community. This has been a long tradition based on the notion of self-regulation.

It is recommended to have a national oversight body.

The following aspects need to be considered

Local and/or national handling of cases? Ad hoc or standing committees?

Allegations are typically handled by:

- Standing local committee(s)
- Standing national committee(s)
- Both for each case or occasionally
- An ad hoc committee (for a specific case)

Some committees assume an advisory role, while others make decisions.

- **Advantages of local handling/bodies**

There are many reasons why handling research misconduct at the local level (by the home institution), perhaps even at the lowest possible local level, can be advantageous. The local institution is most often the employer of the accused researcher(s) (as such most often the one who decides regarding sanctions) and has knowledge about the local circumstances. Moreover, the local institution is responsible for the research enterprise in general, including fostering good research practice and a positive research culture, providing training in research methodology and research integrity, and responsible for promoting collaboration among researchers within and outside the institution.

- **Ad hoc vs. standing committees**

In special circumstances it may be an advantage to have an ad hoc committee, but in general, standing committees are preferable, especially if they have a breadth of subject matter knowledge and a depth of experience. Standing committees will have acquired experience whereas ad hoc committees will have to be trained from the beginning of how to handle cases. They will almost have to start from scratch. Some standing committees at smaller institutions will, however, have limited experience due to a low number of cases. Different cases will often require different approaches and for this reason, it may be an advantage for smaller institutions to establish joint standing committees. As a further benefit, this may diminish Conflicts of Interest (CoI).

Standing or permanent committees can offer collective long-term experience over time, with selection of ad hoc members with relevant subject matter expertise. Committees that are completely ad hoc will need significant guidance on procedural matters related to the investigation and their role as such. In any case, a designated individual who understands the institutional process can help to ensure continuity between cases and assist committees in performing their function, whether ad hoc or standing.

- **The benefits and possible tasks of a national oversight body**

ENRIO has experienced the benefit of having national oversight bodies/offices. The tasks and responsibilities vary among the countries that have established such national bodies. There are different "models". For example: Some national bodies deal with and conclude major cases (without local handling), others give a second opinion after local handling while still others function as advisory bodies without dealing with specific cases.

Potential bias and Conflicts of Interest at the local level are probably the most important reasons for having national oversight bodies. But there are other potential benefits.

In short, some of the potential benefits of having national oversight bodies (stemming from different approaches/models and therefore not necessarily applicable to all countries/models) are the following:

i. A national body/office may enforce or ensure that similar cases/situations are treated similarly across institutions;
ii. The threshold for making an allegation may be high at the local level.

It may be easier to turn to a national body which could then transfer the allegation to the responsible local body (or if applicable) deal with it itself;

iii. It allows discussions of the handling and outcome of locally handled (serious) cases. This will require that the institutions are obliged to inform the national body. A dialogue between the institution/ committee in question and the national body could enhance a more uniform handling of cases within the country;

iv. They can serve as an appeal body or body for a second opinion;

v. They can decide to deal with "special" cases e.g. if they involve several institutions, if conflicts of interest are prevalent;

vi. They can give an opinion regarding issues/cases of special interest or complexity etc.;

vii. A national body can ensure that cases are dealt with in a fair and impartial way;

viii. They can ensure transparency and openness, without hampering the need for confidentiality;

ix. They can function as a national repository for the "knowledge base" or as advisor for individual persons and institutions, including giving general advice regarding anonymous cases, procedures etc.;

x. They can gather "national" experience, including issuing yearly national reports based on known cases and issues dealt with;

xi. They can gather knowledge about international developments regarding RI, special cases in other countries etc. and communicate this knowledge to the research community, governmental offices, among others;

xii. A national body can more easily take part in relevant international panels and discussions, exchange experience with other relevant/ similar national bodies;

xiii. They can serve as a contact point for scientific journals, professional associations etc. regarding RI issues or actual cases;

xiv. They can serve as a contact point for other national RI bodies across Europe and beyond;

xv. They can drive initiatives aimed at preventing research misconduct and in promoting good research practice;

xvi. A national body can assist in establishing and supporting relevant RI

networks within their country;

xvii. They can take part in evaluating and revising the "national RI system" whenever needed.

In 2010, the **European Science Foundation** published the Executive Report **"Fostering Research Integrity in Europe"**. This report contained some recommendations and considerations from a working group regarding "structures" for promoting good research practice, including dealing with research misconduct.

Part of the conclusion aligns closely to the above-mentioned benefits regarding national oversight bodies (p. 10):

> **Properly constituted national research integrity governance structures can resolve many of the issues with self-regulation […]. National offices can provide consistent advice, support and guidelines across both the public and private research sectors. They can also provide true independence for investigative processes and equality in access and treatment of cases, making conflicts of interest less likely. Importantly, national standing committees can develop professional competence. Moreover, their authority for dealing with GRP [*Good Research Practice, editorial note*] and investigations is clear to everyone. Such research integrity governance can also facilitate international cooperation and mutual learning. The emerging framework should make the best use of opportunities to establish links with other national offices [...].**

When setting up a system (committees or the like) for dealing with research misconduct, there should be a clear mandate, such as an authoritative national/local statement, charter, or legislative support. This should include a transparent description of how members are appointed, their role and responsibility, the length of the term, and possibility of re-appointing.

In some countries, committees only deal with investigations, while in other countries they may also have responsibilities concerning preventing misconduct, promoting research integrity and research ethics in general.

Autonomy and independence of the committees should prevail.

It is of utmost importance that once a (national and/or local) committee or the like is appointed, no outside influence or interference should be allowed to affect the process or outcome of investigations, conclusions etc.

The institutions or bodies involved should do their utmost to protect or support members of committees or others (like experts) involved in investigations etc. from any retaliation or mistreatment. A system should be in place to make clear whether legal or other protection will be provided in the event of a conflict involving committee members.

