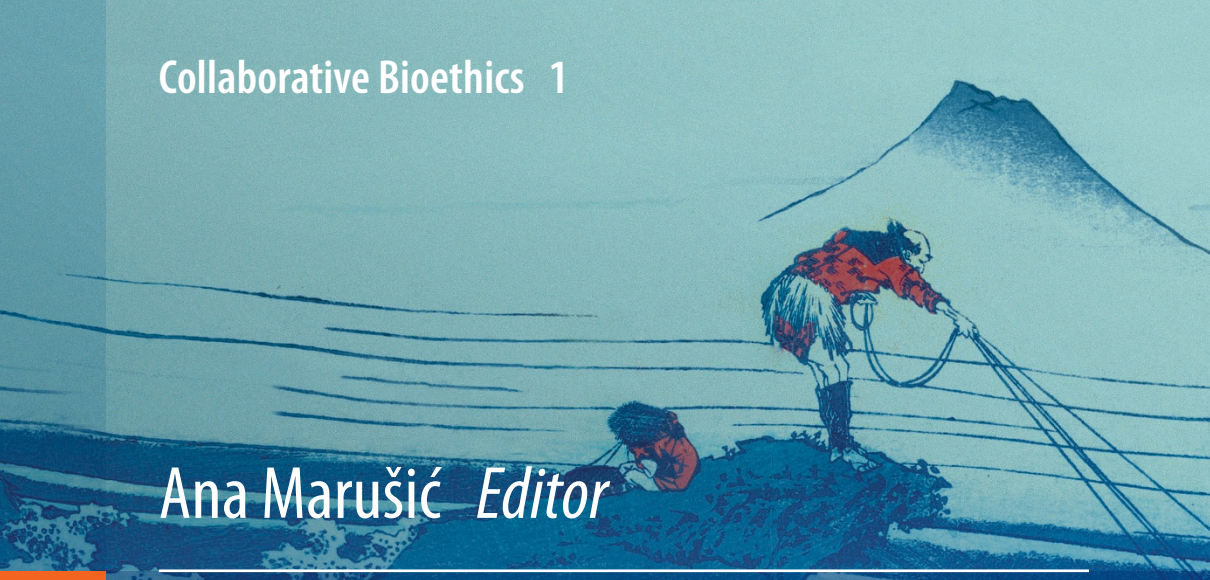
Collaborative Bioethics 1



Ana Marušić *Editor*

A Guide to Responsible Research

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Collaborative Bioethics

Volume 1

Series Editor
Insoo Hyun, Harvard Medical School, Boston, MA, USA

The aim of **Collaborative Bioethics**, is to draw attention to an underexplored but increasingly important area of scholarly thought and action: bioethics as a co-creative activity of ethicists working with scientists rather than as always a reaction to biomedical developments after the fact. The scope of this series is determined by each major subfield of science and medicine that raises ethical uncertainties for researchers, regulators, and the public.

Collaborative Bioethics is a series that will provide a central hub for timely publications addressing ethical issues that are emerging right alongside the science. As such, this series will be of interest to a wide swath of readers: bioengineers and scientists at all professional levels; bioethicists intrigued by bioengineering and medical advances; research regulators and funders; and the general public.

Ana Marušić
Editor

A Guide to Responsible Research

Springer

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Preface

You have surely heard or read about a case of scientific fraud or misconduct – such cases are rare but are usually highly visible in the media. As an early career researcher, you may wonder if research misconduct can happen to you. It can, but the probability is low. You may more often succumb to poor research practices, which are small transgressions in performing everyday research but very common so that they impact science more than serious research misconduct.

This book is not about research misconduct. We do not mention famous cases (although much can be learned from them) – we talk about how to do good research, what your responsibilities are in your research work and what your expectation from your organisation should be about responsible research. The inspiration and background for this book comes from the EU-funded project EnTIRE –" Mapping Normative Frameworks for EThics and Integrity of Research", whose aim was to create a platform for research ethics and research integrity. The Embassy of Good of Science is a meeting place for researchers to learn, contribute and discuss integrity and ethics issues, and thus support research excellence and society's trust in science.

In our contacts with different stakeholders in our training activities, especially with early career researchers, we recognised the need for a guide through The European Code of Conduct for Research Integrity. This Code is closely integrated in the EU research framework – it is a part of any research grant agreement, and must be followed by researchers funded by EU grant. It is a brief document that outlines the four principles of responsible research and describes good research practices.

Our book is also brief and concise. It is not an extensive academic treatise on research integrity but a practical guidance and advice from both experienced and early career researchers about translating principles of good research into practice. The book provides explanations and concrete recommendations on how to achieve good research practices in relation to the research environment, training and supervision, research procedures, legal framework for research, collaborative research, research publication and dissemination, and research review and evaluation. We also offer basic information about how to react to or make allegations of research misconduct and what to expect from an investigation of such allegations. We tried to be practical and concrete in our explanation and advice. We come from different fields – from medicine to social sciences and humanities, and we have tried to bring

our multidisciplinary experiences. Of course, we work together in a biomedical research environment, so most of the examples in the book are from biomedicine. We hope that they are relevant to other research fields, and we are sure that you will think of similar problems (and solutions) in your own research.

Have an exciting voyage to research excellence!

Split, Croatia Ana Marušić

Foreword: Research Integrity is a Pillar of Collaborative Bioethics

I am delighted to present this inaugural volume of the Collaborative Bioethics book series – *A Guide to Responsible Research* by Ana Marušić and colleagues. Bioethics can be defined as the interdisciplinary examination of ethical issues in biomedical research and bioengineering, healthcare delivery, and health and science policy. Bioethics – as a field of intellectual inquiry and as a guide for practical action – thrives insofar as it is propelled by the collaborative work of thinkers and practitioners informed by different disciplines, experiences, and perspectives. It is in the spirit of such collaboration that Marušić and colleagues offer a close look at the many aspects of research integrity, especially through a practical lens.

Research integrity is a central pillar of our collective scientific aim to expand knowledge for the good of humanity. Without attention to research integrity and best practices, we risk undermining the sacred trust of scientific advancement. Furthermore, no other issues in bioethics are as fundamental as research integrity, since without it, all other discussions around, for example, obtaining informed consent from human participants, or the just distribution of research benefits, are rendered irrelevant. When scientific inquiry lacks integrity – either in its conduct and reporting or its capacity to deliver the wholeness of truth – then all these other issues simply become handmaidens to a fruitless and ethically unjustified exercise.

Readers will find this volume very useful for their endeavors as researchers and as champions of scientific advancement. I am confident that readers, too, will find within it not only a guide for conducting responsible research but also a peek into what it means to engage in collaborative bioethics.

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Foreword: Research Integrity as an Object of EU's Policy Attention

Fostering research integrity has traditionally been seen as a prerogative of academic institutions and of Member States. Throughout the last few years, a number of European countries have adopted laws and procedures, and several research funding organisations across Europe have developed codes or guidelines in order to safeguard the integrity of research. Many EU Member States have today national codes of conduct for research integrity. At the level of the European Union, the "European Code of Conduct for Research Integrity" prepared by All European Academies (ALLEA) and following a wide consultation with all major stakeholders was included in Article 19 of the Horizon Europe Regulation and subsequently adopted by the Horizon Europe Framework Programme as a reference document.

The European Commission has adopted several initiatives that highlight the key role of research integrity as an essential element of all efforts to ensure the high quality of science and as a prerequisite for achieving excellence in research and innovation in Europe and beyond.

These EU-wide initiatives include the funding of scientific projects in the domain of research integrity including EnTIRE –"Mapping Normative Frameworks for EThics and Integrity of Research" that aim at developing guidelines as well as training and mentoring material and platforms. These initiatives that aim at integrating research integrity norms into the EU-funded research ecosystem indicate a strategic view of research integrity as part of the Responsible Conduct of Research and as an important component of the EU's ethics appraisal structures and mechanisms. Advancing research integrity across Europe is therefore of the utmost importance in order to foster high-quality research relevant to society.

Given the potential impact of the new and emerging technologies and the challenges associated with the need to maintain the integrity of the underlying evidence, the European Commission, more than ever before, is working hard for the shaping of a culture of research integrity in which responsible behaviour is expected at individual and institutional level. In order for research integrity to become a cornerstone of societal trust in researchers and research institutions, the Commission services are putting special emphasis on the training of young researchers, the exchange of good practice in addressing misconduct and the development of practical guidance

for researchers, expert reviewers and research managers.[1] These policy actions could not only help researchers navigate the maze of various norms and procedures on the conflict of interest, responsible authorship and data management but also empower them to act in a responsible manner.

Within this frame, we are thrilled to welcome this inaugural volume of the Collaborative Bioethics book series – *A Guide to Responsible Research* by Ana Marušić. The book is expected to contribute to the practical handling of the serious challenges associated with research integrity. Given the variety of policies, structures and even definitions of research integrity and misconduct across the European Union, initiatives of this kind could facilitate the sharing of expertise and best practices and could become a credible point of reference among researchers in Europe and beyond.

Efforts, such as the current publication, have the potential to become a mental compass to researchers to develop responsible research practices for research institutions to identify and handle breaches of the EU framework and for funders and policymakers to safeguard that appropriate policies, governance arrangements and advice mechanisms are put in place.

Its concise character and applied approach is expected to offer practical guidance to early career researchers and a valuable tool to translate principles of good research into practice. The book's recommendations on how to achieve good research practices provide a solid basis for the practical support of the research community across different scientific disciplines and fields. In view of the ongoing global dialogue on principles and values for international research and innovation cooperation,[2] initiatives of this kind enrich our understanding of the complex nature of research integrity and support all international efforts to discuss standards and facilitate the exchange of best practices in a domain that is the backbone of excellence and trust and is gradually becoming more visible in the policy radar.

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[1] See "The Embassy of Good Science", a major initiative to establish a communication tool and an information bank for all concerned. https://embassy.science/wiki/Main_Page

[2] https://presidence-francaise.consilium.europa.eu/en/news/conference-on-international-cooperation-for-a-global-europe-in-the-field-of-research-higher-education-and-innovation/

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Research Environment

1

Lana Barać

Abstract

Successful research environment requires joint effort by individual researchers, research groups and the organization. This chapter describes the basic principles and good research practices in the context of the research environment and serves as a guide to good, responsible research for research newcomers – researchers at the beginning of their scientific career. In this chapter we will help you navigate the organizational pathway to doing good research. The first step to understanding your rights, obligations and responsibilities in research is knowing that they exist. This chapter offers an introductory level orientation to codes, rules and regulations but also serves as a guide on how to identify whether your organization goes above and beyond offering guidance and assistance regarding research integrity or whether it provides a bare minimum or even nothing at all, and who/what you can turn to in the latter case. Furthermore, this chapter also describes the responsibilities that you as a researcher have towards the organisation regarding the importance of maintaining research integrity, so that you are aware of your accountability and the possible consequences if you disregard organizational responsibility for responsible research.

Keywords

Research climate · Research culture · Research ethics structures · Research integrity structures

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What This Chapter Is About

Successful research environment requires joint effort by individual researchers, research groups and the organization. This chapter describes the basic principles and good research practices in the context of **research environment** and serves as a guide to good, responsible research for research newcomers – researchers at the beginning of their scientific career. In this chapter we will help you navigate the organizational pathway to doing good research. The first step to understanding your rights, obligations and responsibilities in research is knowing that they exist. This chapter offers an introductory level orientation to codes, rules and regulations but also serves as a guide on how to identify whether your organization goes above and beyond offering guidance and assistance regarding research integrity or whether it provides a bare minimum or even nothing at all, and who/what you can turn to in the latter case. Furthermore, this chapter also describes the responsibilities that you as a researcher have towards the organisation regarding the importance of maintaining research integrity, so that you are aware of your accountability and the possible consequences if you disregard organizational responsibility for responsible research.

Case Scenario: Research Environment and Research Integrity

This hypothetical scenario was adapted from a narrative concerning the links between research environments and research integrity. The case scenario was developed by the Members of The Embassy of Good Science and is available at the Embassy of Good Science. The case below is published under Creative Commons Attribution-ShareAlike license, version 4.0 (CC BY-SA 4.0).

After 6 months of working as a novice researcher in a research lab at a university school, you meet up with a colleague who graduated with you and is now working as a novice researcher in a commercial research organization. She tells you that she may have encountered a potential research misconduct concerning intellectual property. She knew what she had to do because the company is very committed to making sure all employees are fully informed about all existing rules and regulations. Her action prevented the misconduct. That conversation made you think that you were never been briefed or informed in detail about rules and regulations regarding research when you signed your employment contract with your organization. You heard your mentor casually mention “standard rules of conduct in research,” expecting you to know what they are. The day after your meeting with your colleague, you check your school’s webpages for information on research integrity. Although there is no explicit mention of research integrity, your University’s website refers to its own code of conduct as well as the European Code of Conduct for Research Integrity. Furthermore, a university-wide academic

integrity complaints procedure and a research integrity committee are mentioned but details of which, however, cannot be found on the university's public webpages. After talking to your fellow novice researchers, you realize that they too are uncertain about whether your school has written guidelines for research integrity. You also realize that they feel pressurized to generate more and more research outputs and that insecurity, linked to short-term contracts and scarce opportunities for professional advancement, means that they perceive the incentives to succeed in research and academia as outweighing the incentives to comply with the norms of good research practices. They not only feel that your school does not adequately promote research integrity but that that pressure comes within the organization, also as a result of the culture of "*publish or perish"* After talking to them you realise that there is more to this problem than just ignorance or integrity issues with individual novice researchers and that their views could indicate an environmental problem in academia.

Questions for You

1. In light of this case scenario, what do you think which person(s) or groups should be responsible for the early-career researchers' general lack of knowledge concerning the university's research integrity guidelines, codes of conduct and complaints procedures? What are the reasons for your answer?
2. In what ways could a research organization make its research integrity standards, guidelines and processes more visible to its researchers, especially early-career researchers? What initiatives should be promoted in a research organization in order to engage early-career researchers with research integrity standards, guidelines and processes?
3. Thinking about the ways in which your organization currently engages early-career researchers with research integrity standards, guidelines and processes, what could be done to improve such engagement at the level of your organization and the level of your department or laboratory?

The Responsibilities of the Organization: Above and Beyond, or the Bare Minimum?

Good research practice from the European Code of Conduct for Research Integrity:
Research institutions and organisations promote awareness and ensure a prevailing culture of research integrity.

When starting at a new job in a new research organization you have to understand that an organization is a living organism – a system with organized structure that functions as an individual entity and is, as all organisms are, prone to constant change. One change that has been having a huge momentum in Europe in recent years is the initiative to encourage activities that show commitment of organizations to make **research integrity (RI)** and **responsible research** in general as a top priority. Empowering sound and verifiable research and fostering a research integrity culture, thus creating a proper research environment, is now empowered by embedding these principles as requirements in EU funding schemes. As **research environment** is a dimension that needs to be considered by all involved stakeholders, activities conducted in order to foster good research practices and a culture of research integrity will impact researchers at all levels.

When we talk about organization as a system, the terms organizational climate and organizational culture are sometimes used interchangeably or considered as complementary constructs. The two terms are different. **Organizational climate** is usually defined as shared perceptions of policies, practices and procedures experienced by the employees, as well as the behaviours the employees perceive as rewarding. It is considered to be the measurable manifestation of **organizational culture**, which is defined as the system of basic assumptions, deep values and beliefs that are prevalent in the organization. Organizational culture is something that has to be built, maintained and nurtured by supportive environment.

As a part of organizational culture, research integrity has become an integral part of a university's mission, vision and strategy. For example; universities in France will, in the near future, in what seems to be the first national initiative of its kind, go as far as requiring Ph.D. recipients to take an integrity oath on the day they successfully defend their thesis. Research integrity is also dependent on human factors – collegiality, openness, reflection, shared responsibility and work satisfaction are vital elements of a successful working environment. As a novice researcher, you should try, from the very beginning of your career, to comply with the highest standards of ethics and integrity in the performance of your research.

How can you figure out the ethical landscape at the very start of your career? The **first step to understanding your rights, obligations and responsibilities is knowing that they exist**.

Rules, codes and regulations can be created by the organization itself but also by national or international bodies. They can have different names and vary in scope, but they are always a written set of instructions issued by an organization. Depending on the scope of action, codes can cover issues prescribed by **legal regulations** such as: human subject's protection, animal care, intellectual property and confidentiality, legality and mechanisms to identify and procedure for reporting and dealing with research misconduct. Other than binding legal issues, codes can also cover **fundamental principles of research** which serve organisations in creating and preserving an environment for responsible research. Fundamental principles presented by the most widely recognized and accepted documents – *European Code of Conduct for Research Integrity* (All European Academies 2017) and *Fostering Integrity in Research* (US National Academies of Sciences, Engineering, and

Table 1.1 Research integrity principles in the European and USA documents

Principles in *European Code of Conduct for Research Integrity*	Principles in *Fostering Integrity in Research*
Reliability (Ensuring the quality of research by proper use of methodology, analysis and resources)	**Accountability** (Being able to demonstrate the validity of research which will be possible by using a proper methodology)
Honesty (Being honest, fair and transparent in developing, conducting, evaluating and reporting research)	**Honesty** (Honesty is a prerequisite of good research and other principles)
Respect (Respecting colleagues, research participants, society and environment)	**Objectivity** (Researchers' independence in performing research, avoidance of pressure and biases to be able to present research results truthfully)
Accountability (Researchers and research organizations are responsible for their research and its impact, mentoring, education and training)	**Openness** (Being transparent in all researcher phases, presenting all relevant information to other researchers, research participants and society)
	Stewardship (Good stewardship toward other researchers, organization and science overall)
	Fairness (Being fair in research evaluation or toward research participants and animals when conducting research; acknowledging the work of others fairly)
	Accountability (Being accountable for research behavior, work and actions; researchers have an obligation to explain the validity of their work, as well as the responsibility of being trustworthy toward organization and society. Funders are accountable for evaluating research proposals and providing grants)

Medicine 2017), might not be identical in the naming of the principles but the meaning of the principles in RI perspective is similar (Table 1.1).

Not all research or academic organizations are as big or as well developed to have the resources to promptly and adequately inform you about all rules and obligations regarding research. That does not mean you are not required to follow them or that your rights are not protected by them. Organizational guides and codes should be easily accessible on the organization's webpages and/or intranet. You should be provided with adequate training, tailored to the research discipline and the type of organization, and briefed about standard rules of conduct in research. Bear in mind that the organizational support structure is usually proportional to the size and complexity of the organization. Apart from having binding documents about responsible research, your organization should have established channels to facilitate an open dialogue at and between all levels; from management and senior researchers to novice researchers and other members of staff. Ideally, your organization should, apart from the standard rules and regulations, develop and implement a research integrity promotion plan (RIPP). This is a document that describes, on a general level, how the organization promotes research integrity and which concrete

methods are employed or are being developed to foster research integrity and to deal with allegations of breaches of research integrity. Procedures to increase transparency of research investigation procedure and safe and effective whistle-blowing channels and the protection of alleged perpetrators should also be implemented in line with the legal principle of the presumption of innocence – someone accused of research misconduct is considered innocent until proven guilty.

When navigating the research environment, it is always advisable to consider the human factor. Some organizations are very organized. Some are not. Even though an organization may be committed to following the prescribed rules, do not expect to be given a clear and user-friendly version of these rules upon arrival. Some organizations have rules and regulations because they had to comply with national or international regulations. Other organizations have them because the management is devoted to actively promoting responsible research. Some organizations are understaffed, so the lack of organizational documents may not necessarily reflect the moral of the organization. In brief, even if your organization does not have instructions for the new employees written on a (virtual) bulletin board, that does not mean that they do not exist, so no matter whether you were briefed or not these rules apply to you and you should be governed by those rules.

Here is some advice for you on how to navigate responsible research environment in your organization:

1. **Always get familiar** with existing laws, codes and regulations in the organization and country where you work. If you are a member of a professional organization or if you are professionally bound to the code of ethics of your profession, check whether the professional code is aligned with that of your organisation. Some organizations may provide a **checklist** with sources and links to different guidelines and rules of procedure for good research practice available online. Do not forget to get familiar with international principles and EU standards such as The European Code of Conduct for Research Integrity, principles prescribed for different professions (e.g., The Declaration of Helsinki or Convention on Biological Diversity) and national guidelines, but first and foremost to the documents and guidance provided by your organization.
2. **Consider** that different views of research ethics around the world reflect differences in culture and legal frameworks, which can lead to differences in regulations. For example, the European General Data Protection Regulation (GDPR) has a very expansive definition of personal information that may warrant protection, whereas in the United States (US), there is a narrower (and often domain-specific) characterization of privacy-sensitive information. Even within the EU, there are differences among EU member countries – the examples are different laws on stem-cell research and human embryos. Differences in regulations unfortunately may lead to *ethics dumping* – the practice of researchers trained in cultures with rigorous ethical standards to go and conduct research in countries with laxer ethical rules and oversight, in order to circumvent the regulations, policies, or processes that exist in their home countries.

3. **Keep in mind** that codes and regulations change and can evolve. For example, The Nuremberg Code; which is a set of research ethics principles for human experimentation was created by the US vs. Brandt et al. court case, as a result of the Nuremberg trials at the end of the World War 2. The core elements of the Nuremberg Code are the requirements for voluntary and informed consent, a favourable risk/benefit analysis, and the right to withdraw from a study without consequences. That standard was confirmed in 1964, when the WMA's Declaration of Helsinki was endorsed and again specified that experiments involving human beings needed the informed consent of participants. The Declaration of Helsinki has been updated overe the years, so make sure that you consult its latest version. Another example is the infamous Tuskegee syphilis study, funded by the US Public Health Service. The study was conducted between 1932 and 1972 at Tuskegee Institute in Alabama to evaluate the natural history of untreated syphilis in African American males. The study was conducted for 40 years without ethical review and denied participants the effective treatment for this curable disease. The study became a milestone in the history of US research regulations, as it was conducted without ethical re-evaluation in spite of both The Nuremberg Code and the Declaration of Helsinki being accepted and established as a standard during the study. The aftermath of the public disclosure of the Tuskegee study led to the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research and the National Research Act that requires the establishment of institutional review boards (IRBs) at institutions receiving federal support.

   Codes and regulations can also change due to scientific advancements that lead to new fields of research (e.g., the emergence of experimental psychology) or new technologies (e.g., gene editing, artificial intelligence). The changes can also come in response to changes in cultural values and behavioural norms that evolve over time (e.g., perceptions of privacy and confidentiality).
4. **Consider emerging ethics topics**, even if they are not listed or mentioned in current codes of your organization, such as *bystander risk* (impacts of research on other people; e.g. genetic testing and genetic research, second-hand exposure to a contagious disease) *big data and open science* (concerns about the potential to compromise privacy), and *citizen science* (involving community participation in science, allowing the research population to become researchers).

Good research practice from the European Code of Conduct for Research Integrity:
Research institutions and organisations demonstrate leadership in providing clear policies and procedures on good research practice and the transparent and proper handling of violations.

Knowing, understanding and using existing codes and regulations for good research is important and useful, but there may be times when you are in doubt about how what is written in a code translates into real life. Therefore, it is important to learn how to interpret, assess, and apply different research rules and how to make decisions to act ethically and responsibly in different situations or at least know **who to turn to when in doubt**. To put it simply: pure existence of the codes does not make an ethical environment. Or, in words of Aristotle: "One swallow does not a summer make."

If codes, rules and regulations are the foundation of research integrity culture, building strong pillars to rest upon, establishing **research ethics structures** is the next crucial step for organizations to ensure proper research environment.

Different organizations may have different supportive mechanisms to ensure that researchers adhere to research ethics and integrity requirements. Depending on the size and the type of the organization, key organizational bodies and staff dealing with research ethics and integrity might quite vary in name and scope of work. It is important to understand that, depending on type of research organisation, you may encounter organisational bodies (or individuals) with various scope of activities regarding research ethics and integrity. This may seem confusing at first, as the concepts of ethics and integrity may seem intertwined and actually, for the most part, they are. **Research ethics (RE)** is the term that encompassed fundamental moral principles and **research integrity (RI)** is the quality of having moral principles, defined as active adherence to the ethical principles and professional standards essential for the responsible practice of research. Both of them are a necessary part of responsible conduct of research.

Ideally, your organisation will have all necessary structures, processes, and dedicated and adequately trained staff to uphold best research practices and standards, and deal with procedures relevant to the various research areas and disciplines within the organisation. Listed below are some of the common research ethics and integrity bodies (names might vary). If there is only one of these at your organisation, the scope of their responsibilities is probably wider and you can still contact them regarding any doubt and insecurity you might have about responsible research.

Ethics Committee or **Institutional Review Board** is probably the most common body at academic and research organizations, because it has the longest history. Research Ethics Committees were developed after the World War 2, particularly in response to The Nuremberg Trials, as bodies responsible for oversight of medical or human research studies. The role of an Ethics Committee is to scrutinise research proposals and ensure that the proposed research adequately addressed all relevant ethics issues. This means that they make sure that proposed research protocols protect rights, safety, dignity and well-being of participants, that research protocols involving animals follow the highest animal care standards and that they facilitate and promote ethical research that is of potential benefit to participants, science and society. In smaller organisations that do not necessarily have other bodies, the role of the Ethics Committee would also be to facilitate and promote research integrity

and good research practices, to have mechanisms to identify and procedure for reporting and dealing with allegations of breaches of research integrity (research misconduct).