The following aspects need to be considered

Self-regulation or legislative vs. voluntarily based systems

Guidelines for research integrity do not serve the same role or function as legislation. The guidelines primarily serve as tools for researchers and the research community. They identify relevant factors that researchers should take into account, while acknowledging that researchers often have to weigh different factors against each other, as well as against other requirements and obligations.

The distinction between law and guidelines on research integrity is often unclear. They are both normative, but research integrity or responsible conduct of research primarily state what researchers should take into consideration and do for their research to be responsible. Research integrity is in accordance with the principle of academic self-regulation. The primary responsibility for research integrity will – according to the concept of self-regulation – lie with researchers and research institutions. Self-regulation and/or academic freedom do not exclude duties and obligations.

In most countries self-regulation has been prevailing (the sole regulator) for many years.

Within the last some 10-20 years a number of countries in Europe and across have established statutory regulation of research and researchers, although still very much based on (some degree of) self-regulation. Such statutory regulation is based on mutual agreements or voluntarily based systems or it is based on legislation. Legislation will often focus on prohibitions or how to react (with penalties or sanctions) if someone breaks the law, but it will most often also refer to different norms: In this case RI-norms or the norms regarding responsible conduct of research or norms regarding how to handle allegations concerning research misconduct. In this way legislation or other regulations, including voluntarily based system, support

self-regulation focusing on the behavior of researchers as well as the behavior of the responsible institutions.

The balance between self-regulation and regulations (e.g. legislation) differs very much between countries in Europe due to different traditions and values. This does not leave room for a common recommendation although it is recommended to discuss and evaluate the balance between (external) regulations and (internal) self-regulations.

4
Conflicts of Interest

Individuals involved in an investigation should be objective and unbiased in their review of allegations. Any real or perceived Conflict of Interest (CoI) or partiality should be avoided or disclosed and managed when appointing members of committees, panels or experts and throughout investigations. CoI should be handled in a transparent fashion during the whole investigation process, and if a CoI emerges during the process, it should be disclosed and managed. CoI disclosures of committee members, internal or external experts, and others handling allegations should be documented as part of the transparency of the process.

5
Composition and competence of investigation committees

Investigations should involve competent researchers/peers. Investigation committees should consist of members of the research community with relevant subject matter expertise and legal experts or other people with special competence/experience regarding research integrity if necessary or applicable.

To diminish risk of bias, local committees should include independent members from outside the institution in question. National committees/bodies should consider including independent members from other countries. This is particularly important for smaller institutions and countries.

Smaller institutions should consider having joint committees with other institutions or affiliating with the committees of larger institutions.

Internal or external experts should complement members of a committee (during a

specific investigation) when a needed professional competence within the specific field of research or other kind of competence is lacking.

When an unbiased person from outside the institution is included it will generally increase the acceptance and credibility of the committee amongst all parties involved in an investigation.

It is recommended to have standing committees as opposed to ad hoc committees.

The mandate for the chair and vice-chair should be clear, along with the mandate for the other committee members. This includes specifying roles/responsibilities, thresholds, and timelines for completion should be clearly described to its members.

Members of committees should be appointed with due respect to a balance between women and men, younger or more senior persons, and different research areas.

Preferably one or more members should have prior experience with cases concerning research misconduct and/or breaches of responsible conduct of research.

Committees should be comprised of those with broad and relevant academic competence related to an allegation, and, ideally, at least one or two individuals who have investigated previous cases.

The following aspects need to be considered

In some countries most committees are standing but one will often need to include experts from the field in question when dealing with a specific subject matter. The experts could be part of the committee while the investigation is ongoing, or they could be involved on a case-by-case basis. Experts could be internal, but because of possible CoI, external experts also provide an advantage.

Discussions in "collective peer bodies/committees" are a strength. The investigation committee should serve as representatives of the research community. Their primary goal is to safeguard the integrity of research and to secure a fair and just process for those involved. In other words: "Legitimacy and trustworthiness" are crucial and provide another reason for independence and no undue interference during an investigation.

The role of committees should be clearly described to its members, with a discussion of the amount of time that may be required to complete the investigation process. A committee should not consist of too few persons (although the committee may on a case-

by-case basis be expanded by including experts with specific competence). On the other hand, very large committees also present challenges.

> *A committee should consist of an appropriate number of individuals. 3-7 persons seem to be good numbers.*
>
> *Whenever possible, committee members should be acknowledged for their service (without revealing any confidential case information) with, for example, letters to department heads to thank them for their contribution to promoting integrity within the institution.*
>
> *The circumstances and use of external experts as advisors during an investigation should be clearly described. It should be considered to disclose any payment to external experts, to prevent any accusation of bias or conflicts of interest.*

The chair of the committee is often an experienced researcher and/or a person with a legal background. Most important is that the chair possesses qualities of fairness, objectivity, and ability to assess information in an unbiased fashion while having compassion and respect for everyone involved.

6

Transparency versus confidentiality

> *Transparency and openness should prevail provided this does not conflict with (national) regulations etc.*

When it comes to the level of transparency and confidentiality regarding investigations, traditions and legislative mandates vary across Europe.

The following aspects need to be considered

There are two main approaches:

- Cases are dealt with in confidence and decisions are generally NOT made public;

- Cases are dealt with in confidence (i.e. during the process) and decisions are generally made public often in an anonymized form regarding persons (and sometimes also regarding institutions) involved.

According to administrative law, in some countries the public may have the right to fully access to decisions and even underlying documents (including names/ identities).

There seems to be at least two different or conflicting considerations: the protection of individuals (parties) involved vs. the protection of research quality and integrity. Some argue that revealing names may result in a "life sentence" and could ruin the career of a researcher. Others argue that the research community needs to know the name of persons who have committed (serious) research misconduct. One reason is, that besides trust, these researchers often have misused public funding and violated public trust. Another reason is that they may (despite imposed sanctions etc.) simply move to another institution or country and "incognito" start all over again with serious breaches, get funding, be a supervisor etc., and thereby perpetuate unacceptable behaviour. Some may be capable of rehabilitation and not perpetuate unacceptable behaviour, while others may continue to conduct research in a manner that is unacceptable according to international norms.

In sum, whether to reveal names is not an easy question and this issue raises dilemmas. The various implications should be discussed in developing policies and processes.

It is important to stress that (serious) allegations should not be handled behind closed doors and/or without following the relevant procedures. Sometimes the responsible institution or other relevant bodies (think they) may have an interest in keeping the allegation confidential and may even try to reach an agreement between involved parties (e.g. a whistleblower and an accused researcher). Such agreements or mediation may be appropriate when dealing with minor breaches. However, when it comes to possible research misconduct or other serious breaches, other interests than those of the directly involved parties are at stake (public trust in research, correction of the research record etc.). Thus, it is vital to manage the process in an open, accountable manner and not behind closed doors.

7

Receiving allegations or concerns including guidance[2]

In general, it is recommended to make it possible to obtain advice on a confidential basis from a neutral person (e.g. an ombudsman or advisor who is trusted and has credibility in the research setting) before determining whether to make a formal allegation.

Personal guidance for possible complainants – i.e. before launching a complaint – should therefore be available. This could, for example, be offered by an ombudsperson or other trusted "neutral" person within the research institution with knowledge of the local and/or national procedures on RI.

It may sometimes encourage disclosure of concerns if the first guidance is based on an "anonymized" or hypothetical description of, or question about, the suspicion and/or discussion via a help desk/hotline, mail or phone.

The possible consequences of raising a concern/making an allegation in good faith, including a description of the rest of the process, should be publicly and easily accessible, e.g. on a website. Possible reactions to malicious or bad faith complaints should be mentioned as well, with consequences described (i.e. this is a form of unacceptable practice or even research misconduct).

How to make an allegation and to whom one can turn to (contact point) either at the appropriate level (e.g. local or national level) should be clear and well communicated.

Prior to selecting/appointing the person(s) who receive(s) questions, concerns or allegations the required competence, experience and training of the person(s) should be clear.

When receiving allegations, the investigating/advisory body or the like should immediately consider how the person(s) raising a concern could be protected from potential retaliation.

Any procedure should at least specify:

- *To whom allegations should be submitted.*
- *From whom allegations will be accepted.*

[2] ENRIO plans a further statement with recommendations on protection of whistleblowers.

- *Whether anonymous allegations will be accepted.*
- *Whether allegations from third parties (e.g. a lawyer representing a complainant) are accepted.*
- *In what form (oral, written or electronical) allegations will be accepted.*

It may be an advantage to have a written form that can be used for making an allegation. This form could also include guidance.

- *Any further responsibility or duties of the whistleblower (complainant) should be pointed out. The same goes if others will take over the responsibility or duties of the whistleblower.*
- *That the complainant shall receive a copy of the policy to understand the process.*
- *Whether it is possible for the responsible body to investigate without an allegation i.e. by its own initiative (e.g. based on news/information in media, social networks, forums etc.).*

8
Handling allegations

It is highly recommended that all allegations (substantive or grounded suspicions) regarding research misconduct (such as FFP or similar serious breaches) are dealt with according to relevant codes of conduct/overall guidelines and specified procedures.

Procedures and processes regarding possible serious breaches (research misconduct) should be detailed, fair, thorough, comprehensive and objective.

Irresponsible or unacceptable research practices should also be addressed although not necessarily in the same manner as investigations of serious breaches defined as research misconduct.

The procedures should specify which entity (for example institution's office, national organization or independent body) should lead or manage any investigation.

There are many different unacceptable practices or minor breaches. Some of them may not directly distort the research record but will still damage the reputation of researchers and

society's trust in research. Several studies show that unaccepted research practices are far more prevalent than FFP and thus more damaging for the research enterprise. For this reason:

> *It is important to handle allegations regarding unaccepted practices in a proper and thorough way and thus safeguarding research integrity. This is mainly the responsibility of the local/home institution that should have procedures for doing this.*

The following aspects need to be considered

When it comes to the decision which steps to take or which phases to implement, various approaches are implemented in different countries. In some countries there is a clear delineation of responsibilities, i.e. procedures/rules regarding the persons involved in dealing with cases in different phases. In other countries it may be the same committee making decisions for all phases. The phases are often categorized differently, such as a) fact finding/screening evaluation/screening or preliminary inquiry and b) decision-making process/detailed investigations etc. In any case, clear criteria for proceeding from one phase to another should be described and explained to committee members. In spite of these differences, there seems to be a common intention which is to first evaluate whether the allegation possibly falls within the scope of research misconduct (or irresponsible research practices) and, if so, then to investigate or proceed with uncovering the truth surrounding the allegation.

> *Although handling allegations should be thorough it is of utmost importance to have a speedy process preferably with clear deadlines for each procedural step. A proper balance between thoroughness and speediness should therefore be considered.*

Procedures: Overarching/core principles

The procedures should reflect the principles proposed by the **OECD Global Science Forum** on "Investigating Research Misconduct Allegations in International Collaborative Research Projects"[3]. In the following, these principles will be outlined mostly verbatim and partly paraphrased, with minor additions where seen appropriate.

[3] OECD Global Science Forum. Investigating Research Misconduct Allegations in International Collaborative Research Projects. A PRACTICAL GUIDE. April 2009, 6 ff.

Integrity of the process

Investigations into research misconduct allegations must be fair, comprehensive and conducted expediently without compromising accuracy, objectivity, and thoroughness. Investigations often take a long time, which can become burdensome to the parties involved.