Board/Office/Commission for Research Integrity is a body that promotes responsible research conduct, serves as a knowledge base for questions regarding research integrity and research misconduct, informs on policies and procedures in and outside of the organization, handles allegations of research misconduct and conducts investigations, advises on administrative action and also responds to allegations of retaliation against whistle-blowers. It is responsible for providing advice for researchers on how to adhere to responsible research practices, usually through guidelines, checklists and other documents in which good research practices are presented. The organisational structures of RI committees and their responsibilities regarding cases of research misconduct may vary depending on the organisational or national regulations. For example, the **Office for Research Integrity** in the US is a governmental body that has monitoring and oversight role to ensure that researchers and organisations which receive federal funding for health research comply with existing regulations; it offers support to further good practice research and promote integrity and high ethical standards, as well as to have robust and fair methods to address poor research practices and misconduct.

Another individual position you may encounter at your organisation is the **Research Integrity Officer (RIO)**, a professional with a complex role. An organisation's RIO promotes responsible research, conducts research training, discourages research misconduct, and deals with allegations of or evidence of possible research misconduct. The details of an RIO's job vary from country to country, but the position is mandatory in many. For example, in US organisations, a RIO serves as the liaison between the federal Office for Research Integrity and the organisation of the researchers. In the EU, countries have different requirements and roles for their RIOs, but their task is essentially the same. Some countries do not have such bodies, and their role is most often taken by Ethics Committees.

Your organisation may have a **Research Integrity Ombudsperson** or **Confidential Advisor on Scientific Integrity** or **Research Integrity Advisor**. The aim of such an advisor is to promote fair, non-discriminatory and equitable treatment related to research integrity within the organisation and improve the overall quality of the research working environment. Such a position should be well known in the organisation, and there should be a low threshold for contacting this person. Researchers who experience research integrity dilemmas or have come into an integrity-related conflict should be able to discuss their case with the ombudsperson in a strictly confidential manner. The function of the ombudsperson should be clearly separated from a formal research integrity committee or ethics committee, so that it is clear to researchers that contacting the ombudsperson *does not imply a formal registration of an allegation* but a confidential and informal assistance in resolving research work-related conflicts, disputes and grievances (including, but

not limited to complaints/appeals of researchers regarding conflicts between supervisor(s) and early-stage researchers).

Good research practice from the European Code of Conduct for Research Integrity:
Research institutions and organisations support proper infrastructure for the management and protection of data and research materials in all their forms (encompassing qualitative and quantitative data, protocols, processes, other research artefacts and associated metadata) that are necessary for reproducibility, traceability and accountability.

Even as an early-career researcher you probably realise that, while doing research, dealing with a fair amount of different types of data is inevitable. Ten years ago the *Science* journal polled their peer reviewers from the previous year on the availability and use of research data, and, about half of those polled stored their data only in their laboratories. If you had walked in any type of research organisation 10 years ago you would have had probably been briefed about keeping your lab notebook records and advised about keeping your data somewhere other than your lab desktop computer. Today, when we talk about data management, we go well beyond keeping your lab or research notebook in order. While maintaining a lab notebook is still essential for anybody performing research as a document of completed work so that research can be replicated and validated; or a legal document to prove intellectual property/invention, **data management on an organisational level entails much more**. It comprises the infrastructure (technology, services and staff support), training for researchers, and policies on data management (DMPs). Therefore, you should expect from your organisation to provide instructions and policies regarding data curation (repositories), management, use, access, publishing, and sharing. Regarding the technology for data management, your organisation should provide appropriate storage media that enables collecting, organizing, protecting, storing, and sharing data. It should also inform you about available data repositories, networks and different authentication systems. Research organisations should make DMPs easily accessible and organisations' websites should provide extensive information about the concept of data sharing in general, as well as detailed information on DMP requirements and how to comply with them. Services and staff support for data management are highly dependent on the amount of funding and size of an organisation because the amount of work and time involved in these processes is extensive and costly. Some organisations have whole departments and others at best a single person for data management.

In 2019, Science Europe released its *Practical Guide to the International Alignment of Research Data Management*, and, as a follow-up, compiled the document to showcase some best practices. The document also demonstrated the variability of data management processes in different organisations. Although the readiness to develop DMPs can differ according to discipline, most research funders require researchers to include a DMP in their project proposals. You should expect

from your organisation to have in place the structures and procedures to facilitate data management and curation procedures that are aligned with **FAIR** principles, which say that data should be **F**indable, **A**ccessible, **I**nteroperable, and **R**eusable. Bear in mind that researchers' knowledge about research data management could be limited in countries and organisations where open science policies are not well developed. This leads to misunderstandings about the need to store and archive data. For detailed guidance on data practices and management throughout the lifecycle of research data and instructions to preparation of data management plans (DMPs) see Chap. 5.

Good research practice from the European Code of Conduct for Research Integrity:
Research institutions and organisations reward open and reproducible practices in hiring and promotion of researchers.

No matter whether you have been in research for some time or you are a novice researcher, you have probably heard the catchphrase "*publish or perish!"* because it has been uttered in whisper by stressed and burned-out researchers all over the world for years, putting pressures on individual integrity and potentially fostering practices harmful to scientific research. *Publish or perish* culture thrives on metrics (number of articles published and impact factors of journals) but fails to adequately take societal and broader impact into account. Some aspects of research are indeed quantifiable and cannot be and will not be ignored, but recent efforts towards more inclusive evaluation scheme of research and researchers could be a "game-changer", meaning that yes, you are still required to publish, but the scientific efforts that translate better to a broader community will not be ignored.

When it comes to hiring and promotion in research, the need for transparency should be self-explanatory, but what does promoting open practices mean in reality? Geographically speaking, Europe might be ahead of the curve in endorsing and implementing changes as the new framework programme Horizon Europe makes Open Science mandatory throughout the programme and includes Open Innovation as one of three framework pillars. What does this mean for you? Although the attitude and the level of commitment of the organisation toward endorsing open science principles could vary and very much depend on the human factor, there is no reason for you not to be aware of the change to come and strive to fulfil the general idea of *quality*. Producing *quality science* would imply **producing substantive, impactful science**, science that reaches broader audience and addresses valuable questions, but is also reliable enough to build upon. This mean that evaluation and appraisal procedures may assess a researcher's contribution to addressing societal needs and publishing all research completely and transparently, regardless of whether the results were positive or negative. This would also imply implementing open research practices and embedding these skills in training of early-career researchers, making preliminary results and final results available to the general public, potential users

and the research community, in order to facilitate broader assessment and accountability of research.

There are also indications that the EU is moving towards a structured CV which would include Responsible Indicators for Assessing Scientists (RIAS), and other related information. For example; the department of psychology at LMU München added a paragraph to a professorship job advertisement which asks for an open science statement from the candidates: "Our department embraces the values of open science and strives for replicable and reproducible research. For this goal we support transparent research with open data, open material, and pre-registrations. Candidates are asked to describe in what way they already pursued and plan to pursue these goals." Another example is University of Liège, where depositing papers in the repository is now the sole mechanism for submitting them to be considered when researchers underwent performance review.

Check whether your organisation has procedures related to the publication and communication of research results, such as preregistration, preprints, and online repositories, the organisational approach to open access, FAIR data curation, expectations about the use of reporting guidelines, procedures for avoiding predatory journals, strategies for responsible peer review practices, and mechanisms to support and acknowledge public communication of research findings. Also, check whether your organisation is ahead of the curve in promoting Open Science (Fig. 1.1) check for procedures and practices through the organisation's own website or other established platforms on organisational or national level, check whether your organisation has signed any declaration relevant to Open Science.

The Responsibilities of the Researcher

Ask not what your *organisation* can do for you – ask what you can do for your *organisation.*

While The European Code of Conduct for Research Integrity (ECoC RI) provides general guidance for good research practices and serves as a framework for self-regulation, the document that details your role, responsibilities and entitlements as a researcher is The European Charter for Researchers. The Charter is a set of general principles and requirements that addresses all researchers in the European Union at all stages of their career, covers all fields of research and takes into account the multiple roles that researchers can have.

Being a researcher is highly related to context and not defined only by job positions, formal qualifications level of education or by seniority at work. According to The Frascati definition; ***Researchers*** *are* ***professionals engaged in the conception or creation of new knowledge****. They conduct research and improve or develop concepts, theories, models, techniques instrumentation, software or operational methods.* The tasks performed depend on job characteristics and personal strengths but have to be related to research and innovation. Activities of a researcher are many, but first and foremost entail: conducting and evaluating research and innovation,

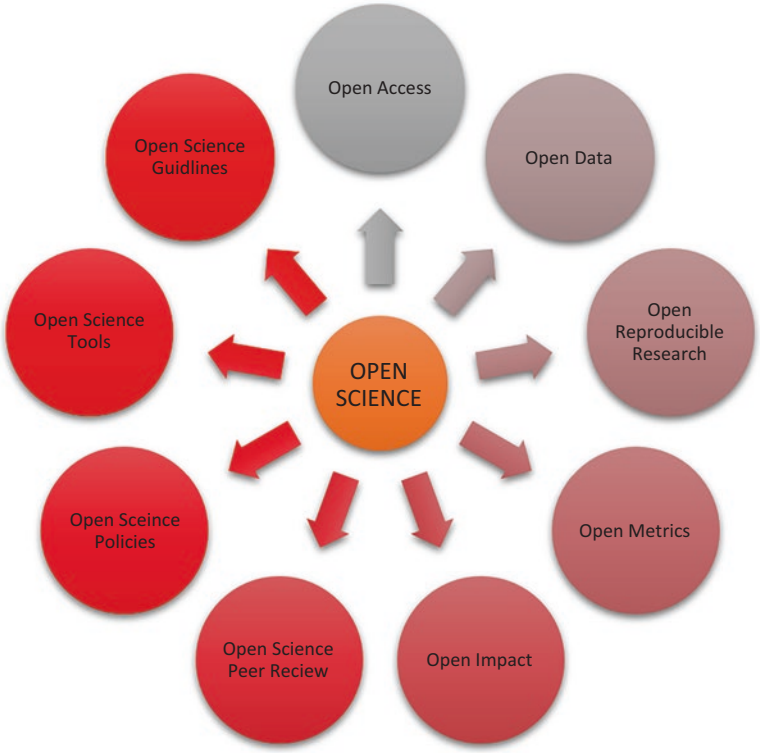

Fig. 1.1 Core principles of Open Science. For details, see the FOSTER project

applying for research funding, managing projects and teams, managing, sharing and transferring the generated knowledge (including through scholarly communication, science communication to society, knowledge management for policy, and knowledge transfer to industry) and higher education teaching.

As an early-career researcher, you should keep in mind that **everything you do reflects upon your organisation**. So be sure to comply with the highest values and ethical standards and aim at excellence. Even as a novice researcher, at a beginning of your career be aware that your organisation will treat you as a responsible adult and will **hold you accountable**. Also, depending on the applicable rules, your organisation might be held accountable for your wrongdoing, so, even if you are there for a brief amount of time (post-doctoral or project-based position) **remember** that you are a part of the research environment and are expected to contribute to a positive, fair and stimulating research culture.

Science is by definition a joint endeavour and you should learn to accept responsibility because that is what being accountable entails. **Accountability** refers to an obligation or willingness to accept responsibility for one's actions, meaning that, when individuals are accountable, they understand and **accept the**

consequences of their actions for the areas in which they assume responsibility. Remember that you, as an employee, have **contractual and legal obligations.** That basically means that you are liable in case of breach of contract and you have to adhere to such regulations by delivering the required results (e.g. thesis, publications, patents, reports, new products development, etc), as set out in the terms and conditions of the contract or equivalent document. You should be familiar with the strategic goals, seek all necessary approvals before starting your research or accessing the resources provided. You should, at all times, keep a **professional attitude**. This included maintaining a professional etiquette at workplace – respectful and courteous demeanour towards colleagues and respect in the sense of responsibilities (e.g. informing your supervisor if you are not able to meet deadlines).

As a researcher, you should, first and foremost, focus your research for the good of mankind and for expanding the frontiers of scientific knowledge. **You should be guaranteed the freedom of thought and expression**, and the freedom to identify methods by which problems are solved, according to recognized ethical principles and practices. But, bear in mind that **there is a difference between using research freedom and abusing it.** You should, by all means, recognize the limitations to this freedom that could arise as a result of particular research circumstances or operational constraints (e.g. for budgetary or infrastructural reasons or, especially in the industrial sector, for reasons of intellectual property protection). Such limitations should not contravene recognized ethical principles and practices in research. When it comes to **ethical principles**, you should adhere to the recognized ethical practices and fundamental ethical principles appropriate to your discipline, as well as to ethical standards defined in different national, sectoral or organisational codes of ethics. It is highly recommended to conduct **ethics self-assessment** at the very beginning of planning your research. Ethics self-assessment helps getting your research protocol *ethics-ready*, as it may give rise to binding obligations that may later on be checked through ethics checks and reviews. Consider that ethics issues arise in many areas of research and, as of recently, major scientific journals require researchers to provide ethics committee approval before publishing research articles. You should also adopt safe working practices, in line with national legislation, including taking the necessary precautions by preparing proper back-up strategies.

As we mentioned before, **Open Science practices** should be the norm, especially when performing publicly funded research, as they improve the quality, efficiency, responsiveness of research and trust in science. You should guarantee open access to research publications and research data and foster innovation in sharing research knowledge as early as possible in the research process, through adequate infrastructures and tools. You should ensure, in compliance with your contractual arrangements, that the results of your research are disseminated and exploited. **Be public and open about your research**. There are, of course, legitimate reasons to restrict access to certain data sets (for instance in order to protect the privacy of research subjects) so be guided by the principle "*As open as possible, as closed as necessary"*. Ensure that your research activities are made known to society at large in such a way that they can be understood by non-specialists, thereby improving

public understanding of science. Direct engagement with the public will help researchers better understand public interest in priorities for science and technology and also their concerns.

You should seek to **continually improve** yourself by regularly updating and expanding your skills and competencies. This may be achieved by a variety of means including, but not restricted to, formal training, workshops, conferences and e-learning.

Do not be afraid to **diversify your research career**, as research community is diverse in talents and expertise and can produce a wide range of research outputs (from scholar publications to scientific advice for policy makers, science communication to the public, higher education teaching, knowledge transfer to industry, and many others). Explore different career paths within the research profession, so that your talent finds the best place to produce richer research results.

If You Want to Learn More

The Embassy of Good Science

Case scenario – Research Environments and Research Integrity
Guidelines – Creating a map of the normative framework informing and governing the state of Good Science
Education – Literature and tools in research integrity and ethics

Published Articles

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Guidance

The European Code of Conduct for Research Integrity - framework for self-regulation across all scientific and scholarly disciplines and for all research settings. ECoC is a reference document for research integrity for all EU-funded research projects and as a model for organisations and researchers across Europe. All European Academies (ALLEA). (2017). https://allea.org/code-of-conduct/

The Bonn PRINTEGER Statement – Working with research integrity; guidance for research performing organisations

SOPs4RI Toolbox – Standard Operating Procedures and Guidelines that Research Performing and Funding Organisations can use to develop their own Research Integrity Promotion Plans

LERU – The League of European Research Universities (LERU) is a prominent advocate for the promotion of basic research at European research universities comprising of League of European Research Universities 23 leading universities pushing the frontiers of innovative research

Science Europe – Implementing Research Data Management Policies Across Europe: Experiences from Science Europe Member Organisations

Ask Open Science – Hosted by Bielefeld University, discussion (Q & A) on Open Science

The LSE Impact Blog – Six principles for assessing scientists for hiring, promotion, and tenure

The European Charter for Researchers – The European Charter for Researchers is a set of general principles and requirements which specifies the roles, responsibilities and entitlements of researchers

Training, Supervision and Mentoring

2

Ružica Tokalić

Abstract

This chapter aims to introduce you to important aspects of early-career research, particularly doctoral training, including its formal and informal aspects, and to map what is expected from the individuals at different hierarchical positions in their research environment. The purpose of doctoral training is to provide you with knowledge and skills for research that answers important questions, that research is conducted with care and high standards, that you anticipate the implications and applications of its results, and that your research is replicable, transparent and open. This is not and cannot be achieved only through formal training, but through various forms of what is called a hidden curriculum. In this chapter, we will talk about shadowing and role models, research collaboration and international relationships, networking, summer schools and research exchanges. Considering the complexities of relationships in the research setting, we will also talk about the role of doctoral students, and their involvement in supervising others (such as Masters' students). We will address the principles of respect, honesty and accountability in these networks of collaboration, with special attention to students and supporting staff in academia. Finally, we will discuss the aspects of work and life balance for doctoral students and the importance of existing support networks, with special attention to mental health support and principles of open communication.

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Keywords

Mentors · Supervisors · Mentees · Training · Collaboration · Rights and responsibilities

What This Chapter Is About

This chapter aims to introduce you to important aspects of early-career research, particularly doctoral training, including its formal and informal aspects, and to map what is expected from the individuals at different hierarchical positions in their research environment. The purpose of doctoral training is to provide you with knowledge and skills for research that answers important questions, that research conducted with care and high standards, that you anticipate the implications and applications of its results, and that your research is replicable, transparent and open. This is not and cannot be achieved only through formal training, but through various forms of what is called a hidden curriculum. In this chapter, we will talk about shadowing and role models, research collaboration and international relationships, networking, summer schools and research exchanges. Considering the complexities of relationships in the research setting, we will also talk about the role of doctoral students, and their involvement in supervising others (such as Masters' students). We will address the principles of respect, honesty and accountability in these networks of collaboration, with special attention to students and supporting staff in academia. Finally, we will discuss the aspects of work and life balance for doctoral students and the importance of existing support networks, with special attention to mental health support and principles of open communication.

Case Scenario: Silent Expectations of Doctoral Training? *In Omnia Paratus*

This hypothetical scenario was adapted from a narrative concerning the links between research environments and research integrity. The original case scenario is developed by the Members of The Embassy of Good Science and is available at the Embassy of Good Science.

Lane is a doctoral student working on gene expression in hepatic tumours. This is her second year of doctoral training, and it is safe to say that her work and life balance has gone out of the window. She spends her weekends in the laboratory, her working day evenings are reserved for data management or catching up on her background research reading, and she hasn't seen her friends for weeks. This is taking a toll on her wellbeing, as she has also given up on her hobbies. Her laboratory is one of the top in this field of research. This also means that the climate at the lab is highly competitive. Senior researchers are not always keen on providing support. On several occasions, Lane has seen unfamiliar authors' names appear on papers at the submission stage.

Lane's supervisor is prof. Smith, famous for breakthrough research in cell signalling. Prof. Smith aims to publish in most prestigious journals such as *Science* and *Nature*, as he wants to secure tenure in the next 5 years. He has so far dismissed Lane's results as too insignificant and wants her to continue working until she gets more impressive results. This means that Lane might not finish her PhD in time. Lane is starting to no longer enjoy this work, and feels like she's never going to get the results Prof. Smith wants. She believes she has enough data to publish in a smaller journal, which would be enough for her doctoral thesis. She also doesn't feel comfortable keeping these results unpublished. As the lab is publicly funded, Lane feels it is only right that the public gets access to the results. Also, other research groups might publish similar research before them, making Lane's efforts unpublishable.

Meanwhile, Prof. Smith is nowhere to be seen in the last 3 months – he hasn't visited the lab since the summer, and his emails get short responses at best. Lane feels like the only people she talks to are lab technicians and her fellow doctoral students, who are in a similar position. There are two postdocs in the lab who seem nice, but they are too busy with their work. One of them, Kirk, told Lane that this is how it is in highly competitive labs – she should quit now if she can't handle the pressure.

Questions for You

1. Is Lane's experience realistic of what doctoral training should look like? What is the rationale for your answer?
2. What is the role of Prof. Smith in Lane's education? Should Prof. Smith's professional ambitions influence Lane's doctoral education? In what ways?
3. How should Lane address her concerns to Prof. Smith?
4. What could be done to improve Lane's doctoral education?
5. Who should Lane talk to about her options? What initiatives are there to support students like Lane?

Mentors and Mentees: Roles and Responsibilities

A doctoral degree (dr. sc. – doctor of science, ScD – scientiae doctor, or a PhD – philosophiae doctor), is a title awarded to those who have successfully completed a specific study program, written and defended a dissertation. But what does it exactly entail?

The Greek word *'philosophia'*, translates to 'love of wisdom'. In that sense, doctoral (PhD) training is an exploration of your love for knowledge and discovery. Hopefully, in that journey you contribute to the knowledge of the living world and the things around it. Just like the Greek hero Odysseus, you will meet new people on that journey, some of which will help you navigate the waters of research, and some that will try to lure you into poor practices with seductive songs of quick success. While you might not have Mentor or Athena, you will have a mentor who should guide you in your doctoral training.

Good research practice from the European Code of Conduct for Research Integrity:
Senior researchers, research leaders and supervisors mentor their team members and offer specific guidance and training to properly develop, design and structure their research activity and to foster a culture of research integrity.

In doctoral training, your mentor plays a very important role. Studies have shown that choosing your mentor well is one of the most important factors that influence the success of your doctoral study. How do you choose a mentor? Firstly, you will have to identify what interests you and where your passions lie, i.e. which research topics you would like to study. Then you should find a researcher at your or some other research/academic organisation who already does research in that or a similar topic, and are preferably successful at it. That seems like a good idea, right? Maybe at surface level. Researchers who are most popular might be at the top of your

search results, but that will tell you nothing about their everyday work, team leadership or supervision/mentorship qualities. What you want in a mentor is someone who knows what they are doing, someone who loves teaching and mentoring, and someone who will be available to you for help when you need it. There are too many absent mentor jokes and memes online for this to be ignored. 'See you with two unhelpful comments on your dissertation in six months' might seem funny while you scroll one more social media page filled with fellow students' self-deprecating comments, but a 'ghost' mentor might be a bitter reality for the future you. While the waiting itself might be an inconvenience, it might be slightly more than that. It might cost you paid time you could have gotten on a job with a doctoral degree. It could cost you the opportunity to apply for a new position on time. It could cost you your doctoral degree, if situations like that continue indefinitely. Of course, you can always try to find a different mentor, but that will open a Pandora's box of problems with ownership of research data, ideas and funding that you might not want to get into. And it will give you back exactly zero minutes of your time and effort. So, now that you're properly frightened, how do you choose a mentor?

Most doctoral training programmes stipulate that you have to have at least two supervisors, one main supervisor and a co-supervisor. Notice how in this chapter we use the word mentor, not supervisor. Those two are not the same thing (Box 2.1), but we will not go into detail on their differences here. Broadly speaking, supervision is the process of overseeing work in a technical manner, ensuring everything is up to prescribed standards. Mentoring is a more nuanced concept of guidance which helps you develop beyond technical skills. It is more personal and should be a process in which both parties benefit and grow. Even though the word supervisor is used more often, it is important to know that supervising is not enough in PhD training. It should also involve sharing of knowledge and generation of ideas and giving credit where credit is due. People who guide your PhD training should push you into new opportunities and experiences selflessly. Unfortunately, in the 'publish and perish' culture, this is not always the case.

Box 2.1 Mentoring vs Supervising

Mentoring:

- Educational: introducing and integrating learning,
  - Personal: managing transitional states,
  - Professional: maximising students' potential to become a fulfilled and achieving practitioner,
  - High level of commitment,
  - Reciprocal but asymmetrical.

Supervision:

- Task oriented;
  - Organising, monitoring and directing research;
  - Technical, one-directional.

First-hand experience with a professor whose classes you have attended or a researcher that you listened to at a scientific meeting are a good guide for the start of your search for a research mentor. Ask if you can help with their current research projects, so that you can gather valuable experience and skills and get the feeling of the group and the subject area before you commit to it in a doctoral training programme. This might be a good idea not only in your search for the right mentor, but also in your search for the right subject of research. Your impression of science might be slightly different than its reality – a regular working day in research is usually much less impressive and much more repetitive than it might seem from the outside. It is always good to try it yourself (within a team, with all of the safeguards!) and see how it fits your desired lifestyle. Research experience will also give you the opportunity to communicate with the team of PhD students and other researchers who already work with the potential mentor.

That brings us to the next piece of advice. What might be most helpful in your search for the perfect mentor fit is the good old word of mouth. Contact your friends, colleagues, former students and online communities and see who they recommend. What to look for? Here are some tips:

A mentor who is open in communication, but not '*cruel in the name of being honest'* (Taylor Swift got it right, even if she didn't write that lyric with a doctoral supervisor in mind).

A mentor who is professional, but not completely reserved and distant.

A mentor who is a friend, but who also knows and respects boundaries.

A mentor who does good research, but also knows how to transfer the necessary skills to their fellows.

A mentor who provides help and advice when you need it, but also does not do the work for you.

While it might seem pretty cool to have a mentor who takes care of your manuscript, and the lab equipment that broke down again, and sweet-talks the librarian who does not reply to any of your emails, it might not be so nice once you are out there on your own with a doctoral degree. Your mentor will not always be there to write a reply letter to peer reviewers for you. You have to learn to do it yourself. Some might call this 'tough love', but it might be more appropriate to say 'skilful mentorship'.

Good research practice from the European Code of Conduct for Research Integrity:
Research institutions and organisations ensure that researchers receive rigorous training in research design, methodology and analysis.

A good mentor will also guide your education, in your specific academic discipline and in research integrity and ethics. Your doctoral education should equip you with skills of proper research design and conduct, asking the right questions and using the right methods to find the answers. It should also enable you to report research results in an appropriate manner, encourage you to share data publicly and to acknowledge help you receive from co-authors, technical staff and research subjects. During your doctoral studies, you should acquire habits of staying up-to-date with relevant research and new knowledge, recognizing your field of expertise and getting comfortable with being wrong, accepting constructive criticism, and applying that experience into future work. Doctoral studies are as much character-building as they are knowledge-building. While learning to report your results, transparency, accountability and fairness all come into play. You should be transparent in reporting all the methods you have used, all of the data you have collected and all analyses you conducted, including those that have changed since the original protocol. You should be accountable in crediting all of those who helped you in the process, and fair in acknowledging funding and support you received along the way.