Parties involved in the procedure, especially those carrying out or assisting the investigation process, must ensure that any interests they may have which might constitute a CoI are disclosed and managed.

Detailed and confidential records must be maintained on all aspects of the procedure. Any evidence collected related to the allegation(s) should be gathered in accordance with pertinent local laws/guidelines. Evidence should be protected and secured throughout the process to prevent tampering. Consideration should be given to providing secure access to evidence secured (or copies made) so as to enable continuation of work if appropriate.

Measures should be taken to ensure that investigations are carried through to a conclusion.

Uniformity

Procedures for dealing with misconduct should be described in sufficient detail so as to ensure the transparency of the process and uniformity within one domain of jurisdiction from one case to another.

Transparency is also important for seeking uniformity across institutions when dealing with similar cases, ensuring consistency of application of procedures.

Fairness

Investigation of research misconduct allegations should be conducted in a manner that is fair to all parties and in accordance with relevant laws or regulations. Principles of due process or procedural fairness should be described in policies.

Persons accused of research misconduct must be given full details of the allegation in writing and must be afforded a fair process with regards to responding to allegations, asking questions, presenting evidence, calling witnesses (if applicable), and providing responses to information or evidence presented.

Witnesses (if applicable) should be accompanied by or seek advice and assistance from anyone of their choosing (e.g. a peer, a lawyer etc.).

Not all institutional or national procedures include oral testimony/hearings and/or witnesses. However, it is the experience of some ENRIO members that this may be very useful and sometimes even crucial for the conclusion of an investigation. Consideration should be given to recording/transcribing interviews (after acceptance from the interviewed person(s)) to ensure the accuracy of the record and prevent disputes.

Any sanction or action(s) taken should be subject to appeal.

In several European countries the conclusion of an investigation cannot be appealed but any imposed sanctions may typically (at least in several countries) be appealed according to law.

There should be an authority issuing the final decision.

Confidentiality

The procedure (i.e. the investigation) should be conducted in a manner as confidential as possible to protect those involved in the investigation (including those who raise allegations, those accused, those serving as witnesses, and those investigating allegations as committee/panel members). Such confidentiality should be maintained provided this does not compromise the investigation of the allegation, health and safety, or the safety of participants in research.

Where revealing information related to an investigation is deemed necessary, any disclosure to third parties should be made on a confidential basis.

If the organization and/or its staff have legal obligations to inform third parties of research misconduct, those obligations must be fulfilled at the appropriate time and through the correct mechanisms, with confidentiality being respected whenever possible.

Considerations should be given to sponsors that may be required to terms and conditions of grant awards for sponsored research.

No detriment

Anyone accused of research misconduct is presumed innocent until proven otherwise.

No persons should suffer any penalty when accused of research misconduct before the allegation is proven.

One must be cautious regarding penalties or consequences before the possible appeal process has concluded.

No person should suffer any penalty or detriment for making an allegation of research misconduct in good faith, but action(s) should be taken against persons found to have made allegations in bad faith.[4]

Balance

Occasionally the investigating committee or panel may need to strike a balance between disclosure of identities and confidentiality. Such decisions should be made keeping in mind that the primary goal of the investigation (procedure) is to determine the truth of the allegation.

Consideration should be given to reasonably and appropriately restore reputations of those wrongfully accused. Those accused and found not committed research misconduct should be asked about actions to be taken to restore their reputations prior to taking any action of this sort. Sometimes there may be a need to restore other's reputation as well. This may regard e.g. co-authors or other cooperating researchers etc.

Proportionate action should be taken against persons found to have committed research misconduct.

Different phases of handling allegations

Handling of allegations will go through different phases especially when they concern possible serious breaches such as FFP. Some institutions and/or countries will have formal requirements or strict delineation between the different steps or phases (e.g. an initial evaluation/preliminary enquiry or fact-finding and an investigation proper/decision-making or the like). In other countries proceedings are conducted without a clear phase separation. In *Figure 1*, a prototypical process in handling research misconduct allegations can be found. In the following, critical issues in each phase will be raised.

1. Initial evaluation and screening inquiry

In making an initial evaluation of an allegation and establishing whether further action will be needed, the **following questions are some that could be considered**:

- Does the allegation involve research? Is/Are the alleged person(s) researcher(s)? Has the allegation already been dealt with or is another institution presently dealing with the allegation?

[4] ENRIO plans a further statement with recommendations on protection of whistleblowers.

Figure 1. Prototypical process in handling research misconduct allegations.

- Does the allegation concern possible serious breaches of good research practice or irresponsible research practices?
- Are there implications for notifying external funders based on terms of funding agreements?
- How serious is the allegation? This could determine how and by whom it should be further handled.
- Does it fall within the definition or description in guidelines of unacceptable practices/research misconduct?
- Is there sufficiently evidence to support an in-depth investigation, or is further documentation required before deciding on this?

The adopted procedure will determine whether allegations concerning research misconduct and other (e.g. minor) breaches should be handled separately or in common.

2. Investigation and inquiry

Where a bone fide case is established and the allegation will proceed to investigation, **the following are some of the questions that should be considered**:

- Does the responsible committee have the necessary expertise or is there a need for external experts?
- Has the committee documented their real or perceived conflicts of interests?
- Has the committee been advised of their role and which standards they should apply in assessing the allegation(s)?
- Does the responsible committee require training in the national/institutional policy/guideline and in handling allegations of this sort?

- Is there a need for further documentation? How should it be obtained?
- Is it possible to expand the investigation during the process if "new evidence or allegations" occur?
- Is there an established timeline for completion of the investigation and a mechanism for extending timelines when justified?
- Is there any individual to assist with coordinating committees in performance of their role?