Where and how do you learn about these research principles? They will very likely be a part of research integrity and research ethics courses. You might think that research integrity and ethics education means being familiar with ethics codes and regulations – just another box that needs ticking. While it is true you should be aware of regulations that apply to your research, research integrity (RI) training encompasses more than that. RI training should look beyond boundaries of discipline, culture and politics. As described in the European Code of Conduct for Research Integrity, it should strive to cultivate good research practices, led by principles of reliability, honesty, respect and accountability. Training in research integrity should include topics and problems that are not traditionally included in similar education, like time management, recognizing and preventing poor practices. Real life examples, both in the form of case scenarios and personal experience, help you to be more engaged and help create a learning environment.

Good research practice from the European Code of Conduct for Research Integrity:
Research institutions and organisations develop appropriate and adequate training in ethics and research integrity to ensure that all concerned are made aware of the relevant codes and regulations.

Your university should offer training in ethics and research integrity, with the minimum requirement of introducing you to relevant codes and guidelines for your research. Some universities develop their own training, which we strongly encourage you to search out for. Some offer theirs online, via platforms like Epigeum, while others host their own training, with downloadable tools and materials. It is not unusual for universities to have ethics and integrity training embedded into research methodology courses, or courses on animal research or ethics in general. While this is certainly better than no

inclusion, it would be best to have separate, dedicated learning time and sources for research ethics and research integrity. Materials and educational tools that are free to use are available at ENERI training page, RRI Tools, and The Embassy of Good Science training page, where they are continuously updated.

A large proportion of these educational materials are focused on norms and regulations. Some RI trainings have departed from rule-based learning and are focused on virtues and values that should guide practice. VIRT^{2}UE train-the-trainer course is based on virtue ethics, with the idea that that development and cultivation of virtues will equip researchers with skills necessary to act appropriately in different situations, without the need to know all of the rules. This way, researchers would know how to react in situations that we have not yet anticipated and created rules for.

While being technically good at research methods and practising research skills are important for being a good researcher, they are not nearly enough. A good researcher will also be open, conscientious and reflective, self-critical and willing to admit mistakes, learn from them and improve. These principles are common to every discipline, but are often taken for granted, overlooked and poorly addressed in doctoral training.

Good research practice from the European Code of Conduct for Research Integrity:
Researchers across the entire career path, from junior to the most senior level, undertake training in ethics and research integrity.

Training in research integrity and iterative work on the integration of these values in everyday work is necessary if we want to build the generations of researchers who are good for society. However, this does not mean that only novice researchers and students should undertake such training. We cannot and should not expect that doctoral students should bear the weight of research integrity while everyone else keeps doing what they always did. Senior members of the research environment, as well as non-research staff, benefit from reminders about the core values of research and what roles they have in the fragile ecosystem of science. They should lead by example and participate in continuous education and improvement of their practices.

Your mentors should also provide you with funding and opportunities for networking. Learning how others work in your discipline and socialising through research exchanges and summer schools is a valuable part of doctoral education. It is important that mentors enable and support those experiences. Your mentors will also help you prepare your work for presentations and guide you with their own example on how to communicate research results, both with the research community and with the society as a whole. They should guide you and introduce you to the standards of quality that are expected in research. Research misconduct often happens because of poor mentorship that led to poor research practices, especially in large research collaborations.

There are numerous disputes and even more opinions on the duality of professional and private life in research, many of which stipulate the importance of

personal values, both of those who judge and of the subjects of their judgement. Separating the art from the artist might be tough and whatever your stance on it, you might feel like a hypocrite for doing so. You might want to work with the superstar researcher in your desired field, but are you willing to ignore the stories about their inappropriate behaviour at conferences or past relationships that erased all boundaries between their work and personal life?

While it is important to strive towards a good balance between your personal and professional life, it is unreasonable to think that one will not influence the other. That might especially hold value during your doctoral training, which is more than a job. It might be a paid position, yes, but not for everyone. However, for the majority of doctoral students, it will be a path of education and growth. In that period of your life, you will learn new methods and skills, in research and in communication. You will also grow as a person and might (if you are lucky) find what you want to do and what you most definitely do not want to do. In that process, you might want to be guided by a person who shares your values and whose life you look up to. This 'life' will not only be reflected in the number of books and citations your potential supervisor has, tenured positions offered and grants awarded, but also in the supervisor's impact on the lives of people in the research group.

In everyday settings, this might describe a mentor who greets the janitor by their name every morning, a mentor whose former students reach out to them for help or simply to catch up with, and a mentor who is not afraid to speak up when they recognize injustice. In the words of virtue ethicists, you might very well want to have a good moral exemplar as your supervisor, which will make them a mentor in the full sense of that word. If you recognize someone you know in these words, by all means, talk to them and ask if they would be willing to guide you through a doctoral journey. If you do not recognize anyone, do not fret – you are not alone. Supervisors and mentors like these are hard to find. If they were easy to find, we would not have nearly as many PhD Comics.

If one of your doctoral co-mentors/supervisors fails your needs and expectations, you can always try to find help from the other. Of course, it might happen that you do not get much help from your co-mentor either. This is why it is almost equally important to have a good support network as it is to find a good mentor. Your support network can come from your personal life, but also from your professional life. Sometimes, those two will blend. You might make friends with fellow doctoral students, with post-doctoral researchers, students, lab technicians, librarians or any other members of the research group or organisation. Those people can be a part of your mentorship and support group. Likewise, you will be a part of theirs. This leads us to the next question – what is your role, as a doctoral student?

As a doctoral student, you have to keep in mind your goals. Be prepared to fail and to learn, and to work hard. Be committed, ask when you don't know something and when you want to know more. Be open and be kind. Is this specific for doctoral training? No. Is it very important then? Yes. Nurturing these values will set up the foundations you need to be a good researcher. It might also help you become a person people want to be around with, someone they will look up to one day. If you end up working in a research group, it might be expected of you to supervise a

younger student. These opportunities are a part of the training in which you learn how to mentor others. You might want to use this to gather feedback on your performance – ask the students to share their experience and any suggestions they might have. This will be your opportunity to help build a better research integrity culture.

Through communication with your colleagues and fellow doctoral students, you will also have the opportunity to engage in more or less formal peer mentorship. After all, your colleagues understand your experience best and you have the opportunity to learn from each other. You can make this process more formal and follow the example of medical researchers, by organising monthly meetings with a 5/10/30 rule: 5 minutes at the beginning of the meeting are spent on checking in on everyone; 10 minutes for the discussion of short-term goals; and 30 minutes to discuss long-term goals and steps to achieve them. This way you are encouraged to assign specific actions for your goals and to work on them in smaller, but less intimidating, tasks.

Doctoral training can feel intimidating, partly because there is a general understanding that it involves long working hours, little to no days off, and low pay. While it is true that there are toxic environments like that in doctoral programmes, it does not mean yours has to be. When starting your doctoral studies, schedule your day in a way that is compatible with your tasks and fits your productivity hours. Keep in mind that this schedule might change as you progress. At the beginning, you will likely want to engage in more social activities related to work. This is your opportunity to get to know everyone you will be working with and start relationships that you can cultivate throughout your time there and beyond. Social hours will likely take place in your schedule later on as well, but will probably be more networking oriented.

Your working hours do not have to be 12 hours a day, 6 or 7 days a week, even if it feels like they should. Of course, the culture of your organisation, your research discipline and your mentor will have a direct influence on this, and having a more open and accommodating leadership will make it easier for you to find the optimal schedule. What might help is that, while you work, you remain focused on that activity only. Few focused productive hours are better than many hours interrupted by social media or long lunches. If you like your work, it is very likely you will be doing it in your free time. That is more than fine. However, make sure you do not do it because you feel you have to, and make sure you take some time every week when you completely switch off from work. Some form of physical exercise will do you loads of good and will help you get back to your work refreshed and ready to go on.

Doctoral training can be very demanding and ‘research fatigue’ is a real thing. If you start feeling like you are losing interest in things you used to care about, are low in confidence, have difficulties trying to concentrate, take a step back and re-evaluate. These might be signs of a burnout and signal that you need to take some time off. More than 40% of postgraduate students’ report symptoms of depression, emotion or stress-related problems. Organisational climate can impact mental health of the employees, and while raising awareness is a good first step, more needs to be done. Providing resources and training for well-being, as well as good mentoring practices, could be a step in the right direction. Rewarding researchers for

accomplishments for less traditional outcomes, for practices that foster RI, is another initiative that could improve the climate.

European Council of Doctoral Candidates and Junior Researchers (Eurodoc), an international federation of doctoral candidates and early career researchers' organisations, have started a Mental Health Working Group with the aim to raise awareness, identify risk factors and promote good practices for mental health of doctoral students in Europe. Researcher Mental Health and Well-being Manifesto was published in 2021, and calls for *"the assessment of how the mental health and well-being of researchers can best be nourished and sustained through actions and initiatives at the policy, institutional, community and individual levels.*" See if your university supports initiatives like this and if they want to do more. Your university likely offers individual support and counselling services, and it might be good to seek out their advice even if you don't suffer from severe burnout.

If You Want to Learn More

The Embassy of Good Science

Mental health in academia
Poor mentoring or supervision of early career researchers
Responsible mentoring
Responsible supervision
Respectable and honest supervision ensures responsible and ethical research in the future
Superb Supervision: integrity training for supervisors
Supervision
Supervision guidelines
PhD-pizza – Gathering for PhD-candidates to talk freely

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Research Procedures

3

Ivan Buljan

Abstract

This chapter offers a guide on how to implement good research practices in research procedures, following the logical steps in research planning from idea development to the planning of analysis of collected data and data sharing. This chapter argues that sound research methodology is a foundation for responsible science. At the beginning of each part of the chapter, the subtitles are formulated as questions that may arise during your research process, in the attempt to bring the content closer to the everyday questions you may encounter in research. We hope to stimulate insight into how much we can predict about a research study before it even begins. Research integrity and research ethics are not presented as separate aspects of research planning, but as integral parts that are important from the beginning, and which often set the directions of research activities in the study.

Keywords

Research plan · Research question · Study design · Sample · Measurement · Protocol registration · Reproducibility

What This Chapter Is About

This chapter offers a guide on how to implement good research practices in research procedures, following the logical steps in research planning from idea development to the planning of analysis of collected data and data sharing. This chapter argues that sound research methodology is a foundation for responsible science. At the

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https://doi.org/10.1007/978-3-031-22412-6_3

beginning of each part of the chapter, the subtitles are formulated as questions that may arise during your research process, in the attempt to bring the content closer to the everyday questions you may encounter in research. We hope to stimulate insight into how much we can predict about a research study before it even begins. Research integrity and research ethics are not presented as separate aspects of research planning, but as integral parts that are important from the beginning, and which often set the directions of research activities in the study.

Case Scenario: Planning Research

This hypothetical scenario was adapted from a narrative about the process of poor research planning and its consequences. The original case scenario is developed by the Members of The Embassy of Good Science and is available at the Embassy of Good Science. The case is published under the Creative Commons Attribution-ShareAlike License, version 4.0 (CC BY-SA 4.0).

Professor Gallagher is a leader of a research project on moral intuitions in the field of psychology. She is working on the project with Dr. Jones, a philosopher, and Mr. Singh, a doctoral student. Although she has little experience in the matter, Dr. Jones is put as the principal investigator in the study design and analysis of the two experiments, while Mr. Singh prepares materials and conducts the experiments.

After the first experimental study, Mr. Singh sends the results to Dr. Jones for analysis. After some time, eager to enter the results in his thesis, Singh asks Dr. Jones about the results of the study. She admits that she forgot to formulate the hypothesis before data analysis, and now the results can be interpreted as confirmatory, regardless of the direction. They decide to formulate a hypothesis that will result in a positive finding.

Mr. Singh and Dr. Jones present the results to Dr. Gallagher, who is satisfied and proceeds with paper writing. In the second study, Dr. Jones formulates multiple hypotheses before the study begins. Mr. Singh conducts the study and sends the results to Dr. Jones. She performs the analysis by trying to find only significant differences between groups. Finally, to achieve significance, she excludes participants over 60 years from the analysis and while presenting the results, admits that to Prof Gallagher. Prof Galagher is happy about the results and proceeds with the paper writing, while Mr. Singh enters the results in his dissertation.

Before Mr. Singh has the public defense of his dissertation, one of the internal reviewers notices that some data has been excluded from the second study and only significant results were reported. She invites Mr. Singh for an examination board meeting during which MR Singh admits that the data has been excluded and that in the first study hypothesis was formulated after the results were known.

Questions for You

1. Why is hypothesizing after the results are known, as described in the first study, considered problematic?
2. What was wrong about reporting only significant results in Study 2?
3. How would you improve the entire research process described in the scenario?

Good research practice from the European Code of Conduct for Research Integrity:
Researchers take into account the state-of-the-art in developing research ideas.
Researchers make proper and conscientious use of research funds.

What to Do First When You Have an Idea?

It is difficult to come up with a good research idea, and if you struggle to come up with a new research direction, that is perfectly fine. Creative processes are the highest form of learning and developing an idea requires significant cognitive effort. In some cases, you may have an epiphany, where you would suddenly come up with a great idea for your research project. This is something popularized by stereotypes about scientists as eccentric figures who come up with brilliant ways of tackling things using only their intelligence and intuition. However, scientific work resembles ore mining. It takes a tremendous effort to read relevant scientific literature, communicate with your peers, plan, and, in some cases, attempt and fail before you even start digging for gold. As in a mine, you will need to dig a lot of rocks before you come across diamonds and gold.

Usually, the most important decisions are made before digging even begins. To decide where you will start mining, you start with the exploration of the terrain. In research, this means knowing your field of study. You may read an interesting piece in the scientific literature or listen to a presentation at a conference and then

think of a hypothesis whose testing will answer an interesting and important question in your research field. On the other hand, sometimes you have to adjust your research interest so that they fit the specific aims of grant funding calls. It does not matter what the source of the idea is, there are always two things to consider when developing research ideas: the current state of the field and the resources available to you. Good research practice is to consider the state of the art in developing your research ideas and make the proper use of research funds. This does not mean that you are not allowed to develop research ideas if they address a research topic that has been neglected. It is the responsibility of a researcher to combine the best of the "old" evidence with new research developments. It is important to keep in mind that research is not performed in a vacuum and that the funds and resources provided by public or private funders are given with an expectation of an honest answer to a specific research question. The main responsibility for the proper use of research funds is on the researcher, and this is overseen by funders during and at the end of the proposal. Another recommendation refers to the use of state-of-the-art information as a basis for your research. The control system in this case is other scientists who read or evaluate your research, and who will recognize outdated research results.

Let's get back to the analogy of the mine for a moment. If you are paid to dig in the mine, you are expected to find important ore. In our case, a research funder is an employer, and the researchers are workers who need to go down the mine and get their hands dirty in the search for new true information. If you are set to dig a deep hole in the ground with the possibility of finding gold and diamonds, but you do not get any guarantee that you will find them unless you chose an appropriate place in a specific period, you would probably spend a lot of time planning and trying to decide where to start digging, what to do when specific problems arise and to avoid ending with a huge number of worthless rocks instead of gold and diamonds. The process is similar to research planning since a significant amount of the research process can be defined before data collection begins. As valuable as it can be, a research idea is just a thought which needs to be translated into research practice to gain its full impact.

How to Formulate a Good Research Question?

Research is performed to answer a specific question. The research process can be observed as a complex tool that, if used properly, can give a clear answer to a posed question. The research question is the compass of the research process (or the mine if we continue with our mine analogy) since it determines the steps of the research process. It translates into specific research aims and, consequently, into testable research hypotheses. Formulation of a research question is a skill that develops over time, a skill that can be learned. Your research question should have a FINER structure, which stands for: **F**easible, **I**nteresting, **N**ovel, **E**thical and **R**elevant.

Although initially developed as a set of recommendations for quantitative research, FINER recommendations can be applied to formulating a research question in any given field of science.

The feasibility of a research aim is often defined by time restrictions and funding because research is often burdened by deadlines and output requirements set by the funders. **F**easibility is also affected by the availability of technology, geographical restrictions, availability of participants, or availability of collaborators. If one considers all those factors, it is obvious that research interests play only a small part in the formulation of a research question. Ask yourself: What research can be published in an excellent journal if you have limited funds and only 1 year for research, with limited access to a specific technology? (Today, highly specialized experts may be a greater problem than the technology in question). You might experience that the formulation of the research question is mostly defined by non-research factors, because, in the end, it is better to have a completed than never-finished research.

There are other elements of the research question that are as important as feasibility. The first one to consider is **E**thics, which affects all parts of the research process due to its broad nature. If research is not ethical, then it should not be conducted. In a mining analogy, ethics is training and safety, which helps you to protect others and yourself during the entire process. To get back to the best research practices, researchers should make proper use of research funds and fulfill the basic research aim – the benefit to society. This also implies treating members of that society with respect, respecting their privacy and dignity, and being honest and transparent about the research process and results. Therefore, when determining the feasibility of a research study, ethics aspects are the first to consider, along with the objective factors of time, cost, and manpower.

Interest, **N**ovelty, and **R**elevance from the FINER guidance are the elements of the research question that increase the chances of getting funding or the chances for a journal publication, and they are closely aligned. Regardless of the audience (researchers, publishers, non-experts), research should be new to be interesting and relevant. However, doing research just for the novelty's sake is analogous to the digger who starts digging a new mine every couple of days. It gives you the thrill of a new beginning, but you have not dug deep enough to get to the real results. Relevance, defined in this context as a significant add-on to the current knowledge, can be assessed with a high probability of success by a thorough search for available evidence. The main aim of that process is to identify research or practice gaps that can be filled to improve general knowledge.

Interest is related to the principal internal motivation of an individual to pursue research goals. The interest to pursue research aims is difficult to assess. When planning research, do you consider that research is interesting to you, your peers, potential users, or all three? Probably the last, but here is the catch. Interest is the most subjective part of research planning. Research planning could be understood as a balance between your interest and all other factors that affect the research outcome.

A good research idea is often the compromise between objective possibilities and a desire to make a research discovery. If the research idea is interesting but extremely difficult (or even impossible) to conduct in given circumstances, you will end up frustrated. On the other hand, if you decide to perform research based solely on convenience (because it is something for which is easy to get funded or someone is offering you a research topic you are not interested in), it will be very difficult to stay motivated to complete the study.

The more structured your research question is, the easier it is to determine which research design is best to test the hypothesis and statistical analysis is more straightforward. Let's look at several examples of research questions in biomedical research: Are psychedelics more effective in the treatment of psychosis than the standard treatment? What are the opinions of young fathers on exclusive breastfeeding of their spouses? Which percentage of the population has suffered from post-COVID-19 syndrome? Intuitively, for each of posed research questions, we would try to find answers differently. In cases of comparison of treatment methods and assessment of population percentage, we could express the results quantitatively, e.g., we could state explicitly how much the psychedelics treatment is better compared to standard methods in terms of days of remission or everyday functionality or an explicit number of people in the sample who had COVID-19-related symptoms. On the other hand, the answers to the question about the opinions of young fathers about exclusive breastfeeding are not straightforward or numerical, but more textual and descriptive. It is an example of the research question that would be more suitable for qualitative research. Qualitative and quantitative study designs answer different types of research questions and are therefore suitable for different situations. It is important to carefully consider and choose the most appropriate study design for your research question because only then can you get valid answers.

To conclude, research question development is the crucial factor in setting research direction. Although framed as a single sentence, it defines numerous parts of the research process, from research design to data analysis. On the other hand, non-research factors also have an equal role in research questions and need to be considered.

Literature Search

In a literature search, researchers go through the relevant information sources to systematically collect information, i.e. foreground knowledge, about a specific research phenomenon and/or procedure. While research information is readily available online not only to researchers but to the whole public, the skill of systematic literature search and critical appraisal of evidence is a specific research skill. A literature search is closely tied with the development of the research aim, because you may want to change it after you read about previous research.

When doing a literature search, you must be careful not to omit previous studies about the topic. Here we have two directions that must be balanced. The first one is to do a very precise search to find specific answers, and the other one is to perform a wide, sensitive search that will include many synonyms and combinations of words to discover articles that related to a specific term. Both of those approaches have their advantages and disadvantages: a precise search is less time-consuming and retrieves a small number of studies. However, it may omit important results, so you may end up performing studies for which we already have established conclusions. This creates waste in research because you will spend time and resources, and involve participants in unnecessary work, which would be unethical. You may also miss citing important studies. On the other hand, if you perform a search that is too wide, you will spend a lot of time filtering for useful articles, which leaves less time for doing research.

Good research practice from the European Code of Conduct for Research Integrity:
Researchers design, carry out, analyze and document research in a careful and well-considered manner.
Researchers report their results in a way that is compatible with the standards of the discipline and, where applicable, can be verified and reproduced.

What Is the Optimal Study Design for My Research?

Study designs are one of the main heuristics related to the reader's perception of the credibility of research information. Also, different study designs give answers to different research questions. It is intuitively easy to understand that different approaches should be taken if the question is about the percentage of infected people in the population vs about which drug is the most effective in the treatment of the disease. The roughest categorization of the study designs is observational and experimental (Box 3.1). However, in different scientific areas, even that type of categorization is not enough, since study designs can be theoretical, as in physics or mathematics, or critical, as in humanities, and those types of research will not be covered in this chapter.

For some research areas (e.g. health sciences, social sciences), there is another type of research often referred to as evidence synthesis, or literature review. The literature review is a review of evidence-based on a formulated research question and elements. They differ in their scope and methodology (Box 3.2).

Box 3.1 Types of Study Designs

Observational study designs:

Case study/case series/qualitative study: All three types of study designs take into account a small number of participants and examine the phenomenon of interest in-depth but cannot make generalizations about the entire population.

Case-control study: Individuals with a certain outcome or disease are selected and then information is obtained on whether the subjects have been exposed to the factor under investigation more frequently than the carefully selected controls. This approach is quick and cost-effective in the determination of factors related to specific states (e.g., risk factors), but it relies too much on records and/or self-report, which may be biased.

Cross-sectional study: Best study design for determining the prevalence and examination of relationships between variables that exist in the population at a specific time. Although it is simple to perform, and relatively cheap, it is susceptible to various types of bias related to participant selection, recall bias, and potential differences in group sizes.

Cohort study: Participants are followed over a certain period (retrospectively or prospectively) and data are compared between exposed and unexposed groups to determine predictive factors for the phenomenon of interest.

Experimental study designs:

Randomized controlled trial (RCT): Participants are allocated to treatment or control groups using randomization procedures to test the strength of the interventions.

Quasi-experimental trial: Participants are allocated to treatment or control groups to test the strengths of the interventions, but there is no randomization procedure.

How to Assess which Study Design Is Most Suitable for Your Research Question?

Based on the research aim, one may already get a hint about which study design will be applied, since different study designs give answers to different research questions. However, very often a research question is not so straightforward. Sometimes the research aim could be to determine whether category X is superior to category Y, related to the specific outcome. In those cases, one must determine what the core outcome of the study is (e.g., testing of the effectiveness of two interventions, the scores on current differences between two groups, or the changes over time between

Box 3.2 Most Common Types of Review

Systematic review: A type of review that searches systematically for, appraises, and synthesizes research evidence, often adhering to guidelines on the conduct of a review.

Scoping review: Type of review which serves as a preliminary assessment of the potential size and scope of available research literature to identify the nature and extent of research evidence (usually including ongoing research).

Meta-analysis: Statistical synthesis of the results from quantitative studies to provide a more precise effect of the results.

Rapid review: A type of review that assesses what is already known about a policy or practice issue, by using systematic review methods to quickly search and critically appraise existing research to inform practical steps.

Umbrella review: Specific type of review that searches and assesses compiling evidence from multiple reviews into one accessible and usable document. Focuses on broad conditions or problems for which there are competing interventions and highlights reviews that address these interventions and their results.

different groups), and then it is not difficult to determine the study type in question. In principle, a single research question can be answered with a single study design. However, what we can also use are substitute study designs that can give approximate answers to the question we are asking but will never give as clear an answer as the appropriate design. For example, if we want to explore the reasons early-career researchers seek training in research integrity using a survey approach, we could list all possible answers and say to participants to choose everything that applies to them. The more appropriate study design would be to use a qualitative approach instead because in the survey approach the assumption is that we already know most of the reasons. The survey approach gives us the answer which answer is the most frequent of all. It is a subtle, but important difference. Similarly, although we can test causation using a cohort approach, the evidence for causation is never strong enough in a cohort study as it would be in an experimental study, simply because in a cohort study the researcher does not have control over the independent variable. For example, if we would test the effects of alcohol uptake on the occurrence of cancer, we would compare participants who drink versus those who do not drink to determine the incidence of cancer and make the conclusion about the association between alcohol and cancer. However, the true study design for testing the causation is the randomized controlled trial, where participants are randomized into the interventional and control group, the researcher can give an exact amount of alcohol based on persons' weight, over a specific period, and in the end, compare the incidence between two groups. However, that type of study would not be an ethical

study, so it is not possible to do it. So, there are subtle, but important differences which answer whether can specific and good formulated research questions can be tested and answered fully with only one study design, but due to the various reasons (time restrictions, ethics, cost-benefit analysis) we often use substitute study designs.

Good research practice from the European Code of Conduct for Research Integrity:
Researchers design, carry out, analyze and document research in a careful and well-considered manner.