3. Formal hearings of involved parties or witnesses

- This could be done in writing and/or in verbal hearings.
- Documentation of written/oral hearings to maintain an accurate record (record/transcribe) should be considered.
- It should be ensured that due process/procedural fairness and all relevant employee/grantee contractual agreements have been considered.

4. Writing of a report including a conclusion

Any investigation should involve careful analysis of the facts and application of the pertinent standards (rules, regulations, guidelines as appropriate) and end with a clear and concise conclusion.

- Is this misconduct (e.g. FFP) or other unacceptable/irresponsible research practices?
- Did the researcher's actions demonstrate intent to deceive or distort?
- Other behaviours or misbehaviour?
- What is the basis for the decision?

It is an advantage if the adopted procedures contain minimum requirements for the final report and conclusion. These can include the source of research funding, the type of misconduct, the research record in which the misconduct occurred (grant applications, progress reports, publications, other?), relevant dates and description of pertinent standards applied to the facts of the case along with analysis of those facts in light of whether misconduct is deemed to have occurred.

It is often seen as good practice to let parties involved (particularly those raising concerns and those accused) have the opportunity of commenting on the facts of the case before disseminating the report.

Any mitigating factors should be considered (e.g. if a mentor/supervisor created an environment that contributed to pressure upon research staff and unacceptable practices).

The following aspects need to be considered

- On what ground an allegation regarding serious breaches of good research practice (research misconduct/FFP or the like) will be rejected i.e. not leading to a full investigation.
- On what ground allegations regarding minor breaches (i.e. unaccepted/ irresponsible research practices) are rejected.
- How substantive suspicions regarding serious breaches will be investigated (i.e. the duties of the responsible committee/body or the like, formal hearings, writing of a report/conclusion, appeal, follow-up/sanctions etc.).
- How grounded suspicions regarding minor breaches will be dealt with.
- Whether a person who is suffering from an "unjust" suspicion will have the right to be "cleared" during the course of an investigation or even after a conclusion of an investigation (i.e. launching a new or separate investigation).
- Whether there is the possibility of processing an investigation irrespective of a) the complainant withdrawing the allegation at any stage, b) the respondent admitting or having admitted the alleged misconduct in full or part c) the respondent or the complainant having already resigned their post.

This is important to address as investigations have at least two purposes: 1) Concluding whether an alleged person has committed research misconduct (or other unaccepted practices) and 2) Safeguarding the research record/the trust in research.

The following aspects need to be considered

- The requirements for a final report/conclusion including who should or may be formally informed.
- How cases are concluded efficiently and timely holding in mind that dealing with cases often takes a long time. No person should be part of an investigation longer than strictly necessary.
- Whether there is the possibility of appeal or second-opinion.
- The policy regarding sanctions and follow-up regarding involved/affected

persons or bodies.

- Which entity (for example institution's office, national organization or independent body) should lead or manage any investigation.
- Dissemination and communication strategy during and after an investigation.
- Possible reactions to systemic failures and improvements based on experience.

9

Appeal or second opinion

The possibility of appeal concerning investigations/conclusions differs across countries. In some countries the possibility of appeal follows (general) regulations or law. In general, there are three possible approaches:

- Appeal at the local/institutional level
- Appeal (or second opinion) to an external (often national) body
- No formal appeal system

It may also be possible to appeal regarding "administrative considerations" or consequences separate from appealing the actual "misconduct" conclusion or imposed sanctions.

10

Sanctions and follow-up

It is recommended that procedures regarding sanctions are set out, and that those sanctions are made known as part of a policy.
It should be clarified whether an appeal from a process and sanctions is available and to whom.
Time limits should be considered for each kind of sanction.

Whether the conclusion of an investigating committee is deemed "final" or taken as "advisory/recommendation" differs across countries. Sometimes the board or the rector of a university will make the final decision, depending on the policy, which should be clear.

Funding agencies

Funding agencies may impose sanctions when informed (which they should be) that a researcher funded by the agency has committed research misconduct. These sanctions may include:

- Withdrawal of funding
- Supervision attached to future funding
- Prohibition on submitting applications for funding (usually for a limited period)
- Prohibition on functioning as a peer reviewer or bodies giving advice regarding funding
- Obligation to pay back funds

Scientific journals

Scientific journals should be informed when relevant and may be involved in sanctions such as retractions, corrections etc.

It may be necessary to inform other authorities which may decide to sanction as well.

Imposing sanctions will primarily take place at the institutional level. Sometimes at different institutions if the researcher in question is connected to different institutions/ employers. It is not uncommon that committees (local or national) recommend certain sanctions.

Monitoring of sanctions should be considered in institutional or national approaches (i.e. is there a system to make sure the individual is not serving as an advisor or receiving grants for the designated period of time?).

The follow-up or sanctioning may include[5]:

- Supervision
- Additional training
- Mediation

- Suspension from research-related work
- Inability to supervise for a limited time
- Limitations regarding applying for external funding and/or submitting articles, participating in conferences etc.

- Warning/reprimand
- Withdrawal of internal funding

[5] National systems for handling cases of research misconduct. The Danish Agency for Science, Technology and Innovation (2013).

- Withdrawal of title/degree (only possible in some countries and under certain circumstances)
- Disciplinary action (academic probation, dismissal)
- Retractions
- Follow-up concerning co-authors, co-researchers, involved PhD students etc.

In most countries any sanctions (e.g. regarding title/position) may be appealed according to law.

Imposed sanctions are most often kept confidential, in some countries for legal reasons.

This is not recommended as far as research integrity is concerned. It may be challenging to decide on sanctions especially as the knowledge about how other similar cases have been sanctioned is minimal. From an RI perspective it would be preferable if imposed sanctions were described/disseminated. This could be in an anonymized form (including anonymization of the report that led to the sanction). This would be of great help when deciding on future sanctions by other responsible institutions and could lead to more uniformity and fairness in the process.