When describing people involved in the research process, researchers often refer to them as "participants" or "respondents" (in the case of surveys). A more precise term would be to name the group based on the population they are drawn from (children, people with specific diseases, or people from a specific geographical area). The appropriate term to use would be "participants", since people are willingly involved in the research process, and the generation of new findings depends on them. Being a participant in a research process means that a person has willingly entered into a research, without any real or imagined coercion, possesses respect and interest for the research topic, with the understanding that positive aspects of research findings encompass the research situation and contribute to general knowledge. This would be a definition of an ideal participant and the researcher should avoid a situation where the participants are coerced to enter research, whether by situational factors or personal reasons because that will probably result in a decrease in motivation for participation and lower quality of research findings. To act ethically and to improve the quality of the research you have to inform participants about the reasons for the study, its purpose, research procedure, their rights, and expected outcomes. A potential pitfall in the research process can happen if all information were not given to participants at the beginning of a research. On the other hand, if a participant enters willingly into the trial, but possesses no real interest in the research topic, it may also affect the motivation for participation in research, because those participants may consider the topic irrelevant and not take the research process seriously (it is easy to imagine a situation where teenagers in a classroom willingly decide to take the survey and participate in research about personality traits, but quickly lose interest after the second page of the questionnaire). All those things are not reflected in the research report but may have an enormous influence on the research findings. Therefore, it is important to define the population of interest and try to motivate participants by providing them with all information before the research begins. Some additional ways to increase participant retention are financial rewards or similar incentives. There are several sampling strategies used when approaching participants for a study (Box 3.3).

It is difficult to give clear criteria on when to stop collecting data. In the case of pre-registered studies, the stopping rule is defined in the protocol. Examples include time restrictions (e.g. 1 month), or the number of participants (e.g. after collecting

Box 3.3 Most Common Sampling Methods

Simple random sampling: Each member of the defined population has an equal chance of being included in the study. The sampling is often performed by a coin toss, throwing dice, or (most commonly) using a computer program.

Stratified random sampling: The population of interest is first divided into strata (subgroups) and then we perform random sampling from each subgroup. In this way, the sample with better reflects the target population in specific (relevant) characteristics.

Cluster random sampling: In cluster sampling, the parts of the population (subgroups) are used as sampling units instead of individuals.

Systematic sampling: Participants are selected by equal intervals set before the data collection begins (e.g., every third of every fifth participant who enters the hospital).

Convenience sampling: Participants are approached based on availability. This is perhaps the most common sampling method, especially for survey research.

Purposive sampling: This is the most common approach in qualitative study designs. Researchers choose participants (or they define their characteristics in detail), based on their needs since participants with those special characteristics are the research topic.

data on 100 participants). If the research protocol has not been pre-registered, then the stopping rule should be explained in detail in the publication, with reasons. In the latter case, it is never completely clear if the stopping happened after researchers encountered the desired result or if it has been planned. The practice of stopping after you collect sufficient data to support your desired hypothesis is highly unethical since it can lead to biased findings. Therefore, the best way of deciding to terminate the data collection is to pre-register your study, or at least define the desired number of participants by performing sample size calculation before the study begins and pre-registering your study. More about pre-registration and biases which it eliminates will be said later in the chapter.

Ethics of the Sample Size: Too Small and Too Big Samples

A common problem in sampling is that researchers often determine the desired number of participants in a study. The problem is that the response rate is always lower than 100% (in survey research it is often around 15–20%), and a certain percentage of participants drops out of research, resulting in a sample size significantly lower than initially planned. The sample used in research can be too small, and there

is a possibility that you will not find a true effect between groups, and in that case, you would make a type II error. The reason is that in small-scale studies the error margin is big, and you would need an extremely large effect size to reach statistical significance. On the other hand, in cases of a big sample, the problem is different. If you have big samples, even small effects will be statistically significant, but the effect size may be negligible. The reason is that within big samples, the margin of error is small, and consequently, every difference is statistically significant. Once again, the proper solution (practically and ethically) for this issue is to calculate the minimum sample size needed to determine the desired difference between groups to avoid the issues with small samples and report effect sizes also, to avoid issues related to (too) big samples.

What We Can and What Cannot Measure?

When it comes to measuring in research, that part is mostly associated with statistical analysis of research data. The principal thing in statistical analysis is to determine the nature of the main outcome variable. In qualitative research (e.g. interview, focus group) or a systematic review without meta-analysis, statistical analysis is not necessary. On the other hand, for quantitative studies (a term often used for mostly case-control, cross-sectional, cohort, and interventional studies) the most important part of the research plan is to define the outcome which can be measured.

In general, there are two types of variables: qualitative and quantitative. When it comes to statistical analysis of qualitative variables (in a statistical context you will encounter the terms nominal and ordinal variables), we can do only basic functions, like counting and comparing the proportions between different groups, but we are not able to calculate mean or standard deviation, because those variables do not possess numerical characteristics. Examples of qualitative variables in research can be the number of surviving patients in a group at the end of the trial, self-reported socioeconomic status as a demographic characteristic, or any binary (yes/no) question in a questionnaire. In some cases, qualitative variables may be coded with numbers, but that does not make them quantitative. A good example is jersey numbers where numbers serve only as a label and not as a measure of quantity (e.g. if you have team player numbers 2, 4, 6, you probably will not state that the average jersey number is 4 because the very concept of the "average" jersey number is absurd). On the other hand, for quantitative variables, differences between numbers indicate the differences in value (e.g. if you say that person X is 1.80 m high, you know that that person is taller than person Y who is 1.70 m tall). You can also calculate different statistical parameters, like mean and median, and dispersion measures, which gives you a more flexible approach in the choice of statistical tests, especially those tests for differences between groups. On the other hand, applying statistical tests would mean that you are more

familiar with statistics, which sometimes may present a problem for less (and more) experienced researchers.

When Is the Time to Consult with a Statistician (and Do You Have to)?

Some (lucky) researchers possess sufficient knowledge to perform data analysis themselves. They usually do not need to rely on somebody else to do the statistical analysis for their study. For everybody else, statistical analysis is a crossroad where one needs to decide on including a person with statistical knowledge in a research team or to learn statistical analyses by themselves. The usual process is that the research team defines the research aim, spends time collecting data, collects data, and then tries to find a statistician who will analyse the data. If we keep in mind that research often has high stakes (e.g. doctoral diploma) and researchers are under a great time and financial pressure, the decision to include a statistician is sound and logical, but is it really necessary? The inclusion of a statistician in research when the data are already collected is similar to the situation when you give a cook an already finished stew and ask him/her how it can be improved. The cook may help with the decorations and give some spice which would make the food look and taste better but cannot change the essence of the food since it is already cooked. It is the same with data. The golden rule of statistics is "garbage in, garbage out", referring to a situation where poorly collected data or data of poor quality will give rise to wrong conclusions. Researchers should know statistics, not only because of the statistical analysis but because statistical reasoning is important in the formulation of measurable research aims. Therefore, statistical analysis is an important part of responsible research and begins with the formulation of the research aim. Statistical experts should be included in the study at that point.

Statisticians usually analyse data based on the initially set research aim. They send back the results of the data analysis to the research team, and they all together (in an ideal scenario) write the manuscript. The dataset remains in the possession of the principal researcher and the paper is published in a journal. Many journals and funders require that the data are publicly available so that anyone can use it, respecting the FAIR principles. Keeping that in mind, the process when somebody else is doing statistical analysis for you requires an enormous level of trust for statisticians, because they can do analysis wrong but you may never know it. Unless, of course, someone else analyses publicly available data and sees the error. In that case, you are also responsible for the analysis because it does not matter that you did not perform it. In some cases, this may lead to the retraction of the paper, which consequently may lead to certain consequences for you (especially if the articles are the basis for a doctoral thesis). If you are willing to put trust in someone to do data analysis, that is perfectly fine, just be aware of this risk, and remember that people make mistakes, very often unintentionally, and therefore a double check by a third party would be recommended.

On the other hand, if you are willing to learn how to do statistical analysis, the good news is that today there are lots of resources to help you. The first thing about statistics you need to know is that you do not need to know all statistics to do statistics. The only knowledge about statistics and statistical programs you need is the one that would help you do the analysis of your research aim and test the research hypothesis. To do that, you will have to see the data you have and search online for ways to analyze a specific problem. You can use tutorials of the statistical program that simultaneously give instructions about the statistical principles and procedures for analysis. Today, most of those programs have online videos and detailed tutorials. Some of those programs are user-friendly and free (e.g., JAMOVI or JASP), some are commercial (e.g., SPSS, Statistica), and some are less user-friendly but free and available (e.g., R programming language). If you are a beginner, use a more user-friendly program that has detailed instructions and try to do the statistical analysis by yourself. It is expected that you will make errors, so it would be good if someone more experienced looked at the results and provides feedback on your first attempts.

There are many tutorials on how to do statistical analysis, but far less on how to do proper data entry, which is the preparation of data for statistical analysis. Usually, the data entry table is made in a computer program that provides a tabular view of the data (e.g., Microsoft Excel). The golden rule is that each column represents a variable collected in research, by the order it was collected in the research and that each row represents the unit of the analysis (usually participant, text, article, or any other unit). In a separate sheet or a document, there should be a codebook that contains information about each level of each variable in the dataset, in a way that a person who is not familiar with research can understand the nature of the variable. The codebook should always accompany the dataset, so if the dataset is shared publicly, the codebook should also be shared. The rule of thumb for the data entry is that textual variables are entered as texts and quantitative variables as numbers, and textual variables can later be coded with numbers if necessary. The table for data entry should be made before the research begins, and it is good to seek help from a statistician when defining that, too.

Good research practice from the European Code of Conduct for Research Integrity:
Researchers publish results and interpretations of research in an open, honest, transparent, and accurate manner, and respect the confidentiality of data or findings when legitimately required to do so.

Preregistration of Research Findings

Pre-registration refers to the presentation of the research plan before the research begins. This process serves as the quality control mechanism because it prevents a change in the research hypothesis and methodology to fit the data collected.

Pre-registration of research findings should be done after the research has been approved by the ethics committee. There are various registries, some of which are more discipline-specific (e.g., ClinicalTrials.gov for clinical studies) while others are open to different disciplines and study designs (e.g., Open Science Framework). For the pre-registration of a study, one should clearly define all steps related to the research aim, methods, planned analysis, and planned use of data. Pre-registration of data is nothing more than the public sharing of a research plan. However, even that relatively simple procedure helps eliminate specific biases and decreases the probability of unethical behavior. Pre-registration eliminates the problem of hypothesizing after the results are known (so-called HARKing) because you need to state your hypothesis publicly before the research begins. Pre-registration should be done before the actual research begins, since you may have already collected the data and modified your hypothesis so that it fits your data (this is called PARKing –pre-registering after the results are known), which should be avoided since it is not a true pre-registration.

Why is pre-registration good for research? When a study is pre-registered, researchers will follow the research plan and planned analysis and will not alter the study protocol and statistical analysis unless there is a valid and strong reason for protocol modification. Many journals today require that studies are pre-registered and that research data are shared. It is recommended to pre-register not only the study aim and methods, planned analysis, but also planned impact, data use, and authorship. When pre-registering authorship, you make clear from the beginning of the study the roles and expectations of each member of the research team. If during the research process some changes happen with the study protocol, those should be clearly explained and pointed out in the final publication, because deviations from the protocol can sometimes bring suspicion in the interpretation of the results if they are not reported. Pre-registration can be peer-reviewed and some problems, which would affect the final interpretation of the results, can be addressed even before the study begins. Finally, when pre-registered, you have the evidence that it was you who came up first with a specific research idea.

One problem that pre-registration cannot prevent is research spin or exaggeration in the scope of study results. Even if data have been carefully collected and properly analyzed, the interpretation of the results is up to the researcher. You should be honest (and modest) when interpreting the results of your study, by stating the true magnitude of your results and putting them in the context of the previous studies.

After the research has been published, the data used in research should be made available to everyone who wants to use them, since data sharing helps research replication and evidence synthesis. You can read more about data sharing in the chapter on Data Management and the chapter on Publication and Dissemination.

With this knowledge in mind, how would you improve the research procedure from the case scenario at the beginning of this chapter?

If You Want to Learn More

The Embassy of Good Science

Replicability
AllTrialscampaign: https://embassy.science/wiki/Theme:0bb5e4f7-9336-4ca8-92e3-c506413d1450
Forensic statistics to detect data fabrication: https://embassy.science/wiki/Theme:467f5cf6-d41f-42a0-9b19-76556579845d
Pre-registration of animal study protocols
Prospective registration of clinical trials
Statistical pre-registration
Data driven hypothesis without disclosure ("HARKing")
Insufficiently reported study flaws and limitations
Spin of research results.

Published Articles

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Guidance

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Safeguards

4

Marin Viđak

Abstract

This chapter will provide introduction to relevant safeguards in the research environment: codes of conduct, guidelines, and other types of regulation. It will also give advice on how you can find safeguards relevant for your research. Research safeguards help researchers in defining the boundaries and expectations in research planning, conduct, reporting, and implementation. While this kind of regulation often invokes associations of restrictions and limitations, that is not its primary purpose. Safeguards are often principles of good practice, summarised through various checklists and standard operating procedures. They are tools through which we ensure ethical and responsible conduct in research, and support openness and accountability. Their aim is to reduce waste and to help (re) gain public trust and to protect both researchers and research participants. Not less important, they help novice researchers to understand the community in which they work and its common practices.

Keywords

Code of conduct · Guidelines · Regulations · Checklists · Standard operating procedures

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What This Chapter Is About

This chapter will provide introduction to relevant safeguards in the research environment: codes of conduct, guidelines, and other types of regulation. It will also give advice on how you can find safeguards relevant for your research. Research safeguards help researchers in defining the boundaries and expectations in research planning, conduct, reporting, and implementation. While this kind of regulation often invokes associations of restrictions and limitations, that is not its primary purpose. Safeguards are often principles of good practice, summarised through various checklists and standard operating procedures. They are tools through which we ensure ethical and responsible conduct in research, and support openness and accountability. Their aim is to reduce waste and to help (re)gain public trust and to protect both researchers and research participants. Not less important, they help novice researchers to understand the community in which they work and its common practices.

Case Scenario: Safeguards, Data-Sharing and the Disclosure of Sensitive Results

This hypothetical scenario was adapted from a narrative concerning safeguards for data sharing and disclosures of sensitive data and research with children and deprivileged minorities. The original case scenario is developed by the Members of The Embassy of Good Science and is available at the Embassy of Good Science. The case below is published under Creative Commons Attribution-ShareAlike licence, version 4.0 (CC BY-SA 4.0).

In a large study conducted in nine European countries, a group of researchers from different institutions aimed to evaluate the structure and environment of different secondary schools, as well as mental health of the students, by using a screening tool. Each research group has applied for and was granted ethical approvals, and the research plan was deemed to be in compliance with GDPR:

During the study, researchers decided to share the aggregate school-level data with individual schools as well as data from neighbouring schools. They received ethical approval for this change in research protocol. However, data sharing would incur some cost, but the research funders were unwilling to provide extra funding. As some of the sites already shared the data, in the end some schools received these data while others have not.

Leadership of some schools involved with the project were not satisfied with the study results and they made a complaint regarding the potential bias in research. Moreover, some schools with a high portion of a particular ethic minority had poor performance on the test. These schools received a much lower level of funding. Also, the results of the mental health assessment for some students indicated significant mental health problems, potentially requiring medical treatment.

Questions for You

1. Is disseminating the results of the school-level analysis considered a good research practice? Is it ethical to share the data with other schools? Please provide reasons for your answers.
2. Is it necessary to submit for ethics approval before changing a policy regarding the dissemination of results? Where would you look for that information?
3. Is it acceptable to share data with some schools, but not others? How should researchers proceed if they already shared the data but lack the funding to include all schools?
4. Who should investigate the complaints made by the leadership of some schools?
5. Should the students (or their parents) provide informed consent and/or assent before participating in the study? Is it acceptable for researchers to break confidentiality to disclose the clinically significant mental health problems? To whom?
6. Should the possible link between schools' performance, ethnic background of students and public funding be disclosed? What are potential risks in reporting these results?

What Are Safeguards in Responsible Research?

Safeguards in responsible research, according to European Code of Conduct for Research Integrity are: (1) adhering to codes and conducts relevant to scientific disciplines; (2) dealing with research subjects respectfully and with care; (3) taking care of health, safety and welfare of the community and others involved; (4) being conscious to difference in age, gender, religion, ethnicity and social class; and (5) carefully assessing the potential risks and harms of research.

Good research practice from the European Code of Conduct for Research Integrity:
Researchers take seriously their commitment to the research community by participating in refereeing, reviewing and evaluation.

As you begin your work as a novice researcher, checking relevant local laws and regulations can often seem like reading small print in the Terms of Use Agreement for computer programs. People skim them, tick the box 'Agree,' and do not think about them. They often read them carefully only after it is too late. While laws on higher education and science can differ from country to country, several transnational and important (and often non-binding) documents are available for you to read. Check them before you start doing research.

In addition to the European Code of Conduct for Research Integrity, the Singapore Statement on Research Integrity will tell you more about the global approach to research integrity.

If you are based in the European Union and working with personal data, you should check the General Data Protection Regulation (GDPR) to see if it applies to your research. It might not always be obvious that you work with personal data that needs data protection. If you are doing large, population based cross sectional studies based on surveys, GDPR applies to that kind of research as well. If you are working with data from hospital archives and not contacting patients themselves, that also falls under GDPR (and might as well need an ethical approval from the hospital – check your national codes and legislations!).

Speak to your mentor/supervisor and senior colleagues. Write everything down. Check who is the Research Integrity Officer or a similar professional in your organisation. If your organisation does not have one, ask your mentor or directors of your doctoral course who you can ask about research integrity. Check your organisation's rules for the Ethics committee/Institutional Review Board.

Good research practice from the European Code of Conduct for Research Integrity:
Researchers handle research subjects, be they human, animal, cultural, biological, environmental, or physical, with respect and care, and in accordance with legal and ethical provisions.

Research can involve different types of subjects, from humans to animals, biological samples, and it can be based in a laboratory, or it can be field based. You could work with patients or patients' data, or you could do meta-research on published articles or different datasets. Regardless of what you do, you need to respect the participants in your research. Research involving animals is well regulated in most countries.

The codification of human experimentation from The Nuremberg Code (see Chap. 1), became the framework for future rules and codes on human experimentation, which are all relevant today. The Nuremberg Code was followed by the Declaration of Helsinki, developed by the World Medical Association in 1964 (the newest, 7th revision was published in 2013), and the American Psychological Association's Ethical Principles of Psychologists and Code of Conduct (revised in 2010). These codes and declarations have changed since their conception to respond to novel ethical challenges.

These codes are also implemented in Good Clinical Practice (GCP), which is an international quality standard that upholds ethical principles and provides strict guidelines on clinical protocols, record keeping and quality assurance.

To be enrolled in a clinical trial, participants must be fully informed before making a free decision for or against participation. The information for consent must be provided in a language that is easy to understand, adjusted to their age, level of education and intellectual abilities. For medical research, this is usually done using a written informed consent form. If the potential participant is unable to give informed consent (for example, if they are in a coma or suffering from severe mental illness), a legal guardian can give the informed consent in their place. If the participant is underage, a parent or legal guardian can provide the informed consent, while the child should give informed assent (agreement to participate in the study after being informed) from a certain age. It is important to keep in mind that the age of assent differs in different countries. The European Medicines Agency has a document with legal rules about assent age in EU countries, as well as detailed guidance for assent and consent for paediatric clinical trials. Certain societal groups, such as soldiers, prisoners of immigrants, can be particularly easy to coerce into a trial, and are considered vulnerable subjects, which require special consideration in research methods and design.

In practice, every research project that involves human participants, whether it is in health or social sciences, should have some type of informed consent in place, especially if your work is with vulnerable populations, such as children. If you have doubts, speak to the members of the Ethics Committee in your organisation, and ask for advice. Remember: you need approval from the Ethics Committee before you begin your study if you are working with human participants (or their data – check for GDPR requirements!).

To further guide your planning of a research project with special consideration for research ethics and research integrity, European Network for Research Ethics and Research Integrity (ENERI) has developed the ENERI Decision Tree. It is an interactive virtual guide which can help you both plan and conduct research and remind you of the important milestones and guidelines relevant to both RE and RI.

If you are a researcher working in a clinical trial, talk to your principal investigator to see if you need to have a GCP certificate. Several online commercial platforms provide training and certification.

Box 4.1 3Rs Principle

Replacement: Use tissue and cellular cultures instead of animals, or, where possible, replace vertebrates with invertebrates (or go from more to less sentient animals).

Reduction: Use smaller numbers of animals in experiments by careful planning and more advanced statistical analysis.

Refinement: Use non-invasive techniques, pain relief and appropriate environment to reduce the amount of discomfort animals feel.

Working with animals is also heavily regulated. The guiding principle in animal research ethics is the Three Rs principle (3Rs) (Box 4.1). The concept was developed a long time ago, in 1959, and 3Rs stand for Replacement, Reduction and Refinement.

A lot of research on animals is conducted in invertebrate species but the numbers of animals used are often unreported and this type of research is often unregulated. Invertebrates most used are fruit flies (*Drosophila melanogaster*) and nematode worms (*Caenorhabditis elegans*). Research conducted on vertebrates most commonly includes rodents (mice, rats, guinea pigs), fish (zebrafish), frogs, and mammals (dogs, cats). Research is also conducted on non-human primates.

Research on primates presents a special ethics challenge, especially the research that includes invasive research which causes pain or discomfort. The examples include neuroscience (behaviour, cognition), infectious diseases (HIV, hepatitis, emerging diseases), genetics and xenotransplantation. Non-human primates (most used are crab-eating macaques, marmosets, and rhesus monkeys) have complex memory abilities, respond to death, suffering and injury, can manufacture and use tools, plan actions, and anticipate future events and behaviours and can understand and develop complex social relationships and learn and pass knowledge. While the use of great apes in research in the EU is severely limited, it is still possible (see the opinion of the Scientific Committee on Health Environment and Emerging Risks). Additionally, working with genetically modified, cloned, or endangered animals requires additional licence and registration.

So, before you begin your research with animals, check the local requirements as some countries require special certificates in laboratory animal management. When designing your research, consider the 3Rs and look after your animals!

Good research practice from the European Code of Conduct for Research Integrity:
Researchers have due regard for the health, safety, and welfare of the community, of collaborators and others connected with their research.

Science is never done just for its own sake. The ultimate goal of scientific research should be the benefit of humanity in general, but also of the local community. Science and society should work together. This is reflected in the concept of responsible research and innovation (RRI). RRI includes anticipation, reflexivity, inclusion, and responsiveness. In RRI, stakeholders are aware of and respond to values and needs of society. Researchers should raise public awareness and engage the public, especially when conducting publicly funded research. Different types of RRI training can help in making this iterative process better. Different types of RRI training and tools are available online at RRI Tools.

While socially responsible science considers the needs of society, often by employing surveys or focus groups or by directly working with different stakeholders, a special type of public engagement in science is citizen science. Citizen science is a type of research done completely or partly by amateurs in the field, i.e. nonprofessional scientists. In this way, interested laypersons can collaborate with or work under supervision of a professional scientist and contribute to the scientific findings (Box 4.2). Citizen scientists in the EU are organised in the European Citizen Science Association.

Research can sometimes be done in areas that pose risks to researchers and participants. Examples of this include research conducted in regions of conflict, non-democratic countries or developing countries. Measures must be taken to ensure physical safety of everyone involved and protection of research data.

Good guidance for identifying and addressing ethics issues in research is available from the European Commission as a guide on how to complete your ethics self-assessment, aimed primarily for applicants of EU projects. Although it is written to help with the application for EU research grants, it can help you as a guide to

Box 4.2 Examples of Citizen Science Can Be Found in Astronomy, Ecology (Especially Birdwatching) or Informatics

Observing wildlife: several platforms, such as iNaturalist, enable you to record and share pictures of plants and animals, keep track, and discuss biodiversity. There are other platforms dedicated exclusively to birdwatching.

Astronomy: Include both amateur activities of night sky watching using telescopes, measuring changes in star brightness, or tracking asteroids. One example is GlobeAtNight, where enthusiasts can report on the impact of light pollution.

Seismology: European-Mediterranean Seismological Centre watches earthquake activities and has created a mobile app allowing users to report if they had felt an earthquake.

Box 4.3 Ethical Issues Relevant for Ethics in EU Research Grants

1. Human embryonic stem cells and human embryos
2. Humans
3. Human cells and tissues
4. Personal data
5. Animals
6. Non-EU countries
7. Environment, health, and safety
8. Artificial intelligence
9. Other ethics issues
10. Potential misuse of results

recognize and address most ethical issues which can arise in planning and conducting scientific research (Box 4.3).

Different types of technological advancement can be used for the common good, but they can also bring important risks and damages. This is called dual use technology research. Keep in mind that this section deals primarily with technology-oriented scientific fields (STEM – Science, Technology, Engineering, and Math), but that does not mean other fields do not have the potential for dual use technologies.

Dual use technology has potential for civilian, military or harmful applications. Examples of these technologies include satellite and complex camera imaging systems, artificial intelligence, missile technology and different nuclear, biological, and chemical technology. For example, while complex lenses and imaging systems can (and are used) in observing animals (for example at night), they can also be used for observing army troops or in military night vision goggles. On the other hand, missiles can be used to deploy satellites to foster everyday communications but can also be used as ballistic missiles and artillery. Finally, nuclear energy can be used to treat disease and provide energy but is also used in nuclear weapons. On the other hand, findings in behavioural sciences can be exploited in social media algorithms to provide profit without informing the users in an informed way, while history research can be twisted and misinterpreted in the political arena. Scientists should anticipate and recognize these risks when conducting research, applying to and accepting research grants, reporting research findings and choosing research collaborations.

Doing this can sometimes be difficult and not so apparent. The current definition of dual use research states that it is research which can be **reasonably anticipated** to provide **direct application** in military or harmful settings.

Think about potential misuse. Speak to your mentor if you have concerns or you to your local university office for science.

Box 4.4 What Is Open Science?

Open methodology: making research methodology publicly available

Open source: making software source code freely available for modification, use and redistribution

Open data: freely sharing research data for others to use (for example, in their own research)

Open access: freely sharing scientific manuscripts online, free of access charges

Open peer review: practice of sharing the identity of those involved in the scientific peer review process

Open educational resources: freely distributed learning materials, including books, texts, videos, other materials, and organised courses intended for teaching

Why Is Transparent Research Important?

Transparency is perhaps the best safeguard for responsible research. Open science (Box 4.4) is considered one of the three European Commission strategic research priorities (with two others being Open Innovation and Open to the World). Following the Mertonian norms, open sciences expands to all parts of scientific discovery: open methodology, open source, open data, open access, open peer review and open educational resources. Open science intertwines with RRI as both are concerned with the openness to society, to the public and to different stakeholders.

Complete Reporting of Research Results

Your research is as good as your data is. While it is important to collect and analyse data with great care, the "end product" of scientific work is a published manuscript. These manuscripts guide and inspire other scientists, and can have a practical implication in medicine or in informing public policies. That is why they have to be well written so that other scientist can understand the research and its value; more importantly, the research has to be reported honestly and transparently; and relevant outcomes need to be selected (in medicine, Core Outcome Measures in Effectiveness Trials initiative is working towards using objective and relevant outcomes in clinical research). Published scientific papers are also used for secondary research, for example in systematic reviews and meta-analyses.

Writing scientific manuscripts is never easy but writing honestly and transparently is even more difficult. Reporting guidelines can help you in the process. These

are developed as checklists which are written to help the authors in reporting specific types of research. The checklists contain different items which should be described in a manuscript and typically provide more detailed information on those items, as well as good examples of good reporting.

Completeness of reporting is particularly important in health research, as it directly influences health practices through evidence synthesis and recommendations from health practice guidelines. The leading initiative on the use of reporting guidelines in health research is the EQUATOR network (Enhancing the QUAlity and Transparency Of health Research), which is an international organisation devoted to improving the reliability and value of published research manuscripts. Depending on the type of research, there are different reporting guidelines available. For example, for reporting of randomised controlled trials, which are the corner stone in developing and testing new interventions in health, Consolidated Standards of Reporting Trials (or CONSORT) was developed. CONSORT consists of 25 items and a flowchart, instructing scientists to report how the study was designed, statistically analysed and how the results were interpreted. Research has shown that the use of the CONSORT checklist by scientific journals during the submission period is associated with improved quality of reporting of randomised controlled trials. Other useful reporting guidelines are STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) which is designed for reporting of cross-sectional, cohort and case-control studies; COREQ (COnsolidated criteria for REporting Qualitative research) guidelines and checklist for reporting qualitative studies; PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) for reporting systematic reviews, meta-analyses and scoping reviews; and SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines for reporting clinical trial protocols.

One important safeguard we have to ensure honest reporting is the preregistration of research. Preregistration of research is particularly important in clinical medicine, as it is now required by law to register medical interventions on humans in different clinical trial registries. By reporting on the methods and expected outcomes of planned research, it is more difficult to change sample size, study aim or outcomes. The first registry was developed from a database for HIV and AIDS research. Based in the United States, Clinicaltrials.gov is the most recognizable clinical trial registry today. Other registries were created later, for example World Health Organization's International Clinical Trials Registry Platform (ICTRP), which serves as an international coordinating body for other international and national registries.

Initiatives for preregistration are emerging in other research fields, such as animal research, statistical preregistration, and protocols for systematic reviews. Preregistration is important to foster transparency in social sciences and humanities as well, and we predict that more and more scientific journals in these categories will require it before accepting manuscripts for publication. Different platforms can

be used to preregister studies in behavioural and social sciences or humanities, like Open Science Framework.

Good research practice from the European Code of Conduct for Research Integrity:
Research protocols take account of, and are sensitive to, relevant differences in age, gender, culture, religion, ethnic origin, and social class.

Science should be available to everyone, not only through its results and application, but through its selection of ideas, hypotheses, and data collection. However, this is often not the case. For example, women have been historically excluded from medical and pharmaceutical research. This bias had been recognized and addressed since the 1980s, but recent analysis published in the BMJ in 2020 showed that the problem persists. Sex and gender gaps are present at every stage of clinical research. Even preclinical animal studies often include only male or underrepresent female animals, making initial safety and efficacy research dubious for future female clinical trial participants. Post-market pharmacovigilance data show that women have more hospitalizations for drug adverse reactions. Current standards call for the percentage of female participants in clinical trials to be proportionate to the real-world prevalence of women in the researched condition or disease. When preparing your research protocol, regardless of your study area, try to recruit participants from different backgrounds, different ages and levels of education.

Similar to female representation in clinical trials, including people from different ethnic and racial backgrounds in research is important. In trials, there is also an under-representation of black, indigenous and people of colour. This lack of representation has resulted in interventions which have not translated well into everyday clinical practice. For example, research has shown that portable pulse oximetry devices, which measure the level of oxygen in the blood using infrared lights are not precise in people with darker skin tones.

Diversity in research should not be limited just to participants, but should apply to research teams, which is particularly problematic in STEM and medical research fields. Diversity in research teams facilitates problem solving and balances bias. Working in interdisciplinary and diverse research teams enables researchers to exchange ideas and look at problems from different perspectives.

Good research practice from the European Code of Conduct for Research Integrity:
Researchers recognise and manage potential harms and risks relating to their research.

Box 4.5 Causes of Unintended Consequences

Robert K. Merton, American sociologist, listed five possible causes of unanticipated consequences:

Ignorance: lack of knowledge (of relevant information)
Errors: mistake in any phase of action, also including inappropriate approach to analysis of a phenomenon
Focusing on the immediate benefit instead on long-term consequences: lack of anticipation regarding the possible futures
Basic values: actions in line with the dominant set of social values can have the effect on these social values themselves
Self-defeating prophecy: anticipation of a certain negative outcome and working to prevent it can bring prevent the predicted outcome and cause the unintended one

Science, in the broadest sense, includes natural, social, and behavioural, formal, and applied science. While the pursuit of knowledge is a noble human endeavour, scientific research in any form can dramatically alter our everyday lives (sometimes on purpose, sometimes not – this is called unintended consequence). Research from all areas should think about this, and always ask the question – "*what if*?" (Box 4.5). Anticipation is a fundamental part of responsible research and innovation.

In the past, military inventions (nuclear technology, jet engines, duct tape) quickly found civilian use and vice versa (dual use). However, anticipation of new scientific discoveries and innovation is broader. Any new discovery, in all areas of science, can dramatically change the way our society works or have a huge impact on nature. For example, the mosquito nets that were provided to the local population for the prevention of malaria were used for fishing, which in turn ravaged the local fish population. Anticipation is difficult to address (apart from these consequences being difficult to predict on its own) as there is institutional, cultural, and individual opposition to it.

For example, in medical sciences, new discoveries can have direct implications for both individual patient and population (think for example about CRISPR technology, which is an emerging molecular biology technique for gene manipulation), even if potential risks are not completely clear from the beginning (for very rare side effects, it is sometimes necessary to test the treatment on a large number of patients for the rare side effect to emerge). These unexpected side effects can sometimes be helpful (e.g., when it was discovered by accident that aspirin can reduce thrombosis or that sildenafil (Viagra®), which was developed as an antihypertensive, can help with erectile dysfunction).

While being difficult to predict by nature, paper published in *BMC Public Health* provided several ideas on how about and prevent future unwanted consequences: (1) policies should be developed in full and tested; (2) goals of actions should be clearly defined; (3) interventions should be assessed using real-world data; (4) decision should be both evidence based and different stakeholders should be included.

If You Want to Learn More

The Embassy of Good Science

FAIR principles: sharing data for maximisation of results
Anonymisation and pseudonymisation
Methods to increase data availability
Sharing and preserving data in repositories
Balancing harms and benefits
Ethical issues of involving children with disabilities in research
Conducting research in high-risk locations
Confidentiality
Informed assent
Privacy in research
Research with animals
Research with humans
Vulnerable and non-competent subjects in clinical trials
The Hong Kong Principles for assessing researchers: Fostering research integrity
Preprint servers
Standards of authorship
Keeping inadequate notes of the research process
Ignoring substantial safety risks of the study to participants, workers or environment
Discipline specific codes and guidelines on research integrity
GDPR: https://embassy.science/wiki/Theme:61d9a3f5-8f8b-4f6f-8363-fa53f959f131
COMET Initiative
Informed consent in psychiatry
AllTrials campaign
Preregistration of animal study protocols
Prospective registration of clinical trials
Statistical pre-registration

Published Articles

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Guidance

American Psychologists Association Ethical Principles and Code of Conduct
European Citizen Science Association
European Network for Research Ethics and Integrity (ENERI)
ENERI Decision Tree
Enhancing the Quality and Transparency of Health Research (EQUATOR)
Ethics self-assessment
Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups
Declaration of Helsinki
The European Code of Conduct for Research Integrity
Hong Kong Principles
COMET Initiative
CONsolidated Standards of Reporting Trials (CONSORT) Statement
European Medicines Agency
Good Clinical Practice
International Committee of Medical Journal Editors Authorship Criteria
International Committee of Medical Journal Editors Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals

Informed Consent for Paediatric Clinical Trials in Europe
Informed Assent and Consent Guidance for Paediatric Clinical Trials in Europe
NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research
Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)
Singapore Statement
Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)
STrengthening the Reporting of OBservational studies in Epidemiology (STROBE)
RRI tools

Data Practices and Management

5

Rea Roje

Abstract

Employing good data management practices is important for enhancing the transparency and validity of research, as well as the reproducibility of research findings. This chapter aims to help early career researchers translate the European Code of Conduct for Research Integrity principles and guidance on data management practices into everyday research. In this chapter we will guide you on data practices and management throughout the lifecycle of research data – data management planning, organizing and storing data, preserving and sharing data, reusing and citing data. You will also learn about the data management procedures relevant to each of the data lifecycle phases – preparation of data management plans, procedures for storing data properly and securely, examples of repositories for preserving and sharing data, licenses for reusing data, etc. The chapter will also outline the FAIR data principles and data protection requirements and safeguards important when handling personal data in your research (GDPR requirements, pseudonymization, anonymization, and deleting data).

Keywords

Data management · Data management plan · Research data · Personal data · Data protection

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What This Chapter Is About

Employing good data management practices is important for enhancing the transparency and validity of research, as well as the reproducibility of research findings. This chapter aims to help early career researchers translate the European Code of Conduct for Research Integrity principles and guidance on data management practices into everyday research. In this chapter we will guide you on data practices and management throughout the lifecycle of research data – data management planning, organizing and storing data, preserving and sharing data, reusing and citing data. You will also learn about the data management procedures relevant to each of the data lifecycle phases – preparation of data management plans, procedures for storing data properly and securely, examples of repositories for preserving and sharing data, licenses for reusing data, etc. The chapter will also outline the FAIR data principles and data protection requirements and safeguards important when handling personal data in your research (GDPR requirements, pseudonymization, anonymization, and deleting data).

Case Scenario: Data Handling and Record Keeping

This is a hypothetical scenario of a junior researcher who discovers gaps between previously kept records of lab data and what has been published. The original case scenario is developed by the Members of The Embassy of Good Science and is available at the Embassy of Good Science. This hypothetical scenario was adapted from a narrative concerning the links between data management and research integrity. The case below is published under Creative Commons Attribution-ShareAlike license, version 4.0 (CC BY-SA 4.0).

Professor Brown is an epidemiologist who just won a prestigious grant for conducting research about the impact of environmental genetic and clinical factors on the prevalence of obesity in urbanized areas. The research team working on the project is interdisciplinary and includes senior researchers, postdoctoral researchers, and doctoral students. For conducting this research project, the methodology includes collecting data from public Databases (Geographic Information System and Google Street View), data collection from hospital records, studying genetic samples stored in hospital biobank, surveys, and interviews with research participants. While working on the part of the project focused on collecting data from Geographic Information System and Google Street View, one member of the research team insists on sending the datasets to the public repository (making them available to other researchers who want to use the dataset) since the grant agreement requires project members to employ FAIR principles (making data findable, accessible, interoperable, and reusable) in their research. However, not all members of

the research team agree with this. Some members are emphasizing the GDPR requirements that must be respected and intellectual property rights regarding the data collected. Moreover, some members of the research team think that data should be made available to others only after the manuscript publication so no one can endanger their publication plans. For the data collection from hospital records, researchers retrospectively collected laboratory data, histological results, and some personal data of individual patients (age, sex, residential area, occupation). The research team collected these data without obtaining ethical committee approval presuming that it is not necessary to have approval for collecting data from hospital records that were taken a decade ago. Moreover, the informed consent from patients was also not obtained.

Questions for You

1. In light of this case scenario, what data management issues can be identified in this research project?
2. What data management guidelines and practices should be employed in the research described in the case scenario?
3. What data protection practices should be followed in the research described in the case scenario?

Data and Types of Data

Let's first define what data are and what the different types of data are. Data are all unorganized facts that need some processing and organisation to become information. Hence, data are unprocessed information, and similarly, research data can be defined as collected, unprocessed information that will need to be processed, organized, and presented in a certain context to provide information that will support research findings.

Research data can be classified based on different criteria. For example:

- Type: electronic documents, registries, tables, notes and laboratory books, questionnaires, transcripts, codebooks, samples, databases schemes, models, algorithms, protocols, experimental results, metadata, methodologies, etc.;
- Format: textual (word, PDF, XML, etc.), numerical (Excel, SPSS, etc.), audio and multimedia (jpeg, tiff, wav, etc.), software programs, disciplinary-specific (e.g., crystallographic information file, CIF);
- Size and complexity of research data: small, large, simple, complex;
- Research phase: raw, cleared, processed, analysed.

Why Is Good Research Data Management Important?

Data management includes different processes and activities required to manage and preserve data throughout the research lifecycle or research phases (Fig. 5.1):

- planning and preparing the data,
- collecting, organizing, and storing the data,
- analysing, and protecting the data,
- archiving, preserving, and curating the data,
- discovering, accessing, and reusing the data.

Reduced risk of data loss, increased transparency and reproducibility of research results, easier compliance with different requirements (ethical, legal, funders' or publishers' requirements), prevention of errors in research, and research career and reward benefits are just some of the reasons why good data management practices are important and should be considered and applied during every research project.

Good research practice from the European Code of Conduct for Research Integrity:
Researchers, research institutions, and organizations ensure appropriate stewardship and curation of all data and research materials, including unpublished ones, with secure preservation for a reasonable period.

Fig. 5.1 Lifecycle of research data

Planning and Preparing Data

The first step in applying good data management practices in research includes planning before the project has started and even before applying for research funding. The planning process will include thinking about all the types and formats of data that you will collect and process during your project, as well as how the data will be used and by who. Moreover, when you plan and prepare for your research, you should also include getting familiar with the funders' requirements for data management. Research funders usually provide relevant information on data management requirements and helpful guidance on how to fulfil the requirements, so make sure to check it before sending your project application. For example, if you plan to apply to European Commission (EC) research frameworks grant calls, you should check their guidance (e.g., Guidelines on Open Access to Scientific Publications and Research Data for Horizon Europe). Since requirements and conditions may change over time, it is very important to recheck these each time you plan a new research project.

Data Management Plan

Research funders often require writing a data management plan (DMP). DMP is very important for every research project because it helps:

- plan in advance everything concerning your data (e.g., collecting, storing, licensing, sharing, etc.) and how you will deal with your research data during the project;
- anticipate potential issues that may arise during the project;
- enhance data FAIRness (making your data findable, accessible, interoperable and reusable);
- your project collaborators to manage the data in the same way which enhances the integrity of data and ensures proper stewardship.

In your DMP, you should include the information about:

- type of data you will collect, create, or reuse;
- how data will be documented and stored;
- ethical and legal requirements;
- how data will be shared and preserved;
- who will have the access to use or reuse the data;
- data management responsibilities of the team members (project director, research staff, technical staff, supporting staff, etc.);
- data management costs (e.g., costs of transcribing data or costs of long-term preservation).

It is good to bear in mind that in some situations you cannot plan or anticipate all possible scenarios, and hence sometimes you will need to update your DMP if significant changes regarding your data arise (for example, if you decide to collect some new data that was not planned at the beginning). There are many online tools for data management plans that make the work of writing DMP a lot easier. Tools like OpenAIRE guide on DMPs for Horizon Europe and Science Europe Practical Guide to the international alignment of research data management can help you create your DMP.

Collecting, Organizing, Storing, Analysing, and Protecting Data

Once you have planned your data management activities and started with your project, it is time to implement good data management practices in collecting, organizing, storing, analysing, and protecting the data. Usually, you have already defined in your research protocol or plan how your data will be obtained and which procedures and methodology will be used for collecting and analysing the data.

Data Formats

The data format can also be defined in advance since it depends on the type of data you collect (e.g., text files or audio files) and type of preservation (long-term or short-term). There are some general recommendations, for example, the preferred format for images is *tiff*, and for audio files, the preferred format is *wav*. For long-term preservation, it is always better to use open formats, which will ensure accessibility to a wider audience. Moreover, there is a possibility that in the future we will not be able to use some outdated formats or software to open and reuse data, hence the best option is to store data in open formats and formats with widespread use. For example, when dealing with the textual data you can choose between open (e.g., *docx*, *txt*, *pdf*) or closed (e.g., *doc*) formats. Similarly, if you have table data, you can choose between open (e.g., *xlsx*, *csv*, *ods*) or closed (e.g., *xsl*) formats.

Organizing Data

Once you decide on the formats, it is time to organize your data properly. It is important have a clear and consistent naming and organizing both your paper and electronic data. You should use consistent, unique, and descriptive names and develop name conventions that will be followed by everyone involved in your project. This will reduce the risk of losing data, and make research and exchange of data between different project participants a lot easier. Naming conventions should be

written in a separate file and stored properly so that everyone in your research team can access them and check if there are some uncertainties. Moreover, you should track versions of your data by, for example, documenting in a separate file which changes have been made in which version and who made the changes. Do not forget that your raw data should be preserved as they are, so it would be best to store them separately to ensure they will not be lost. There are many options for naming conventions, and you should use those that fit your data and research best. For example, when dealing with structured tabular data, it is very important to write naming and description of used variables and codes. When naming your files, you can follow the convention like "project name/acronym_subject_activity phase" or "version_type of data_researchers initials". Some recommendations for naming conventions include:

- develop naming convention upfront;
- use letters and numbers from A–Z or a–z and 0–9;
- use ISO standards for the date (YYYYMMDD);
- do not use period punctuation mark or special characters;
- use a low dash or CamelCase instead of space (e.g., CamelCase.docx instead of Camel Case.docx or Camel_Case.docx – the name comes from visual "hump" created by a capital letter in the file name).

Another important thing to consider when organizing your data is developing a folder structure or a map. Your folder structure should be properly developed and logical so that you can find all your data easily. For example, you can have a folder named after your project. In that folder, you can have folders called "data", "documentation" and "methodology". In your data folder, you will have files related to your data (raw data and different versions) while in your documentation folder you can keep related data, such as invitation letters and informed consent forms. You can also use tagging which can help you find your data on the computer.

Documentation Describing Data and Metadata

Your data can be accompanied by other relevant information that can help other researchers understand and reuse your data. When sharing your data or depositing the data in the repository, you can also include a README.txt or INFO.txt file in which you will provide basic information regarding your data (Box 5.1). These can include, for example, general information (title of the dataset, author information, date of data collection, geographic location of data collection, information about funding sources), sharing or access information (licenses and restrictions, links to publications, links to other locations of data, recommended citation for the dataset), data and file overview (list of files included in your dataset, explanation of the relationship between the files), methodology, and specific information for certain files. You can include any information that you think is helpful for other researchers to understand and replicate your data.

Box 5.1 Example of the Content in an INFO.txt File

1. Title of the dataset
2. Author(s) information (name, institution, email)
3. Date of data collection (exact date or approximate date; suggested format YYYYMMDD)
4. Geographic location of data collection (city, country)
5. information about funding sources (who funded the research)
6. Licenses/restrictions placed on the data
7. Link to accessible locations of data
8. Recommended citation for the dataset
9. File list (list of all files contained in the dataset with a brief description; relationship between files)
10. Versions of the dataset (if there are multiple versions)
11. Description of methods (for collecting data, methods for processing data; links to publications)
12. Instruments or software used in the analysis
13. Quality assurance procedures applied on the data
14. Specific information for files (number of variables, number of cases/rows, list of variables)
15. Abbreviations used

Metadata are data about your research data, and when, for example, you want to deposit your data in the repository you will be asked to fill in the metadata. Metadata can vary depending on the disciplines and research areas. You can visit Metadata Standards Directory to find more information about metadata in your discipline or research area. Metadata include at least the following: author information and contact, name of the organisation, title, type of data, and keywords. Moreover, when depositing in good and trusty repositories your data will be assigned with the digital object identifier (DOI) or another persistent identifier – a long-lasting reference to a digital resource. Metadata, including the persistent identifier, are intended for machine-reading and they enable retrieval and reuse of the data. Even if you are not sharing your data openly (i.e., in open access), your metadata should be publicly available and hence findable and retrievable, in accordance with the FAIR principles.

Storing and Protecting Data

Many options are available for your data storage and backups. The general recommendation is to have at least three copies of data at three separate places – computer, cloud, and portable device. You can store your data in an infrastructure and storage

space provided and managed by your organisation. This is a good option that can minimize the risk of data loss, as organisations usually do regular backups. Using the institutional infrastructure for storage can ensure adequate security level and easier dissemination with collaborators in your project. For ensuring additional data protection, you can define within your research team who will be in charge of data backups and in which timeframes the backups will be conducted (e.g., on a weekly or monthly basis). Moreover, you can also conduct checksums, i.e., check the similarity between files before and after making backups to ensure that you have identical files and that the backup was done appropriately. To conduct checksums, you can use different IT solutions, such as MD5summer. Data can also be stored in cloud services, but this is not the best option as it usually involves third-party access to data and an appropriate level of security is not ensured. If you decide to use cloud services, you should always check the terms and conditions of cloud providers and their compliance with the GDPR.

Researchers often use different portable devices in their work, but portable devices should be used cautiously as the risk of losing data is quite high. Using encryption for protection is recommended in each case, especially when using clouds and portable devices. Make sure to store and protect your password adequately and have strong passwords that are updated regularly. Besides data in the electronic format, researchers are often dealing with data in the paper format. If you have your data on paper, you should make sure to store these properly – preferably in the safe, under the lock. Moreover, it is recommended that you digitalize your paper data as this can ease the usage and exchange of data and increase data safety. You can create documentation that will help you to get around more easily regarding your data storing and protection actions. For example, you can make a file in which you will write where your data are stored (for example, on a computer of your collaborator), who has the access to the data and who can make changes, who performs backup, and how often, etc. Another thing you should pay attention to is whether you store all your data at the same place or separately. This is especially important when you deal with sensitive personal data. For a qualitive interview study, for example, the interview transcripts, informed consents, and other personal identifiable information should be stored separately and protected adequately (e.g., encrypted).

You must protect research participants and their data, especially when processing special categories of personal data that require even more safeguards (such as health data, data on ethnic origin, religious or political beliefs). You must check applicable laws and guidance (organisational, national, and international) on how to process personal data and employ appropriate technical and organisational measures and safeguards. You should pay attention to the GDPR requirements when processing personal data from European Union (EU) citizens. You can find more information on data protection and privacy legislation worldwide at the end of this chapter.

If there is a Data Protection Officer or a Research Integrity Officer in your organisation, check with them how to ensure proper protection of participants' data in your research. Here are some safeguards:

- Data minimization – collect only data that is needed for your research aims;
- Data anonymization – remove all identifiable information from the data;
- Data pseudonymization – substitute identifiable information with the unique identifier.

Whenever possible, you should use data anonymization, because anonymized data are not considered personal data and hence not under the data protection laws and requirements. However, anonymizing data is not always an easy task. It is important to think about the consequences of under and over anonymization, which affects the further use of the data. When dealing, for example, with qualitative data, it is good to use pseudonyms or descriptive names or tags to change participants' names, and it would be best to make a detailed plan on how qualitative data will be anonymized before the transcription process. In this way, you will assure more accuracy and save time for checking the transcribed data. For more information on how to anonymize different types of your research data check the available resources collected by the FOSTER project (Fostering the practical implementation of Open Science in Horizon 2020 and beyond), EU Data Protection Working Party Article 29 opinion on anonymization techniques and OpenAIRE resources.

Ethics

You should also get yourself familiar with ethical requirements related to your research and the protection of research subjects. Do not forget to obtain an ethics approval (if it is needed) before starting your study and store the document properly. When conducting research with human participants, you are required to develop an information letter in which you will describe the aims and purposes of your research study, what participation in research involves, what the rights of participants are if they decide to participate in research, and what potential risks and benefits are for participating in research. Your information letter should also include items regarding the processing of personal data (which personal data will be processed, how and for what purposes; how the personal data will be stored and protected, and for what period; what will happen to data after the storing period expires; who will have the access to the participants' personal data; what the participants' rights are in regard with the processing of their personal data). Besides providing participants with this information, you will also need to obtain informed consent. In the informed consent, you provide statements that participants have to agree with to participate in research (e.g., statements saying that participants understood the information letter and what is expected of their participation in research, statements that participants are aware of how their data will be collected and processed and that they agree with

it, etc.). The informed consent is usually obtained in the written form and signed by participants.