11

Dissemination and communication during and after an investigation

> *A policy regarding dissemination and communication during and after an investigation should be considered.*

It is advisable to include some principles regarding dissemination of the investigation report in the adopted procedures. This helps to ensure consistency in application of procedures and procedural fairness or equal treatment of involved persons from case to case.

The following aspects need to be considered

- How should a report be disseminated?
- Should it include names or not?
- Should institutions involved be named?

On the other hand, there may be special circumstances, e.g. if a case has already been covered extensively by media including names. This may call for openness (also regarding names) perhaps especially if the conclusion has been reached that no misconduct has occurred.

A communication strategy (what to reveal and how) may also be important to consider i.e. during the investigation process (or even from receiving an allegation) and when disseminating the report and/or implementing sanctions.

> *It is recommended to be cautious to reveal the outcome of an investigation if an appeal can be expected.*

Ideally, those responsible for handling procedural aspects of investigations have established open channels of communication with administrative support (vice rector, legal advisors, public relations, human/animal/safety administrators) to make it easy to address concerns when they suddenly arise with a sense of discretion and fairness. As a courtesy, parties involved should of course be properly informed about the outcome of the investigation before any public dissemination and should ideally be alerted before any press release etc. It is also beneficial to track aggregated anonymized data about questions, concerns, allegations, cases that occur in order to address possible gaps and required areas of training as part of improving the research environment. Such data can help inform training and informal discussions around creating a positive research culture.

Reactions to possible systemic problems revealed by an investigation

> *Systemic problems should always be considered.*
>
> *It is recommended that possible systemic problems revealed by an investigation should be handled. The reasons and background for research misconduct (or repeated violations of good practices) should be discussed and evaluated thoroughly. The main purpose is to try to prevent this from happening again. Furthermore, lessons should be incorporated in institutional research integrity programmes or guidelines to help improve the research culture.*

The following aspects need to be considered

- Even if just one person is found to have committed research misconduct, is that person the only one to blame?
- Have other researchers been doing the same?
- Why could this take place, why was it not revealed earlier?
- Did somebody blow the whistle earlier?
- Was the person who committed misconduct influenced by "rotten" incentives?
- Was there specific pressure on them?
- Was there a lack of good stewardship or leadership?
- What is the RI-culture at the relevant institution?
- Is openness and free discussion prevailing among junior and senior researchers?
- Has there been any RI training?
- Are the RI guidelines sufficient and updated, and widely available, disseminated at every opportunity?
- In other words, are there systemic problems (within the specific field, within specific research groups or departments, or more generally on the local and/or national level) and how could RI be promoted to prevent something similar happening in the future?

Questions like these should routinely be asked and discussed after research misconduct is revealed and appropriate actions should be taken to address or solve these problems and challenges. However, systemic problems may be revealed by an investigation even if research misconduct is not proven.

Cross-boundary allegations/investigations

It is recommended to establish agreements early in collaborative (especially cross-institutional and cross-boundary) projects. Accordingly, it is recommended to follow the OECD guideline and the Montreal Statement.

It is further recommended that relevant guidelines/procedures should deal with cross-

boundary allegations within the country where the unacceptable research was performed/funded. Legal aspects need to be taken into consideration.

There is a need for more knowledge about the challenges regarding cross-boundary investigations and subsequently for a common European policy, procedures or statement.

No doubt it is an advantage to have procedures in place before the need for an investigation arises. One main challenge may simply be the fact that the definition of research misconduct may differ. The definition or description of misconduct should be addressed and if possible agreed upon.

The **Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations**[6] addresses this:

> **19. Responding to Irresponsible Research Practices. The collaboration as a whole should have procedures in place for responding to allegations of misconduct or other irresponsible research practice by any of its members. Collaborating partners should promptly take appropriate action when misconduct or other irresponsible research practice by any partner is suspected or confirmed.**

Such procedures are crucial when it comes to international research collaboration but could also be vital regarding collaboration between partners within the same country.

Back in 2009, the **OECD Global Science Forum** published a practical guide: "Investigating Research Misconduct Allegations in International Research Projects"[7]. It recommends the following:

- Define principles and minimum requirements for investigations;
- Have an appropriate structure;
- Define the scope and limitations for investigations and include (agreed) definitions of misconduct;
- Provide a clear sequence of steps for the investigation of an allegation;
- Provide clearly defined procedures for investigative and decision-making phases and associated time guidelines;
- Describe reporting and distribution requirements;
- Establish communication strategy among points of contact.

[6] Montreal Statement: https://wcrif.org/guidance/montreal-statement

[7] OECD Global Science Forum. Investigating Research Misconduct Allegations in International Collaborative Research Projects. A PRACTICAL GUIDE. April 2009, 3.

The guide contains a "**Boilerplate for International Collaborative Research Projects**" (see also *Textbox 1*) and states the following[8]:

> "When a written agreement is developed for collaborative research involving parties from more than one country, the agreement could include the following boilerplate text, and, as appropriate, should be complemented by a more specific document that describes the policies and procedures to be applied in case of alleged scientific misconduct."

We, ( ), agree:

- **to conduct our research according to the standards of research integrity, as defined in "Investigating Research Misconduct Allegations in International Collaborative Research Projects: A Practical Guide" (www.oecd.org/sti/gsf) and other appropriate documents, including: (*specify the national codes of conduct and disciplinary or national ethical guidelines that apply*);**
- **that any suspected deviation from these standards, in particular alleged research misconduct, will be brought to the immediate attention of (*all designated contact point(s)*) and investigated according to the policies and procedures of (*to be filled in with the body with primary responsibility*), while respecting the laws and sovereignty of the states of all participating parties;**
- **to cooperate in and support any such investigations; and**
- **to accept (subject to any appeal process) the conclusions of any such investigation and to take appropriate actions.**

Textbox 1. Boilerplate for International Collaborative Research Projects.[9]

When a cross-boundary allegation or suspicion of irresponsible practice/research misconduct arises, but no agreement or procedures are in place, challenges may arise.