When collecting data in research studies involving children, in addition to the parental consent, you will also need to ask the assent from children of certain ages, depending on national legislation (see for example Informed Consent for Paediatric Clinical Trials in Europe). Make sure to ask assent in a written or some other form by using language that is appropriate to the child's age, so that child can understand what are you asking.

As informed consent and assent documentation contains personal data, you should take appropriate measures to store these documents. This means in a safe place, with restricted access, and not together with other research data that contains information that can be linked directly to the individual. For example, you should never store your interview transcript together with the research participant's informed consent.

Deleting Data

Once you no longer need data or data storage period was predefined in your study protocol and data management plan, make sure that data are disposed of securely. Just deleting data from your computer may not be enough, as deleted files can be retrieved. Similarly, just tossing your papers in the trash can is not a proper way of disposing data. You should always use appropriate measures such as shredding machines and computer software that will ensure that data is not retrievable.

Good research practice from the European Code of Conduct for Research Integrity:
Researchers, research institutions and organizations provide transparency about how to access or make use of their data and research materials. Researchers, research institutions and organizations acknowledge data as legitimate and citable products of research.

Archiving, Preserving, and Curating Data

Preserving and sharing your data with other researchers has many benefits. We already talked about data storing, which mainly focuses on how you can store your data for your own and your research team's purposes. The preservation of data is more related to long-term availability of data. This means enabling proper storage and preservation of data even if you or your research team do not have the data anymore or you are not reachable by other researchers who would perhaps like to use your data. Good preservation and sharing practices can increase the visibility, impact, and citations of research, ensure validation of the research data, encourage

collaborations and enable reuse for new research findings. However, before sharing the data, you must consider several factors:

– make sure there are no constraints regarding sharing (such as data containing personal information that identifies individuals).
– think about how data might be reused.
– think about the costs of sharing and long-term curation.
– check funder's data-sharing policies and requirements.

To preserve and share your data, you can use project, discipline, national, or international specific repositories. However, before deciding on where to deposit your data, you should check if a repository is reputable and safe and whether there are persistent and unique identifiers that will be added to your data and that will make sharing data easier but also ensure that proper contribution is given to data owners.

Some recommendations for finding a good and reputable repository include checking:

– whether your data formats are acceptable by repository;
– whether the backups of the deposited data are regularly performed;
– whether the repository has a certificate (that ensures it is long-lasting and reputable);
– whether you can track the statistics related to your data in the repository (e.g., how many times your data were downloaded);
– whether the repository is in accordance with the FAIR principles.

To find relevant repositories, you can use the Registry of Research Data Repositories – a database of international repositories for research data. For more guidance on choosing a repository for your data, take a look at the Science Europe Practical guide to the international alignment of research data management, which offers guidance for selecting trustworthy repositories. Some of the well-established repositories are, for example, Figshare and Open Science Framework, where you can share different types of data and preprints. In Open Science Framework you can also register your research protocols (see Chap. 2 on Research Procedures).

Discovering, Accessing, and Reusing Data

One of the important aspects of preserving and sharing research data is also deciding on the terms and conditions on which other researchers will use your data. This may be especially important if you have to share your data before publishing your research (e.g., because of funders' requirements). By licensing your data, you will ensure that data is used under the conditions you set and that appropriate credit is given to you. You can check the Creative Commons licenses or Open Data Commons to learn about different levels of data sharing. When depositing your data in the repository, you will be able to choose between different types of licenses. You should carefully consider which licence is suitable for your data, e.g., how you want

your data to be used, taking into consideration any other intellectual property rights related to your data. You should also bear in mind that licenses with fewer restrictions provide more opportunities for reusing the data. Once you choose the license it cannot be changed, which is another reason to carefully consider the licences for your research.

For example, the Creative Commons (CC) licenses are widespread and commonly used licenses that enable you as an author to copyright your work and set specific conditions under which others can use your work. These licences are based on four main types of reuse:

- Attribution (BY): allows distribution, adaption, and building upon the original work by giving the proper attribution to the creator;
- Non-Commercial (NC): allows distribution, adaption, and building upon the original work only for non-commercial purposes;
- No Derivates (ND): the original work can be used only in its original form and changes are not allowed;
- Share Alike (SA): allows distribution and adaption under the same conditions as they stand for the original work.

Based on these, there are a total of 6 Creative Commons licenses that can be used: CC BY, CC BY-SA, CC BY-ND, CC BY-NC, CC BY-NC-SA, CC BY-NC-ND (Box 5.2). There is also a CC0 license ("No Rights Reserved") which stands for the public domain. This means that you are giving your work in the public domain and it is free for use, there are no restrictions and there is no obligation to provide the attribution to the work.

In 2018, a Plan S was launched as an initiative by Coalition S of national research funders, European Commission, and the European Research Council, dedicated to ensuring full and immediate open access to research publications. The Plan contains ten main principles, and the key principle is that all publicly funded research must be published in open access journals or made immediately available in open access without embargo. In that sense, it is important to mention the Rights Retention Strategy (RRS) which was developed to make sure that researchers retain sufficient intellectual rights on their work, so they could freely share it. The RRS also requires researchers to deposit the Author Accepted Manuscript or the Version of Record into the repository with a CC-BY license and with no embargo.

Citing Data

When using data from other researchers or sources in your research, do not forget to cite it appropriately, as proper credit should be given to data owners. When citing data, you should always:

- be consistent with the referencing style that should, in each case, include authors, title, publication date, publisher, and location (a persistent URL);

Box 5.2 Creative Commons (CC) Licenses

CC0: dedicating the works to the public domain, meaning that the creators wave all their copyright and related rights to their works.

CC-BY: allows distribution, remix, adaptation, and building upon the original work in any format; credit must be given to the creator; should be used if you want maximum dissemination and use of your work.

CC BY-SA: allows distribution, remix, adaption, and building upon the original work in any format but adaptations must be shared under the same terms; credit must be given to the creator.

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– include DOI or another permanent identifier;
– separately cite different datasets.

Good research practice from the European Code of Conduct for Research Integrity:
Researchers, research institutions and organizations ensure access to data is as open as possible, as closed as necessary, and where appropriate in line with the FAIR Principles (Findable, Accessible, Interoperable and Reusable) for data management.

The FAIR principles are the guidance on how to make data findable, accessible, interoperable, and reusable. Making data FAIR enables others to discover, understand, and use data. The Final Report and Action Plan from the European Commission Expert Group on FAIR Data says that data should be made open and FAIR as much as possible and closed as necessary following the ethical and legal constraints and requirements.

Findable To make data findable, they have to be (1) described with adequate and rich metadata; (2) contain a persistent identifier that will permanently link data, metadata, and other relevant material, (3) registered or indexed in the search resources to enable other users to identify and use the data.

Accessible Data are accessible once potential users find the data and know how to access it. Making data accessible does not imply that data are open and free for use, since access may require authentication or authorization. Making data accessible means that users should be able to access the data under certain conditions that need to be transparent and defined clearly. It is also very important to mention that metadata should be retrievable and accessible even when data are no longer available.

Interoperable Data are interoperable if integrated with other data. Both data and metadata must use formal and broadly applicable language for knowledge representation and use vocabularies that follow FAIR principles.

Reusable Making data reusable is considered the ultimate goal of the FAIR principles. To achieve this, several metadata and data requirements should be implemented: (1) metadata and data have to be adequately described and have a clear data usage license; (2) metadata and data have to be associated with detailed provenance and meet domain-relevant community standards.

Good research practice from the European Code of Conduct for Research Integrity:
Researchers, research institutions and organizations ensure that any contracts or agreements relating to research outputs include equitable and fair provision for the management of their use, ownership, and/or their protection under intellectual property rights.

Intellectual property rights in research usually refer to patents, copyrights for data and published research, confidentiality agreements, etc. You should check your organisation's intellectual rights policy to ensure you are properly informed about how you and others can use your research. If you want to use research data or other output from other researchers, check any existing intellectual property rights and use output accordingly. You should also check your funders' policies (especially in industry-sponsored research) and agreements established with your collaborators. In any case, you should ask advice from the appointed university office and staff that deals with the intellectual property issues and industry-sponsored research agreements to ensure that your intellectual property rights as a researcher are protected adequately.

Copyright

Copyright is a legal protection given to some original work, whether literary work, music, artistic work, or research. Having copyright means having the exclusive right to use, copy and disseminate your work and at the same time limiting or enabling others or assigning your copyright to others to use your work under certain conditions or without special requirements. See also the *Discovering, accessing, and reusing the data* section in which licenses were discussed. When publishing your work in a journal, you will be asked to choose or be informed about the type of license for publishing your work. You may also have the option to transfer your copyright to the journal, in which case the journal decides upon licensing and crediting the work. However, you should be careful and consider your funders' requirements, especially if your funder is a part of the Coalition S and you have a right to retention.

If You Want to Learn More

The Embassy of Good Science

A Breach of Confidentiality
A Case Study of Secondary Use of Qualitative Data
Protecting Research Subjects
Anonymity Revisited
Failed Patenting Negotiations in Collaborative Research

Published Articles

El Emam K (2011) Methods for the de-identification of electronic health records for genomic research. Genome Med 3:25. https://doi.org/10.1186/gm239

Wilkinson M, Dumontier M, Aalbersberg I et al (2016) The FAIR guiding principles for scientific data management and stewardship. Sci Data 3:160018. https://doi.org/10.1038/sdata.2016.18

Guidance

European Commission. Collaboration in Research and Methodology for Official Statistics. Anonymisation
European Commission. FAIR guiding principles
European Commission. Final Report and Action Plan from the European Expert Group on FAIR Data. Turning FAIR Into Reality
European Commission, Horizon Europe. Guidelines on Open Access to Scientific Publications and Research Data
i-CONSENT Project. Guidelines for tailoring the informed consent process in clinical studies. 2021
Metadata Standards Directory
OpenAIRE. Amnesia guide
Science Europe Research Data Management
United Nations Conference on Trade and Development (UNCTAD) Data Protection and Privacy Legislation Worldwide)

Collaborative Working

6

Andrijana Perković Paloš

Abstract

Research collaborations offer numerous professional opportunities as well as challenges, especially for early career researchers. This is why it is important to know the rights and responsibilities of researchers in collaborations. The aim of this chapter is to help early career researchers apply principles of good research practices of European Code of Conduct for Research Integrity in collaborative working, including interdisciplinary and international collaborations. We will indicate potential problems that can arise in different stages of collaborations. We will also provide recommendations with regard to determining your roles and responsibilities in collaborations, procedures on handling research misconduct, and possible publication disputes.

Keywords

Interdisciplinary collaboration · International collaborations · Collaboration agreement · Authorship agreement

What This Chapter Is About

Research collaborations offer numerous professional opportunities as well as challenges, especially for early career researchers. This is why it is important to know the rights and responsibilities of researchers in collaborations. The aim of this chapter is to help early career researchers apply principles of good research practices of European Code of Conduct for Research Integrity in collaborative working,

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https://doi.org/10.1007/978-3-031-22412-6_6

including interdisciplinary and international collaborations. We will indicate potential problems that can arise in different stages of collaborations. We will also provide recommendations with regard to determining your roles and responsibilities in collaborations, procedures on handling research misconduct, and possible publication disputes.

Case Scenario: Starting a Research Collaboration

This hypothetical scenario was adapted from a narrative concerning the links between collaborative working and research integrity. The original case scenario is developed by the Members of The Embassy of Good Science and is available at the Embassy of Good Science. The case below is published under Creative Commons Attribution-ShareAlike license, version 4.0 (CC BY-SA 4.0).

During a scientific conference, two researchers, who come from different research backgrounds, show interest in the topic that you are currently working on. When you discuss the topic with them in more details during the break, you start to see the benefits from working together. You all live in different countries and are at different career stages – you have just earned your doctoral degree, while the other two researchers are more experienced in their fields. The three of you drafted and submitted a grant proposal but are not sure how to proceed.

Questions for You

1. Who should submit the proposal, through which university?
2. Do all three need to get ethics approval to work on the project?
3. What will happen if their work has practical applications?
4. How should they go about answering these questions?
5. Are there other important questions that should be asked as well?

Planning Collaborative Research

Collaboration on a research project offers numerous professional opportunities and benefits for a career of an early-career researcher, but it also may pose some professional challenges or problems regarding the whole research process and relations between the collaborators. These problems can affect various aspects of the research project, and should be addressed already at the planning stage of the project (Box 6.1).

Box 6.1 What Should Be Addressed in Planning a Collaborative Research Project?

- Goals and outcomes of the project
- Roles and responsibilities of each partner in the collaboration
- Data collection, sharing, and storage
- Modifying potential changes in research design
- Collaborators responsible for drafting publications
- Criteria which will be used for identifying contributing authors
- Collaborators responsible for submission of reports and other requirements
- Collaborators responsible for speaking in public for the collaboration
- Solutions of potential disputes over intellectual property rights and ownership issues
- Potential changes and the end of collaboration

Therefore, it is particularly important that you, as an early-career researcher, know your rights and responsibilities, especially if you participate in interdisciplinary and international collaborations. You should also be familiar with the project application procedure, otherwise, you should ask the project leader(s) and senior responsible officers at your organisation for help.

If this is your first time participating in such a collaborative research project, you may not be sure what your responsibilities are, what problems you might come across, and how you can solve them.

Good research practice from the European Code of Conduct for Research Integrity:
All partners in research collaborations agree at the outset on the goals of the research and on the process for communicating their research as transparently and openly as possible.

Although there is no single model that would guarantee successful research collaborations, there are some recommendations that may be useful. One of the most important things to know before you start a collaboration is that you and all your research partners should reach an agreement around research goals. Some difficulties may arise in this matter so, to achieve agreement, communication is the key. All partners must agree on the goals and outcomes and negotiate every change together.

What Are Potential Problems in Collaborative Research?

One of potential problems is *not determining the roles and responsibilities* of each collaborating partner clearly. A grant proposal may not clearly specify the tasks for each individual partner, which may leave you rather confused about what it is that you will actually bring to the table, what you can expect from this collaboration, and what your partners can expect from you. Given that you and your partners may have different research backgrounds, you can expect to see a *diversity of viewpoints* in the understanding of research goals, use of methodology, vocabulary, and publication outputs. Since this is your first collaboration, you may not feel that you can completely trust your partners and, given that you are at the early stage of your career, they might ignore your opinions and inputs on certain matters. Because of this *lack of trust*, you may also hesitate to express your opinion or ask for help.

What should you do? There are ten simple rules you should follow if you want a successful collaboration:

1. Do not be lured into just any collaboration.
2. Decide at the beginning who will work on what tasks.
3. Focus on your tasks.
4. Be open and honest.
5. Feel respect, get respect.
6. Communicate.
7. Protect yourself from a collaboration that turns sour.
8. Always acknowledge and cite your collaborators.
9. Seek advice from experienced scientists.
10. If your collaboration satisfies you, keep it going.

Build trust to address every issue openly and avoid disputes. Practical suggestions and recommendations concerning **conflict resolutions** can be of help you in this matter:

- Be consistent in your statements.
- Make minor concessions showing efforts to meet the needs of other partners in research.
- Show humbleness.
- Ask other partners in research for help.
- Show an interest in helping other partners in research reach their goals and objectives.
- Give a partner in research return of benefits previously than expected.
- Allow clauses in collaborative agreements that will yield punishment or costs if you do not follow through on your promises.
- Do not make unrealistic promises.
- Update agreements during the project in case of some changes, for example in roles and responsibilities of some partners.
- Show understanding for concerns of your partners in research, even if you do not agree with those concerns.

Good research practice from the European Code of Conduct for Research Integrity:
All partners in research collaborations take responsibility for the integrity of the research.

All partners in a research study should formally agree on expectations and standards concerning research integrity, as well as on the procedures for handling potential violations at the very beginning of a new collaboration. The responsibility should be collective as well as individual. As individuals, we are aware of our research integrity responsibilities, which includes fostering collegial behaviour. Collectively, responsible research includes acknowledging and respecting the existence of various practices and norms that are customary in certain research areas and defining in collaboration agreements how these will be handled. As research integrity standards may vary across countries and research areas, it is important that a research collaboration has good oversight and governance to implement adequate policies and procedures, ensuring compliance, avoiding and resolving potential conflicts, and handling misconduct. If the collaborators do not agree on good oversight or clear rules for handling potential conflicts, this can lead to problems in collaboration. The project leaders are responsible for ensuring appropriate processes, structures, and clear rules that would be applied in resolving these issues.

According to the guidance on collaborative research – "Investigating Research Misconduct Allegations in International Collaborative Research Projects: A Practical Guide," developed by OECD Global Science Forum, it is important to create and sign an agreement addressing the promotion of responsible conduct of research and describing the policies and procedures that would be used in case of alleged misconduct.

If you decide to sign an agreement, you can use a boilerplate text from the Coordinating Committee of the OECD Global Science Forum (Box 6.2), which should be a part of the formal documents of the collaborative project.

The partners should without delay take appropriate actions in case of alleged breach of research integrity. The main issue in international collaborations is how to cope with different laws and regulations existing in countries that participate in the research project. As recommended by the "Practical Guide," investigations of violations of research integrity should be carried out in accordance with the policies and procedures of the institution "with primary responsibility" and at the same time respecting the laws of the countries of all participating partners. There is some practical guidance that may help you as an early-career researcher if you suspect a breach of research integrity. What if the alleged perpetrator is a more experienced collaborating partner and you find it difficult to confront them? Who should you turn to?

Inform your Supervisor As your supervisor guides you through the project, you should share with them your suspicions. This option is probably the best one because you inform a more experienced person who can either help you or take on to handle

Box 6.2 Example of Agreement on Collaborative from the Investigating Research Misconduct Allegations in International Collaborative Research Projects: A Practical Guide

We, [specify the partners], 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 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 [specify 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.

the situation. Your supervisor is also the best person to come for help if you are the victim of a breach of research integrity.

Inform Your Research Group Leader If you do not have a supervisor and you participate in a larger and more complex project, you will probably have a research group leader responsible for managing the research at your research site. If you suspect that one of the partners, whether in your or other research group, has committed a violation or that you are the victim of the breach of integrity, you should consult them about what steps you should take.

Inform the Project Leader If you do not have a supervisor or the project in which you participate does not involve a large number of researchers, you should contact the project leader(s) and senior responsible officers at your organisation and share your suspicions with them.

Good research practice from the European Code of Conduct for Research Integrity:
All partners in research collaborations are properly informed and consulted about submissions for publication of the research results.

Experts in the matters of authorship have stressed the importance of defining the authorship policies at the beginning of any collaborative research. This concerns particularly interdisciplinary and international collaborations, as research areas and geographical regions may differ in authorship criteria.

For authorship criteria in general, you can consult the chapter on Publication and Dissemination.

As for interdisciplinary and international collaborations, you should consult the Montreal Statement which addresses certain aspects of publication and authorship issues in joint research projects. The Statement suggests that:

- All partners should agree on how publication and other dissemination decisions will be made.
- All partners should agree on standards for authorship and acknowledgments. Contributions of all partners, especially, junior partners, should be recognised in publications.

One of the potential problems is defining authorship criteria as they vary across research areas, for instance authorship criteria are different in social sciences and humanities than those in medicine and some research fields in physics. Apart from that, authorship criteria also vary across journals within the same disciplinary field. This can lead to misunderstandings and disputes between the collaborating partners, which is why authorship criteria should be defined before the beginning of research. It could also happen that you, as an early-career researcher, end up doing most of the work on a research paper and not get credit for authorship or you may find your name on a publication without your knowledge and consent. You and your colleagues also may have misunderstandings about the publication outputs. For example, you might want to publish every new finding, whereas your partners in research would maybe want to wait and publish all results in one large publication. What you should do?

If you are not the only author, you must obtain consent from other authors for publication.

If you do not get credit for your contribution or find your name on a paper you have not given your consent to, you should speak up! As a novice researcher you may fear that addressing these issues and perhaps taking actions would put at risk your reputation and career. In such situations, it is always advisable to speak to your supervisor first.

As will all other aspects of collaborative research, discuss your publication plans before you start your research.

Share the credit. Some experts strongly advise developing a system which would provide proper credit to all researchers on the project. This means answering the questions:

– How will authorship be organized?
– Who will be responsible for writing the manuscript(s), and what will be their emphasis?
– If there are patents created, who is included on the patent?

We hope you will have great and productive collaborations in your research!

If You Want to Learn More

The Embassy of Good Science

Collaborative working
High income and low-and middle-income country collaborations
Questionable Research Practices in Collaboration
Intellectual property rights in research collaborations
Cross-boundary collaborations
Beginning a Collaboration
Up, Up, and Away: Clinical Trials Go International
Collaborative science
Responsible conduct of biomedical research: collaborative research
Long Distance Collaboration

Published Articles

Getha-Taylor H, Grayer MJ, Kempf RJ, O'Leary R (2018) Collaborating in the absence of trust? What collaborative governance theory and practice can learn from the literatures of conflict resolution, psychology, and law. Am Rev Public Adm 49(1):51–64. https://doi.org/10.1177/0275074018773089

Marušić A, Bošnjak L, Jerončić A (2011) A systematic review of research on the meaning, ethics and practices of authorship across scholarly disciplines. PLoS One 6(9):e23477. https://doi.org/10.1371/journal.pone.0023477

Vicens Q, Bourne PE (2007) Ten simple rules for a successful collaboration. PLoS Comput Biol 3(3):e44. https://doi.org/10.1371/journal.pcbi.0030044

Guidance

Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations provides a list of guidance for responsibilities of individual or institutional partners in cross-boundary research collaborations.

Singapore Statement on Research Integrity includes four principles and fourteen responsibilities for the ethical conduct of research.

"Investigating Research Misconduct Allegations in International Collaborative Research Projects: A Practical Guide" provides practical recommendations and tools to help in the investigation of possible cases of research misconduct in international research collaborations.

Fostering Research Integrity in Europe, a report by the ESF Member Organisation Forum on Research Integrity

How to handle authorship disputes: a guide for new researchers, the COPE Report

Framework to Enhance Research Integrity in Research Collaborations, a guide by Research Integrity National Forum

Publication and Dissemination of Research Results

7

Jakov Matas

Abstract

This chapter is focused on the integrity of writing and publishing research. Dealing with authorship is an important topic, but we also address other issues that are important during manuscript writing, preparing the article for publication and publishing it, understanding the process of publication and availability of the article during the process and, later on, in communication with the scientific community and the public. We also give advice on how to correct published articles and how to avoid negative publication practices.

Keywords

Scientific article · Authorship · Duplicate publications · Secondary publications · Preprints · Predatory journals · Acknowledgments

What This Chapter Is About

This chapter is focused on the integrity of writing and publishing research. Dealing with authorship is an important topic, but we also address other issues that are important during manuscript writing, preparing the article for publication and publishing it, understanding the process of publication and availability of the article during the process and, later on, in communication with the scientific community and the public. We also give advice how correct published articles and how to avoid negative publication practices.

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A. Marušić (ed.), *A Guide to Responsible Research*, Collaborative Bioethics 1,
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Case Scenario: Deserved Authorship

This hypothetical scenario was adapted from a narrative concerning the links between research environments and research integrity. The original case scenario is developed by the Members of The Embassy of Good Science and is available at the Embassy of Good Science. The case below is published under Creative Commons Attribution-ShareAlike license, version 4.0 (CC BY-SA 4.0).

After recently graduating in biomedicine, you have been offered a temporary position as a laboratory technician at the Department of Physiology. Although you were planning to apply for a PhD position, you have accepted this job, but still continue to pursue doctoral study options. Unfortunately, all of your interviews end up unsuccessfully, as they ask for a candidate with a research publication. In your laboratory, you perform animal experiments and other laboratory experimental work, whilst doctoral students and postdocs do data analysis and interpretation for publication. For one project, you have been asked to perform data analysis, since you have experience with that kind of analysis. The results of your experiment are included in the manuscript which is planned to be sent to a high-impact journal. You ask the Head of the Department, who is also the principal investigator on the project, whether you will be included in the paper as a co-author. He responds that you were employed as a laboratory technician, not a doctoral student, and that your primary duty was to provide technical support, not to provide analysis. When you raise an argument that according to International Committee of Medical Journal Editors (ICMJE) authorship criteria, you are eligible for authorship, he reminds you that the position was opened specifically for you, while the institution is waiting for a doctoral student grant, and that you can discuss authorship when you become a doctoral student. In communication with other colleagues, you hear that this isn't the first time the Head does such thing. One colleague also mentions the case when the Head has added a colleague of his as an author, even though other authors were not aware that he has been working on publication. Will you follow the example of your colleagues and let authorship go in order to get a PhD position, therefore participating in unethical behaviour, or raise the question with University's research ethics committee?

Questions for You

1. Which authorship criteria have been breached in this case?
2. How could adherence to responsible practice in this research be increased, to prevent this situation?
3. If a third person finds out about uncredited authorship, would you be responsible for negligence to report?

When Is a Paper Published?

In pre-internet times, a paper was considered published when it was released in print. Nowadays, many journals make article available online when it is accepted and publish it at a later, scheduled time. Some journals require that you publish the preprint version of your article in a preprint archive, like *eLife*, and some journals have moved to full transparency – publishing the preprint, and then reviewing it in an open peer review process, like *F1000Research* and *Open Research Europe*. All versions of the manuscript (and reviewers' comments) are published and the final, accepted version is indexed in bibliographical databases. It is important that you get acquainted with the publication practices of the journal for your own manuscripts, as that will influence the time when your article will be publicly visible. It will also influence the time at which your article will be cited. For example, Clarivate, which produces one of the largest citation databases and calculated journal impact factors, uses online publishing date as the date to count citations to a published article.