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[8] OECD Global Science Forum. Investigating Research Misconduct Allegations in International Collaborative Research Projects. A PRACTICAL GUIDE. April 2009, 3.

[9] ibid.

The following scenarios, among others are possible:

1) The allegation involves researchers from different institutions a) within the same country, b) from different countries in Europe, c) from different countries across the world.
2) The allegation involves a researcher who may previously have been engaged in wrongdoing when employed at (or connected to) different institutions a) in the same country, b) in different countries.
3) It emerges during an investigation that a researcher is also under investigation at another institution or in another country.
4) A researcher moves to another country a) during an investigation, b) after an investigation has been concluded, and in this way, perhaps "avoids" scrutiny and sanctions but continues the research (gets a new position, new funding etc.) and perhaps even perpetuates wrongdoings despite sanctions.
5) An allegation is proceeding in one country although the research (or part of it) has been going on in or has been funded by another country/funding body.

No matter how complicated, cross-boundary allegations should be investigated in accordance with due process/procedural fairness and should consider all implications for other parties while following procedures of the "internal/local" investigation.

The following aspects need to be considered

- If misconduct occurs, establish agreements early for handling process and documentation.
- If no procedures exist regarding cross-boundary allegations a starting point could be: Which body/country has been the (main) employer or main funder of the researcher/research in question?
- It is important to establish contact points between the involved institutions/ countries to process in accordance to established procedures or to agree on which route to follow.
- If it is difficult/impossible to make contact (within the country or across countries), the national RI body (if such exists) should be able to assist. Thenational body should usually be capable to give advice regarding which

procedure to follow and/or should offer to deal with the allegation itself if appropriate. If there is no national body, one could contact ENRIO for possible assistance or advice (see www.enrio.eu).

Transparency and openness (with due respect to regulations regarding confidentiality) should prevail between contact points/responsible bodies in different settings. It is of the utmost importance to foster mutual trust and cooperation on investigations of integrity.

It should be avoided, if possible, to deal with cross-boundary cases in different countries within closed circles.

Where possible (i.e. if not contrary to regulation or law) the outcome of proven cases should be made public.

While approaches to sanctions vary, some consistency and guidelines would be desirable.

When a person applies for a research position, it should be the responsibility of the hiring institution to institute appropriate measure to satisfy itself that the candidate has not been involved in research misconduct and is not the subject of an ongoing investigation.

Practical tips when confronted with a cross-boundary allegation

Internally

- Coordinate with relevant persons (lawyers, public relations, rectorate) at local institution.
- Seek misconduct policy and responsible persons at other institutions.
- Consult with responsible persons prior to making contact.
- Consider language, cultural and legal barriers, seek "hypothetical" advice.
- Anticipate possible translation and verification costs (have translators sign confidentiality agreement).

Externally

- Find contact/policy at the relevant institution, and if needed, contact national RI bodies or regional networks or at ENRIO (see www.enrio.eu).
- Determine lead institution, or, if possible, find a common platform or agree

on a joint investigation and/or shared responsibility (see OECD Guide[10]).

- Make an agreement/develop common understanding on how to proceed.

14

How to learn from each other

Annual national reports (in English) describing specific (but anonymized) investigations and possible breaches of responsible research practices, findings, main discussions and challenges about RI-principles should be made public in an aggregated way so others can learn from trends.

This will be a great benefit for anyone responsible for doing investigations or giving advice not least because the "common" experience even at the European level is limited as the number of handled cases are relatively small. Most cases will be unique in some way but still contain discussions or challenges relevant when dealing with different cases and will be important for training activities or for promoting RI as such.

Such annual reports are gathered on the ENRIO website (www.enrio.eu).

[10] OECD Global Science Forum. Investigating Research Misconduct Allegations in International Collaborative Research Projects. A PRACTICAL GUIDE. April 2009.

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Originally, the working group was at the same time focusing on two topics 1) Recommendations regarding investigations of research misconduct and 2) Protection of whistleblowers. Later, it was decided to separate the discussions and outcome. **Sanna Kaisa Spoof**, Secretary General of The Finnish National Board on Research Integrity (TENK) was eventually chairing a sub working group on whistleblower protection and facilitated a planning meeting in Helsinki where both topics were discussed by a smaller group. Furthermore, TENK organized a larger meeting in Helsinki with invited speakers. Although focusing on whistleblower protection, this meeting was also very beneficial for the Working Group Investigation. Many thanks to the secretariat of TENK and not at least Sanna Kaisa Spoof and the chair of TENK, **Krista Varantola**.

The Handbook was drafted by the chair of the Working Group Investigation and later revised, based on very appreciated inputs from many members of the working group. Further, the chair of another ENRIO working group (on RI training), **Michael Gommel**, shall be very much acknowledged for suggesting improvements of the draft although not even a member of the working group. And last but not least, **Zöe Hammatt**, who for many years has been working with research integrity and investigations of research misconduct in the US context but also worldwide, is thanked heartfully for substantial contributions regarding many aspects and different anglings based on Transatlantic experience and

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Finally, greetings to all members (former and present) of ENRIO for making the network a true European success and for constantly working to enhance research integrity.

Torkild Vinther

Chair of the Working Group Investigation

Appendix

Appendix

Members of the working group

Country	Organisation	Acronym	Name
Chair			
Norway	National Research Ethics Committees	Etikkom	Torkild Vinther
Members			
Austria	Austrian Agency for Research Integrity	OeAWI	Nicole Foeger
Belgium	Flemish Commission for Research Integrity	VCWI	André Van Steirteghem Bert Seghers
Croatia	Croatian Committee on Ethics in Science and Higher Education	CESHE	Ivica Vilibic
Czech Republic	Commission for the Scientific Integrity of the Czech Academy of Sciences	CAS	Petr Kratochvíl
Denmark	Danish Committee on Research Misconduct	DCRM	Mathias Willumsen
Finland	Finnish National Board on Research Integrity	TENK	Sanna Kaisa Spoof Krista Varantola
France	French Agricultural Research Centre for International Development	CIRAD	Philippe Feldmann
	Internal Office of the French National Institute of Health and Medical Research	INSERM	Ghislaine Filliatreau
	CNRS Ethics Committee	COMETS	Michèle Leduc
Germany	German Research Ombudsman	Ombudsman	Hjördis Czesnick Fanny Oehme
	Team Scientific Integrity *and* Office for Ombudsman Affairs of the University of Hamburg	SciInt	Helga Nolte
Ireland	Health Research Board	HRB	Maura Hiney
Italy	National Research Council	CNR	Cinzia Caporale

Country	Organisation	Acronym	Name
Luxembourg	Luxembourg National Research Fund	FNR	Asaël Rouby
Netherlands	Netherlands Board on Research Integrity	LOWI	Fauzia Roepnarain
	Netherlands Research Integrity Network	NRIN	Claudia Luettke
Poland	National Committee of the Polish Academy of Sciences	PAN	Adrian Kuzniar
	National Science Centre	NCN	Laura Bandura-Morgan
Portugal	Foundation for Science and Technology	FCT	Joana Araujo
Sweden	Central Ethical Review Board	CEPN	Jörgen Svidén Elisabeth Rachlew
Switzerland	Swiss Academies of Arts and Sciences	SAMW	Michelle Salathé
European Network of Research Ethics and Research Integrity		ENERI	Grace van Arkel

Observer

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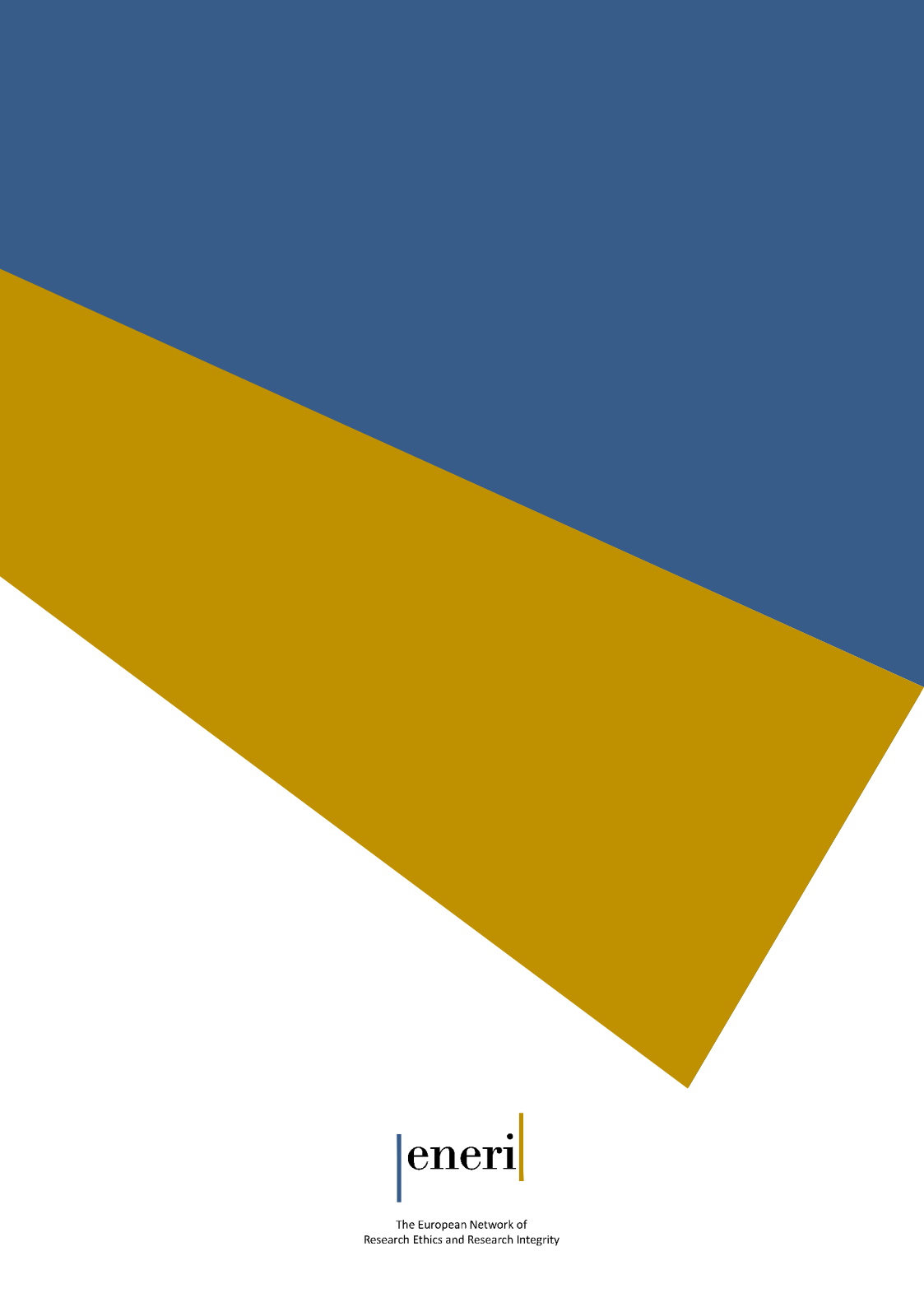
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The European Network of
Research Ethics and Research Integrity