All authors are fully responsible for the content of a publication, unless otherwise specified.

All authors agree on the sequence of authorship, acknowledging that authorship itself is based on a significant contribution to the design of the research, relevant data collection, or the analysis or interpretation of the results.

There are several different definitions of authorship, depending on the research field, ranging from usually a single author in some humanities to several thousand authors in high-energy particle physics. In life sciences and medicine, the definition from the International Committee of Medical Journal Editors (ICMJE) is most prevalent, defining an author as someone who:

1. Substantially contributes to the conception OR design of the work, OR the acquisition, analysis, OR interpretation of data for the work;
   AND
2. Drafts the work OR revises it critically for important intellectual content
   AND
3. Approves final version to be published
   AND
4. Agrees to be accountable for all aspects of the work in the publication, ensuring that all questions related to the accuracy and integrity of the whole work are investigated and resolved.

In other research fields, authorship may have a wider definition. For example, the American Psychological Association (APA), defines the authorship in this way:

> *An author is considered anyone involved with initial research design, data collection and analysis, manuscript drafting, or final approval.*

This means that any of the listed contributions are eligible for authorship, in contrast to the ICMJE definition, which requires all of those contributions for a deserved authorship. APA also defines which contributions are not eligible for authorship:

> *However, the following do not necessarily qualify for authorship: providing funding or resources, mentorship, or contributing research but not helping with the publication itself.*

You should carefully check the standards for authorship in your research field. Defining authorship on a publication is critical because of its academic, social and financial implications, and responsibility for the published work. Keep in mind that good research practice, according to the ICMJE; would be to offer researchers who had participated in research (the first criterion from the ICMJE definition) to contribute to manuscript writing, so that they can deserve authorship on the article.

Although there is no quantitative measure to evaluate authorship, journals often have a contributorship policy to make authorship evaluation less ambiguous. Contributorship policy means declaring individual contributions of co-authors in a published article, which increases transparency and may prevent misuse of authorship. Contribution declaration for published articles with a large number of authors may be challenging, and some journals have developed a visual contribution matrix, which can look like this one in Fig. 7.1.

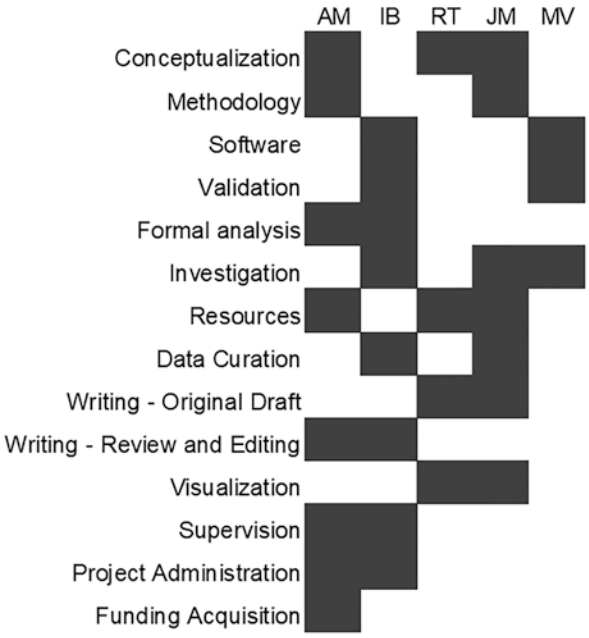

Fig. 7.1 Example of a visual authorship contribution matrix, using CRediT (Contributor Roles Taxonomy) author statement

Box 7.1 Authorship Misuse

Guest authorship means including researchers as authors on articles where they did not contribute. This is quite common in academia, where it is "expected" that the head of the department or similar senior researcher is always an author on the articles from the department.

Gift authorship happens when a researcher prominent in a research field is invited to be an author on an article, although the researcher did not make any contribution. This is done to increase the "importance" of the article and has been described for clinical trials funded by pharmaceutical companies.

Ghost authorship happens when an individual who participates in research or in manuscript writing but is not listed as an author. This is a practice common in large clinical trials, where professional writers are employed by a pharmaceutical company to write the article on a trial. They always have to acknowledged and their role made transparent.

You have to keep in mind that authorship is not only about who did what or who wrote what, but also about responsibility. You have to ensure that all authors agree that the manuscript is submitted to a journal, and that they are all aware that they are accountable for the research and the article. It has become a practice in some journals to send a notice to all authors of a submitted manuscript to confirm their authorship. This may prevent authorship misuse, such as guest, gift and ghost authorship (Box 7.1).

While official definitions of authorship are common, there are few requirements or rules about the order of authors on the byline. For example, the ICMJE Recommendations state that the order of the authors should be discussed and decided by the research team. Standards and practices about the order of authors differ in different research fields. For example, the first author on articles in biomedicine is usually the one that contributed most work (e.g., a doctoral student on a paper from the dissertation). The last author is the senior researcher – head of the research group, principal investigator on a grant, etc. In economics and high-energy physics, the order is usually alphabetical. Knowing these practices is imperative for you to successfully navigate authorship in your research and research collaborations.

In some research fields, where multidisciplinary and multigroup collaboration in common, there is increasing practice of joint first or last authorships, where it is indicated that two or more authors equally contributed to the research, either as first authors (important to early career researchers) or senior (last) authors (important for grant applications).

In large research collaborations, a group of researchers can be an author. The name of the group is stated in the list of authors. If the group has members, their names are usually indexed in bibliographical databases as collaborators or investigators, and not authors. It is important to be aware of such distinctions, because collaboratorship on an article may not be eligible for a doctoral dissertation paper, for example. Researchers in biomedicine should check how different types of authorship are indexed in MEDLINE.

Good research practice from the European Code of Conduct for Research Integrity:
All authors disclose any conflicts of interest and financial or other types of support for the research or for the publication of its results.

A conflict of interest can occur when an investigator's relationship to an organization affects, or gives the appearance of affecting his/her objectivity in the conduct of the research. Financial relationships are the easiest to identify, but other interests, such as personal relationships, academic competition and beliefs may also affect the primary interest of the research. Whilst conflict of interest by itself is not unethical, author's disclosure of interest keeps personal, financial and other relations transparent, and therefore keeps public trust in the scientific process. Good practice is to, when possible, to avoid agreements with study sponsors when they interfere with any aspect of authors work on the research or publication itself.

Some journals require submission of a disclosure form in which you have to identify financial and non-financial relationships and activities relevant to the research presented in the article. In some professions, like medicine, there are public registries of financial relationships. There are also initiatives for public registries for the disclosures of interest in research, such as the Convey Global Disclosure System, developed by the Association of American Medical Colleges.

Good research practice from the European Code of Conduct for Research Integrity:
Authors and publishers consider negative results to be as valid as positive findings for publication and dissemination.

Due to positive-publications-only climate, there is a higher chance for positive results to be published, especially in prestigious journals. Getting a negative result may be demotivating, after you have put in a lot of time and effort. However, the results of studies with a valid methodology should be published, to prevent waste in research. This is especially important in some fields of applicative research, like health, where evidence synthesis, usually in the form of systematic reviews and meta-analysis, provides guidance for practice. Publishing negative results

ensures, for example, that the benefits of an intervention are objectively assessed. Also, publishing negative results prevents unnecessary duplication of effort and waste in research. Some research funders use special publishing platform to promote publishing of all results from funded research. For example, check whether the funder of your research uses the Open Research Central platform for open dissemination of research results. Results can also be published in the open repositories such as the Open Science Framework (OSF), Zenodo and others, or in clinical trials registries.

Good research practice from the European Code of Conduct for Research Integrity:
Authors ensure that their work is made available to colleagues in a timely, open, transparent, and accurate manner, unless otherwise agreed, and are honest in their communication to the general public and in traditional and social media.

Today, research results are often available to the wider public through open access publications. Open access is a part of Open Science (see Chapter on Data Management), making knowledge available to all levels of society, both amateur or professional. Raw data used in the research should be made public, preferably at the same time as the publication, so that anyone can assess it, interpret it, and work with it. Problems and challenges in the research (or eventual reasons for not finishing research) should be communicated transparently, so they can be assessed by other researchers who will conduct similar research in the future.

Communicating Research to the Public

Oftentimes, media create interest in a research topic by overexaggerating study results, generating positive or negative expectations. However, misleading is also caused by scientists themselves or their institution press offices, who may write press-releases which may differ from the actual study findings by using oversimplified language and exaggerating research findings. It is important to bear in mind that people tend to use social media as their primary source of information and knowledge, using little to none critical thinking when acquiring that information, especially if they come from a scientific source.

It is an obligation for every researcher to communicate research finding clearly and unequivocally, to be available for any additional questions by the journalists who will present findings to the public, so that a clear, correct and understandable final information is presented to the public.

You should also be aware that results from a study can be published only once. You may be tempted to publish results of your study in an international journal, in English, and then in your local journal, in your native language (or the other way

around), without acknowledging the primary publication. This is not a good research practice because it creates the impression that you have published two studies instead of one. Such **duplicate publications**, may have a detrimental effect in some research fields, like health, because they distort evidence and may have consequences on practice. What is allowed is a **secondary publication**, which clearly indicates that it is a republication and/or translation of an already published article. Examples of legitimate secondary publications are official statements (like from an association, to be published in all journals published by the association), health practice guidelines (also published in several health journals), republication of important articles, and translation.

You may also be tempted to publish more articles from a single study than it is necessary. This is sometimes acceptable and appropriate: for example, the main results of a clinical trial are published first, and may be followed by articles addressing specific aspects of the study, such as subgroup or ancillary analysis. However, it is not a good practice to artificially increase the number of publications from one study by publishing "smallest publishable units" (the so-called **salami publications**). An example of this practice is publishing separate articles on variables measured in the same study sample, especially if it is not stated in the published article that the sample and study were the same and already published studies are cited. A responsible a practice is to publish all relevant measurements on the same sample in a single study. In that way, there will later be no confusion whether the results come from the same study participants, which is important for evidence synthesis in systematic review and metanalyses.

Preprints vs Peer-reviewed Articles

The quality control in science is peer review (see Chapter Reviewing, Evaluating and Editing), which ensures that the validity of the published articles has been checked by experts. However, peer review is time-consuming, several weeks or months. Even after the final version of the article is accepted by the journal, it takes some time to get to the article to its final form and then publish it. Some journals will publish accepted articles as "online ahead of print" so that they are available to the public as they the final, definitive version is being prepared.

In some fields, it is a custom to publish a paper on a preprint server so that the community can discuss and review it. In some fields, such articles can be later published in a journal, but not necessarily – they may remain in the preprint server and be cited as such. The peer-review journal to which article is submitted later on should be informed that the article has been published in a pre-print archive.

When an article originally published in a preprint server is submitted to a journal, the authors have the obligation to indicate that to the editor. They also have the obligation to go back to the preprint article once the final version of the article is published in a peer-reviewed journal, and update the information about the final publication.

If you want to cite a pre-print in your article, the citation should clearly state that the reference is a pre-print. If the article has been both published as a pre-print, and later on in a peer-reviewed journal, you should cite the journal article, as it is the definitive version of record for the research report.

Good research practice from the European Code of Conduct for Research Integrity:
Researchers adhere to the same criteria as those detailed above whether they publish in a subscription journal, an open access journal or in any other alternative publication form.

Traditional publishing means publishing in a subscription journal, in which access to an article is gained by subscribing to a journal or by buying an individual article. Open-access journals allow access to a publication without any barriers. Somebody has to pay the article publication charges, though – usually the authors or their institutions (the so-called golden open access), and in some cases a funder may support an open-access journal so that there are no charges to the authors (so-called diamond open access). Open access is seen as positive as it makes research readily accessible without restrictions, which is particularly important for publicly funded research. Many open-access peer-reviewed journals are indexed in a community-curated online directory, Directory of Open Access Journals.

However, be aware of predatory journals! These are journals that misuse the open-access publishing model and are not legitimate scientific journals (Box 7.2). Most of published researchers get mails, commending them for the published article and inviting them to make a submission to their journal. You have to carefully check such an invitation, firstly because journals rarely directly solicit articles from authors in such a way, and, secondly, you may be tricked into sending the article into a predatory journal. You will waste a good publication by publishing in an academically unimportant journal. We recommend that you use the tool ThinkCheckSubmit to identify trusted (i.e. peer reviewed, legitimate) journals and publishers.

Box 7.2 Characteristics and Giveaways of Predatory Journals (Pseudo-journals)
- Sole purpose is making profit and not presenting new knowledge
- Not following standard of peer-reviewed research publishing
- Send mass e-mails as calls for publishing in their journal
- Promise rapid publication
- No transparent data available about the journal/publisher
- No retraction policy
- Unprofessional email addresses, websites and communication
- False representation

Good research practice from the European Code of Conduct for Research Integrity:
Authors and publishers issue corrections or retract work if necessary, the processes for which are clear, the reasons are stated, and authors are given credit for issuing prompt corrections post publication.

Despite existing safeguards, mistakes in published articles can happen. Published articles may also be the stage in the research process where research misconduct can be identified. Mistakes can be noticed by authors, reviewers (during the review process) and by editors. Concerns about research misconduct can be raised by reviewers and editors before the publication and by readers after the publication of an article in a journal.

Mistakes and misconduct in published articles must be addressed. Mistakes are corrected by publishing a correction (often listed as an erratum or corrigendum in journal table of contents). If you become aware of the mistake in your published article, you should notify your co-authors and then you need to notify the journal and work with it to publish the correction. If your article is indexed in a bibliographical database, a notice of correction will appear in the bibliographical record, linking to the text of the correction. Sometimes a published article contains a major error that changes the conclusion of the article – meaning that the whole article needs to be changed. If the error is honest (and can be documented), the journal may decide to retract the article and republish the new, corrected version. If an article is no longer valid because of misconduct (falsification, fabrication, and plagiarism), the article must be retracted. Retractions (with or without republication) are also published as notices linked to the original article and are indexed and visible in bibliographical databases.

You should also be aware of the practice in many journals to check text similarity of submitted or accepted articles. Plagiarism (using data, words or ideas of others without proper acknowledgment) is not acceptable. Self-plagiarism (copying from yourself, i.e. using your own already published texts or data without proper acknowledgment is also discouraged.

If your research generates images (e.g., gels, micrographs) you should be aware that many journals will check the images in a submitted manuscript for image manipulation. What does this mean, in the age of common image use on social media? In a research article, it is not allowed to change the information present in the figure – this means that you cannot add, delete, change, move, obscure or enhance any feature of an image. It is also not allowed making composites of images without indicating that they are separate images (such as happens when gel lines are grouped in a single figure). What is allowed is to adjust brightness, contrast or color balance but without changing the information in the image and stating these changes in the figure legend.

To learn more about publication ethics and integrity; check the resources at the Committee of Publication ethics (COPE), and the latest STM recommendations on image alterations and duplications.

Good research practice from the European Code of Conduct for Research Integrity:
Authors acknowledge important work and intellectual contributions of others, including collaborators, assistants, and funders, who have influenced the reported research in appropriate form, and cite related work correctly.

There are three main reasons for referencing in a research article – to give credit to the author who has been cited, to give credibility to the text that the author has written, and to give insight and possibility to read the original material to the reader. There are different styles of references used, but all of them consist of accurate and complete data, which univocally leads back to only one source. By not referencing the original source, author claims the written text as own and as a part of the material the reader is currently reading. If data or information come from author's previous work, this has to be clearly indicated and referenced.

Authors, reviewers and journals can misuse referencing practice for their benefit; authors can cite themselves or their colleagues, therefore artificially raising number of citations on the article. Same practice has been seen by reviewers, who "suggest referencing a certain article in order to improve it", and by journals themselves, by referencing articles previously published by them.

Other important declarations must be also included in a published article. This includes funding support for research, which should always include the official name of the funder and the funding programme and the number of the specific grant(s). Keep in mind that some journals may require a declaration that the funder had no role in the design of the study, its execution, analyses, interpretation of data, or decision to submit the results. Such declaration serves to ensure that the funder did not influence the research in any way, and is particularly common for commercial pharmacological research.

Researchers or other individuals who do not fulfil authorship criteria should be acknowledged in the published article, in the Acknowledgment section at the end of the article). Be aware that some journals may require that you provide a written consent from these individuals (a signed letter, and e-mail) that they agree to be acknowledged in the article.

You will also be asked to provide other types of consent. For example, many journals ask not only for the documentation related to ethics approval and consent research for articles describing research involving human participants, but also consent for publishing potentially identifying data about individuals (photographs in clinical case reports, videos). Although you may think that by pasting a black stripe

over the eyes on photograph is a good de-identification technique, we know from research that this is not the case and that persons can still be identified. So, you have to obtain a signed consent from a research participant for publishing an identifying photo. Endoscopic, ultrasound and other un-identifying photographs can be used without consent.

Approvals from relevant ethics bodies should also be declared, including the official numbers of the document(s).

Another type of declaration includes the information about data availability, where you are expected to state whether and in what form the raw data may be available to other researchers. If the data cannot be shared, such as when they are confidential, this also has to be clearly indicated.

If You Want to Learn More

The Embassy of Good Science

Authorship criteria
Consent for publication – author
Consent for publication – participant
Conflict of interest
Salami publication
Duplicate and secondary publication

Published Articles

Allen L, O'Connell A, Kiermer V (2019) How can we ensure visibility and diversity in research contributions? How the Contributor Role Taxonomy (CRediT) is helping the shift from authorship to contributorship. Learn Publ 32:71–74. https://doi.org/10.1002/leap.1210

Glasziou P, Altman DG, Bossuyt P, Boutron I, Clarke M, Julious S, Michie S, Moher D, Wager E (2014) Reducing waste from incomplete or unusable reports of biomedical research. Lancet 383(9913):267–276. https://doi.org/10.1016/S0140-6736(13)62228-X

Huisman J, Smits J (2017) Duration and quality of the peer review process: the author's perspective. Scientometrics 113:633–650. https://doi.org/10.1007/s11192-017-2310-5

Marušić A, Bošnjak L, Jerončić A (2011) A systematic review of research on the meaning, ethics and practices of authorship across scholarly disciplines. PLoS One 6(9):e23477. https://doi.org/10.1371/journal.pone.0023477

Bošnjak L, Marušić A (2012) Prescribed practices of authorship: review of codes of ethics from professional bodies and journal guidelines across disciplines. Scientometrics 93:751–763. https://doi.org/10.1007/s11192-012-0773-y

Roguljić M, Buljan I, Veček N, Dragun R, Marušić M, Wager E, Marušić A (2022) Deidentification of facial photographs: a survey of editorial policies and practices. J Med Ethics 48(1):56–60. https://doi.org/10.1136/medethics-2019-105823

Guidance

American Psychological Association – Publication Practices & Responsible Research

Committee on Publication Ethics – Guidelines Intended to Advise Editors and Publishers on Expected Publication Ethics Practices

International Committee of Medical Journal – Defining the Role of Authors and Contributors

International Committee of Medical Journal – Disclosure of Financial and Non-Financial Relationships and Activities, and Conflicts of Interest

National Library of Medicine – Authorship in MEDLINE

National Library of Medicine – NIH Preprint Pilot

STM Working Group on Image Alteration and Duplication Detection – Recommendations for handling image integrity issues.

Reviewing, Evaluating and Editing

8

Ana Marušić

Abstract

As an early career researcher, you will probably not be extensively involved in reviewing journal articles or research proposals, or editing scientific journals. However, reviewing, evaluating and editing are important aspects of research. As an early career researcher, especially after getting a doctoral degree, you may be invited by a journal to serve as a peer reviewer, or may edit or work in a scientific peer review journal. It is important that you understand what to expect from a responsible review of your work – when you submit a manuscript to a journal or a grant proposal. In this chapter, we will look at different types of journal peer review. We will address the responsibilities of peer reviewers toward the authors and editor, including confidentiality, objectivity, and competing interests. We will focus on journal peer review, because this is something that you will certainly experience from the author's side, and possibly as a reviewer. The principles of professional and responsible peer review also apply to other types of peer review, such as for grants of academic/research advancement.

Keywords

Peer review · Scientific journals · Confidentiality · Objectivity · Competing interests

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A. Marušić (ed.), *A Guide to Responsible Research*, Collaborative Bioethics 1,
https://doi.org/10.1007/978-3-031-22412-6_8

What This Chapter Is About

As an early career researcher, you will probably not be extensively involved in reviewing journal articles or research proposals, or editing scientific journals. However, reviewing, evaluating and editing are important aspects of research. As an early career researcher, especially after getting a doctoral degree, you may be invited by a journal to serve as a peer reviewer, or may edit or work in a scientific peer review journal. It is important that you understand what to expect from a responsible review of your work – when you submit a manuscript to a journal or a grant proposal. In this chapter, we will look at different types of journal peer review. We will address the responsibilities of peer reviewers toward the authors and editor, including confidentiality, objectivity, and competing interests. We will focus on journal peer review, because this is something that you will certainly experience from the author's side, and possibly as a reviewer. The principles of professional and responsible peer review also apply to other types of peer review, such as for grants of academic/research advancement.

Case Scenario: Peer Review Misuse

This hypothetical scenario was adapted from a narrative concerning the links between research environments and research integrity. The original case scenario is developed by the Members of The Embassy of Good Science and is available at the Embassy of Good Science. The case below is published under Creative Commons Attribution-ShareAlike license, version 4.0 (CC BY-SA 4.0).

Professor Daniels is a well-known sociologist in the faculty of social sciences at a public university. Currently, the research group is working on an interdisciplinary project investigating innovative empirical methods that rely on the use of social media platforms for data collection. With her team of master and doctoral students, she plans to submit a paper on this topic. She receives an email from a new academic to review a manuscript academic journal. After reading the abstract of the manuscript, which seems to have significant overlaps with the research topics of their own manuscript draft, she accepts the journal's invitation to review. Due to the lack of time, Prof. Daniels asks her doctoral student to read the manuscript and develop the review. When the review is ready, Prof. Daniels sends it without reading it to the journal. The submitted review is very critical and recommends major revisions, including additional reference from Prof. Daniels.

Very soon, Prof. Daniels and her team submit their paper to a prestigious journal. The paper receives extremely positive reviews and is outright accepted and published online only 4 weeks after submission. A couple of weeks after the publication of the article by Prof. Daniels and her team, the editor of the journal receives a complaint from the corresponding author of the article where Prof. Daniels was a reviewer, claiming that Daniels' article contains one of the innovative methodological models developed by their group and described in their own article. It is also claimed that the table in Daniels' article presents the main features of their model from the other manuscript. The authors ask for an urgent investigation into the peer review process for Prof. Daniels' article, which they state was compromised. Two weeks have passed and the corresponding author of that article has still not received an adequate response from the editorial office. Because Prof. Daniels is the first author of the paper that contains the suspicious content, the corresponding author of the other article decides to send their complaint to the research integrity office at Prof. Daniels' institution.

Questions for You

1. What do you think about the practice that professors give doctoral students articles for review, which they received from journals?
2. What should have Prof. Daniels done when she received the manuscript for review, which significantly overlaps with her research?
3. What steps could have been taken to increase the transparency of this particular peer review process?
4. What do you think about the practice for a peer reviewer to use ideas that they have identified when reviewing the work of other researchers? If not, what are your reasons? If it is acceptable, what conditions must be met in order for a peer reviewer to employ these ideas in their own work?

What Is Peer Review?

Peer review is the evaluation of someone's work (manuscript submitted to a journal, research proposal submitted to a funding body, research/academic promotion assessment) by peers – experts with similar competencies (research, professional, academic).

Peer review is mostly viewed as an evaluation of a suitability of a submitted manuscript for publication in a journal. Although the first two scientific journals were started in 1665, the first formal peer review was introduced almost a century later, in 1731, when the Royal Society of Edinburgh introduced peer review by society members. Over time, peer review evolved into an assessment external to the

journal and became a standard practice only in the twentieth century. There is a famous story of Albert Einstein complaining to the editor of the Physics Review about reviewing his article and refusing to address the comments on an anonymous expert. The journal *Nature* introduced peer review only in 1967.

You are probably familiar with the most common types of peer review (Table 8.1), which have evolved in different research fields. If you come from biomedical and health research, you are used to the single blind peer review, in which you do not know the identity of the reviewer, who reviews a manuscript with the full information about authors. If you come from social sciences, you are probably used to the double-blind peer review, where neither you nor the reviewers of your manuscript are aware of each other's identity.

New types of peer review are being developed and tested in different journals (Table 8.1), with the aim to reduce the bias in making decisions on the quality and suitability of manuscripts for publication, promoting transparency and replication, and generally preventing waste in research. The future may bring more novel approaches to peer review and discussions in the scientific community.

Similar to scientific research, peer review also raises many ethical issues and problems, and these issues may sometimes be complex and serious. Unfortunately, there is no clear right or wrong way or easy decisions in such cases, so you have to get familiar with the complexity of and expectations from peer review.

Table 8.1 Types of journal peer review

Type	Description	Example
Single blind	Reviewers are aware of the identity of the authors. Authors do not know the identity of the reviewers.	Common in biomedicine and health
Double blind	Neither the reviewers not the authors know the identity of each other.	Common in social sciences and humanities
Triple blind	Authors, reviewers and editors are blinded to the identity of each other. It is argued that it reduces editorial bias in decision making.	The British Journal for the Philosophy of Science
Transferable	Transfer of peer review reports to a journal in the same subject area.	Common in large journals with several "sister" (specialized) journals
Consultative	Reviewers discuss a manuscript in a panel before providing a unified evaluation to the authors.	PNAS
Results-free	Reviewers evaluate the protocol of the study in the first stage (pre-registration) and, if approved, they evaluate the results in the next phase.	Journal of Experimental Political Science
Open	The identities of reviewers and authors are revealed to each other during the review process. There are differences in what information is available to the public.	BMJ
Postpublication	Part of a publishing model, where a manuscript is first published, and then it is reviewed in an open peer review process, fully visible online.	F1000Research

Check the interactive time-line of the evolution of peer review

Good research practice from the European Code of Conduct for Research Integrity:
Researchers take seriously their commitment to the research community by participating in refereeing, reviewing and evaluation.

If you are invited to review a manuscript for a journal, the invitation will come together with the abstract of the manuscript. Keep in mind these questions before you accept the invitation.

Do I Have the Expertise to Review the Manuscript?

Journal editors often ask experts from different research areas to review an article, in order to get a comprehensive opinion on research presented in the manuscript. You do not need to have a high level of expertise in the topic of the article, but you should have sufficient knowledge to be able to provide an objective and professional assessment. Sometimes it is difficult to make this judgement based on the abstract – the basic rule for you may be that the topic of the abstract is close to the general topic of your research (doctoral dissertation).

What Type of Peer Review Is Used by the Journal?

As an early career researcher, who has to build their own research career and is dependent on senior researchers, you may not be comfortable to take part in a fully open peer review process. You may feel more secure to provide critical comments about work of senior researchers if you participate in a blinded (i.e. masked) review, where your identity will not be disclosed to the authors. We know from research that authors are not good at identifying the reviewers of their journal manuscripts (although they often think they know who reviewed it). We also know that it is difficult to fully anonymise a manuscript so that the authors cannot be identified – this means that it is difficult to ensure double blind review, especially in very specific, small research fields. Some journals offer their peer reviewers to disclose their names to the reviewers, and this is fully optional. So, check what type of peer review is used by the journal and accept to review it if you feel comfortable with it.

Do I Have Time for the Review?

Be aware that peer review is a serious work and takes time. Studies and surveys of researchers show that the time for peer review varies, from 2 to 12 hours or more. Make an honest judgement about your workload and see whether you will have time

to do the review. The time will depend on the complexity of research presented in the manuscript, methodological approaches and statistical methods.

Can I Meet the Review Deadline?

Journals usually give 2 to 3 weeks to their reviewers to complete the review and submit it to the journal. Some journals publish so-called "fast-track" articles, where they expect reviewers to complete the review within 24 or 48 hours. Do not accept review tasks if you know that you cannot meet the deadline because of your other obligations (planned research experiments, deadlines for your thesis or manuscripts). If you accept to review the manuscript in good faith but then face a conflicting task or activity, contact the journal editor and ask for an extension of the deadline. Be honest and transparent.

Do I Have Competing Interests (Activities and Relations)?

We will discuss this issue in more detail later on in the chapter. Carefully assess whether you have activities and relationships that may affect your objectivity or increase your bias in reviewing someone else's work. Check carefully the journal's policy on competing interests. If you are not sure, do not be afraid to contact the editor and ask. Honesty and transparency is always the best way to address any dilemmas you may have.

When you agree to review a manuscript, you enter into a contract with the journal to become its consultant and to adhere to the journal's policies and guidelines for the review of manuscripts.

If you have questions or doubts about your ability to review the manuscript, contact the editor and discuss the issues that you identified. It is better to prevent the problem then to try to solve it when it emerges later on.

Good research practice from the European Code of Conduct for Research Integrity:
Researchers review and evaluate submissions for publication, funding, appointment, promotion or reward in a transparent and justifiable manner.

When you accept to review a manuscript, the journal will ask you to provide your personal and professional information in the online submission system. Be careful to provide and accurate and true representation of your expertise.

In the case scenario from the beginning of this chapter, a senior researcher asks a PhD student to review a manuscript and submits it under her own name. This is considered a serious misconduct, as it constitutes impersonation of another individual during the review process.

When you accept to review a manuscript and receive it, you first have to see whether you can perform the review professionally, transparently and responsibly. Maybe the abstract did not provide a full description of the study and you discover that the manuscript is actually outside your expertise. Or you may discover that you have a conflict of interest. You should contact the editor and resolve these issues.

When you have the manuscript in front of you and are ready to assess the manuscript, ask yourself the following questions. First ask yourself if the research described in the manuscript is clear to you – are the aims and methods clearly explained and presented? The next question is about the quality of the research presented – are the conclusions justified by the data and are the methods valid? You do not have to be a statistical expert to assess study design and methodological approaches. Finally, make a judgement about the importance and interest of the results – are they relevant for the journal in question?

This means that you have to read the manuscript carefully before considering the review, as well as journal's guidance to authors and to reviewers, so that you can get familiar with the journal's scope and what is expected from authors to submit to the journal (supplementary information, checklists, permissions, etc.).

Be also aware that peer review has its biases, which may introduce systematic judgement errors. Research has shown that both the editors and reviewers may have bias towards positive results – they get published more often than negative results. Peer review may also be prone against new ideas and results (this is confirmatory bias) and against novel methods.

After you carefully read the manuscript and decide that it is within the scope of your expertise, it is time to write a review report. The purpose of the peer review report is to help editors decide on whether to publish the manuscript, but also to help the authors to improve the presentation of their work. However, keep in mind that your role is advise the journal and not help the authors publish their article. It is not a responsible practice to let a flawed article be published - peer review is considered to be a scientific stamp of approval of the article and its contents.

The format of a peer review report may differ from journal to journal – from a free-text commentary to a checklist with tick-boxes. The following is a guidance to write a comprehensive review report:

1. It is good to start with a very brief outline of the paper, which will show your understanding of the paper.
2. Number your comments – this will make it easier for authors to address them in their response and adequately revise the manuscript.
3. Highlight not only the weaker points of the paper, but its strengths, too, so that you provide a balanced assessment.
4. For each criticism that you have, clearly explain the reasons for it, and also indicate how critical your comments are to the assessment of the manuscript. You can, for example, indicate major and minor points of your critique, or indicate which comments must be addressed and which are optional.
5. Responsible peer review means that you stay with your expertise and not provide comments on the aspect of the manuscript or research presented in it. For example, if you are not an expert in statistics, you do not have to comment on

statistical analysis (even if the journal asks for it). The responsible and transparent way is to state that you do not have sufficient expertise to cover that aspect of the review. In some journals, particularly in medical journals, special statistical reviewers assess the statistics in submitted manuscripts.

6. Check if the manuscript included important references and whether some important literature sources have been missed by the authors. List them in your review report – it will help the authors to improve the manuscript. Be careful about suggesting your own publications, as this may be perceived as self-promotion and a way to artificially increase the number of bibliographical citations to your work. Suggest your articles only if they are really relevant for the manuscript. You may also check whether all references are mentioned in the manuscript and that they are written correctly and consistently.
7. You are not expected to provide language editing of the manuscript. Your task is to assess the quality of research presented in the manuscript and not to improve its language and style. However, indicate when sentences are not clear so that research is unclear, or when the language and style of the manuscript require editing assistance.
8. Write clearly, in a neutral tone, but be decisive and give clear comments and suggestions. Do not write long reviews, be concise. Do not push your own opinions and hypotheses.
9. Do not use hostile or inflammatory language or make libellous or derogatory personal comments. Be aware that some journals have editorial policies to edit such language in review reports, or decline such reviews.

If you follow this guidance, you will grow into a high-quality reviewer (Box 8.1), who will never write poor review reports.

Box 8.1 Responsible Reviewer

- has expertise in the research field of the submitted manuscript.
- does not work in a competitor research group.
- is familiar with research methods presented in the manuscript.
- is able to assess the quality of data and methods.
- is able to assess the validity of the conclusions.
- is able to assess the significance of presented research.
- writes professional, constructive and polite review comments.

Good research practice from the European Code of Conduct for Research Integrity:
Reviewers or editors with a conflict of interest withdraw from involvement in decisions on publication, funding, appointment, promotion or reward.

One of the questions that you have to ask yourself when you get the invitation to review is whether you have any conflict of interest in relation to the authors and the research of the manuscript.

Just as authors are asked to disclose their competing interests, the reviewers also have to declare their own either real or apparent relationships and activities that may influence their judgement (see Chap. 7). Competing interests may stem from institutional or collaborative relationships, personal relationships (family, friends), or financial relationships (funds and moneys received personally or by your organisation). Intellectual passion and personal beliefs may create a conflict of interest.

In the case scenario from this chapter, the researcher did not disclose her conflict of interest stemming from the closeness and competitiveness of her own research in relation to the reviewed work.

If you are not sure about whether your relationships or activities constitute a conflict of interest, contact the journal so that they can provide guidance on how to handle a potential conflict of interest. If you have a clear conflict, recuse yourself from the review.

Good research practice from the European Code of Conduct for Research Integrity:
Reviewers maintain confidentiality unless there is prior approval for disclosure.

Traditionally, confidentiality was at the core of the peer review process. With the move towards open peer review, where the identities of authors and reviewers are revealed to them and/or to the public (Box 8.2), confidentiality may not always be vrequired. However, an early-career researcher may welcome blinded reviews because it may allow them to be more honest in their comments and feel more protected in expressing their professional opinion.

Box 8.2 Types of Open Peer Review

1. Reviewers' names are disclosed to authors together with review reports, but reviewers' names are not publicly disclosed (published with the varticle).
2. Reviewers' names and their reports are disclosed to authors during review; reports are published with the article, but without names.
3. Reviewers' names and their reports are disclosed to authors during review; names of the reviewers are published with the articles, but not their reports.
4. Reviewers' names and their reports are disclosed to authors during review; they are both published with the articles as a publication history.

You should carefully check the journal's policy and adhere to confidentiality requirements.

Generally, you should consider that the manuscript you are reviewing is privileged information, i.e. authors' confidential, private property. In some cases, for example when the results presented in the article have commercial potential, disclosure of such information may harm the authors intellectually and financially.

As a reviewer, you must not publicly discuss the work in the manuscript under review or reveal the identity of the authors.

Your review is also a confidential document, which should not be shared with other people. This means that you cannot seek help from other people with your review. You should keep it in a secure place on your computer. If you print a copy of the article, keep it locked – do not leave it around on your desk. When you complete and submit the review, delete the files or destroy the paper copy.

You should also not contact the author about the work in the manuscript under review.

In the case scenario from this chapter, the researcher who delegated the review to a doctoral student and submitted it in her own name has not behaved responsibly. This behaviour can be considered as a serious form of research misconduct. The proper conduct for a reviewer who is too busy to do the review is to decline it, or suggest another person (an early career researcher, for example) as a reviewer. This increases the transparency and gives proper credit to the person who actually reviewed the manuscript.

If you have any questions or dilemmas about confidentiality issues related to the manuscript you are reviewing, contact the editor and ask for guidance.

Good research practice from the European Code of Conduct for Research Integrity:
Reviewers and editors respect the rights of authors and applicants, and seek permission to make use of the ideas, data or interpretations presented.

Researchers value their role of peer reviewers because reviewing articles for journals gives them access to the latest developments in their field and may give them new ideas and approaches to their own research.

In the case scenario from this chapter, the reviewer and her research group used the new methodology for their own research and published it without reference to the manuscript they reviewed. Such conduct is unacceptable because reviewers should not use what they learned from their review for their own benefit before the reviewed work is published.

When can you use the knowledge you get from peer review? The answer is – only after the publication of the article. Then you can use it in your own research and cite it in your own articles.

What to Do If You Think There Are Integrity and/or Ethical Problems with the Manuscript?

As a reviewer, your primary task is to check the quality and relevance of research presented in the manuscript. However, you should comment on ethics or integrity issues.

Check whether the manuscript addressed ethics approvals for research with human participants or for research on animals.

You may be aware of competing interests that were undisclosed by the authors.

As a reviewer, you are best placed to suspect potential plagiarism or duplicate publication, problems with the integrity of data (falsification or fabrication), or problems with the integrity of analyses or conclusions. You can also suspect that the authors have failed on purpose to acknowledge evidence in the manuscript, which contradicts their results or views.

If you discover such integrity problems, contact the editor. Allegations of research misconduct are a serious issue and you should be able to provide relevant documentation to support your suspicion. Be aware that journal editors will follow established guidelines and protocols, which may include reporting the allegations to the authors' institution(s), which may undertake a formal research integrity investigation. In such cases, journals will wait for the results of institutional investigation before there is action in the journal, such as a correction or retraction of the published article. In some cases, journal editors will publish and expression of concern, informing readers about the problems with the published article. At the end of the investigation, the outcome will also be published and the published record updated.

If You Want to Learn More

The Embassy of Good Science

Online Module: Responsible Research and Peer Review
Peer Review in the Social Sciences and Humanities
Peer review card game
Peer Review. The nuts and bolts

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Guidance

Committee on Publication Ethics. Ethical guidelines for peer reviewers.

Committee on Publication Ethics. Flow charts.

Office of Research Integrity. Peer review resources.

Office of Research Integrity. Peer review.

Office of Research Integrity. Peer review quick guide. Dilemmas.

Office of Research Integrity. Peer review quick guide. Common mistakes.

Cooperation & Liaison between Universities & Editors (CLUE): recommendations on best practices.

Instructions for peer reviewers in major journals and publishers.

Other

Publications from the studies presented at the International Congress on Peer Review and Scientific Publication.

Publications from the studies presented at the PEERE International Conference on Peer Review.

How to Deal with Allegations of Misconduct

9

Ana Marušić and Rea Roje

Abstract

This book is about good and responsible research but you have to be also aware of research misconduct and other unacceptable research practices that may occur during the research process. This chapter offers a guide on what is considered research misconduct, and what other behaviours are considered unacceptable research practices. Moreover, the chapter provides guidance on what to do if you have witnessed research misconduct or if you have been accused of a breach of research integrity. Besides the procedures, the chapter outlines the responsibilities and rights of those involved in the investigation process.

Keywords

Research misconduct · Research fraud · Detrimental research practices · Misconduct allegation · Research integrity investigation · Whistleblower

What This Chapter Is About

This book is about good and responsible research but you have to be also aware of research misconduct and other unacceptable research practices that may occur during the research process. This chapter offers a guide on what is considered research misconduct, and what other behaviours are considered unacceptable research practices. Moreover, the chapter provides guidance on what to do if you have witnessed research misconduct or if you have been accused of a breach of research integrity.

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Besides the procedures, the chapter outlines the responsibilities and rights of those involved in the investigation process.

What Is Research Misconduct?

There is no uniform definition of research misconduct. Different European countries have different definitions of research misconduct, as well as different procedures for dealing with allegations of wrongdoing.

The European Code of Conduct for Research Integrity thus does not provide a definition, but indicates that there are three traditional and most serious forms of research misconduct: fabrication, falsification, and plagiarism, often called FFP (Box 9.1).

These serious forms of misconduct are rare. A metaanalysis of a survey where scientists were asked about their practices reported that 1–4% of researchers admit to falsifying and/or fabricating results. However, they report that 10–20% of their colleagues cheated in research.

Whereas research fraud is rare, just like criminal acts in other parts of life, there are many research practices that are rather common but are unacceptable (Table 9.1). Such practices are often called "questionable research practices" or "detrimental research practices" – they are small deviations from good research practice, but they are so common that they adversely impact the research process much more than serious research misconduct. Meta-analyses on the prevalence of self-reported detrimental research practices show that it is admitted by up to 34% of researchers.

It is important to keep in mind that these practices are considered to be research misconduct in some countries, at the same level as the FFP. Some countries and research organizations may have even more extensive lists of unacceptable research practices. Therefore, you have to be well informed about the policies about research integrity and research misconduct at yout organization and the country where you do research.

Box 9.1 Definitions of Serious Forms of Research Misconduct from the European Code of Conduct for Research Integrity

"**Fabrication** is making up results and recording them as if they were real."

"**Falsification** is manipulating research materials, equipment or processes or changing, omitting or suppressing data or results without justification."

"**Plagiarism** is using other people's work and ideas without giving proper credit to the original source, thus violating the rights of the original author(s) to their intellectual outputs."

Table 9.1 Violations of good research practice – unacceptable research practices according to the European Code of Conduct for Research Integrity

Practice	Description
Manipulating authorship	Not giving credit to all who deserved authorship (gift, guest, ghost authorship); denigrating the role of other researchers in publications.
Self-plagiarism	Reusing own text from published articles without acknowledgment.
Selective citations	Including references in published work that may not be necessary or that are selective.
Allowing undue influence	Allowing funders or sponsors to introduce bias by directing research or publication.
Unnecessary expansion of bibliography	Citing non-relevant publication or biased references.
Malicious accusation against other researchers	Accusing others of research misconduct without evidence or cause.
Misrepresenting research achievements	Presenting own research in a biased way to increase own research importance and value.
Exaggerating research results	Overinterpreting research results when presenting it to the scientific community or the public.
Hindering the work of other researchers	Delaying or adversely influencing the work of others.
Misusing research seniority	Using senior position to lead others into violations of research integrity.
Ignoring of covering up research misconduct	Ignoring or covering up research misconduct of other researchers or inappropriate responses to misconduct by individuals or institutions.
Publishing or supporting predatory journals	Promoting fake journals, whose only aim is to make money from open access publishing model.

What If You Think You Have Witnessed Research Misconduct?

If you think that you have witnessed or had been affected by a breach of research integrity, you have to proceed carefully. Any formal allegation would need to be supported by evidence, and the process will be long and often complicated. As a whistleblower, as well as an early career researcher, you may be in a perilous position, at the crossroads of power pressures at a research organization.

It is very important that you know well the policies and procedures at your organization. Some organizations have a research integrity advisor, who can help you with information and advice. If you decide to make a formal allegation, it will probably be taken up by a formal body with legal power to complete the investigation and make a conclusion or ruling.

What Happens If You Are Accused of Breaches of Research Integrity?

European Code of Conduct for Research Integrity defines two main principles of any formal investigation: integrity and fairness.

Integrity

Good research practice from the European Code of Conduct for Research Integrity:
Investigations are fair, comprehensive and conducted expediently, without compromising.

All investigations concerning research misconduct and other poor research behavior must be conducted in a fair, objective, and comprehensive manner concerning the rights of all parties involved. This can be assured by conducting investigations that follow relevant codes of conduct, guidelines, and specific procedures for investigations.

Good research practice from the European Code of Conduct for Research Integrity:
The parties involved in the procedure declare any conflict of interest that may arise during the investigation.

To preserve the integrity, fairness, accuracy, and objectivity of the investigation process, it is crucial that all parties involved in the investigation process, such as appointed members of committees or experts involved in conducting investigations, disclose any potential conflict of interest. The existence of a conflict of interest should be managed before the beginning of the investigation process. It can also emerge during the investigations and should be also adequately managed. Regardless of when the conflict of interest appears, it must be disclosed properly and transparently, so that potential risks could be mitigated and avoided.

Good research practice from the European Code of Conduct for Research Integrity:
Measures are taken to ensure that investigations are carried through to a conclusion.

The process of investigating research misconduct and other poor research practices should be concluded with a written report on the investigation's findings and the conclusion on what was discovered, i.e., whether allegations were founded and whether research misconduct and other malpractices were committed. Another important aspect is to take care of the timing. It is in accordance with the principle of fairness that all investigation procedures are conducted promptly, as well as

that conclusions are brought forward in a timely manner, as no one should be exposed to the investigation process longer than necessary. This is extremely important if we take into account that investigations can have an impact on a person's everyday work life and activities. The final conclusion should also include the statement on whether there is the possibility for appeal, possible sanctions if research misconduct was confirmed, and who should be notified about the investigation's outcomes.

Good research practice from the European Code of Conduct for Research Integrity:
Procedures are conducted confidentially in order to protect those involved in the investigation.

All investigations of research misconduct should be conducted following the principle of confidentiality as much as possible, in order to protect all parties involved in the process. Sometimes those included in conducting investigations will have to balance the principle of confidentiality and other principles (e.g., fairness) and safeguards. These are the situations when the confidentiality of investigations could be breached to protect some higher interests, for example, the health and safety of research participants. However, if it is necessary to make any such disclosure to the third parties, it should also be made as confidential as possible and appropriate procedures should be followed to ensure that only those who need to be protected by the disclosure are informed and no one else.

Good research practice from the European Code of Conduct for Research Integrity:
Institutions protect the rights of 'whistleblowers' during investigations and ensure that their career prospects are not endangered.

A person who witnessed research misconduct and reported it to the bodies that handle research misconduct cases should be assured that their rights and career prospects will be protected, as well as that measures and procedures will be put in place to ensure the fairness of the investigation. This is especially important for early-career researchers who may be exposed to power pressures and retaliation from those suspected and reported of misconduct. Moreover, by ensuring that those who decide to report the suspected misconduct will not be exposed to unfair procedures and treatment during and after investigations, research organizations encourage researchers, especially early career researchers, to be brave, to do the right thing, and to report the suspected misconduct. If the organization fails to ensure the protection of whistleblowers, a complaint can be raised with a higher authority, such

as a national research integrity body. Such higher authorities can impose sanctions on the organizations, and ensure that whistleblowers' rights are protected.

There are also situations when research misconduct or other unacceptable behaviour did not happen but the allegations were made in bad faith. That is why it is very important that responsible authority takes seriously every allegation and conducts a proper investigation. "Whistlebolwers" who made allegations in bad faith, i.e. intentionally and consciously made false allegations, should be sanctioned.

Good research practice from the European Code of Conduct for Research Integrity:
General procedures for dealing with violations of good research practice are publicly available and accessible to ensure their transparency and uniformity.

Information and documents, such as standard operating procedures, that describe how the investigations are conducted and what bodies are involved in this process, are usually publicly available, so that everyone can get familiar with the process of investigating research integrity allegations. Moreover, this ensures that in all cases, investigations are conducted in the same manner, following the same steps – this ensures the uniformity of the process and contributes to the principle of fairness. Of course, to ensure fairness and uniformity, research organizations must have procedures that are comprehensive and detailed. If you witnessed research misconduct and you want to report it, you should be able to find guidance about investigation procedures in official documents, on organizations' websites or websites and documents of specialized bodies that handle research misconduct allegations. This can help you to familiarize yourself with the process, learn about your rights and responsibilities of involved parties, and find out how to report research misconduct and what it involves. Moreover, it is often possible to have an informative consultation, a non-obligatory talk with the ombudsman, a trusted advisor, or another person in charge of research integrity issues in the organization, who can help you answer the questions you may have about the allegation and investigation processes, help you clear any doubts and concerns, and provide you with advice concerning investigations. Although general procedures for dealing with violations are publicly available, whether the actual cases and decisions, anonymized or not, are made publicly available differs between countries, legislative systems, and institutions. Most often, institutions follow one of the two approaches. The first approach is that investigations are confidential and decisions are not made publicly available, and the second approach is that investigations are confidential but decisions are made publicly available. This is something that is already defined in the institutional and other documents dealing with research misconduct investigations, that are publicly available.

Fairness

Good research practice from the European Code of Conduct for Research Integrity:
Investigations are carried out with due process and in fairness to all parties.

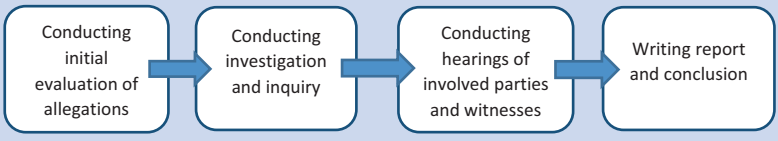
Investigations of research misconduct and other unacceptable practices should be conducted following the principle of fairness, as well as organizational and national policies and laws.

Bodies in charge of handling investigations should ensure that in their work they adhere to the applicable laws and policies, as well as standard operating procedures and guidelines related to the administrative tasks. Organizations should ensure that these policies and legal documents are publicly available, and that all researchers and staff are familiar with every aspect of the investigation process. Moreover, bodies in charge of investigations should ensure that all parties involved in the investigations are informed about their rights and obligations, as well as with all facts and evidence concerning the specific case that is being investigated. The example of how investigation process may look like is provided in the Box 9.2.

Good research practice from the European Code of Conduct for Research Integrity:
Persons accused of research misconduct are given full details of the allegation(s) and allowed a fair process for responding to allegations and presenting evidence.

Organizations and bodies in charge of handling investigations should ensure that the rights of those accused of misconduct are protected and that the principles of fairness and integrity are followed in relation to all involved in the investigation. As in other areas of law, the presumption of innocence should be adhered to. This means that person accused of research misconduct or other unacceptable behaviour should not be considered guilty until proven by the investigation and

Box 9.2 Procedure for Investigating Allegations of Research Misconduct and Other Poor Research Practices



defined in the final decision of the body that handles the case. Institutions and bodies in charge of handling investigations and research integrity issues should ensure that researchers accused of misconduct are not penalized or exposed to any unfair treatment in the organization until their guilt in conducting research misconduct is proven. Moreover, researchers accused of misconduct or other poor research behaviour, as parties in investigations, have rights that should be respected. This includes the right to be notified on time about all details of allegations in writing and about the right to respond to accusations. Moreover, those accused of misconduct should be given enough time to consider the allegations, seek advice, ask questions, and recommended evidence and witnesses in their defence. Researchers accused of misconduct can also, before providing their response to allegations, consult with the institutional ombudsman or other bodies dealing with research integrity issues to discuss their options regarding the investigations and learn more about the process.

Good research practice from the European Code of Conduct for Research Integrity:
Action is taken against persons for whom an allegation of misconduct is upheld, which is proportionate to the severity of the violation.

As we mentioned previously, not all forms of research malpractice are equally serious. Although both research misconduct and other unacceptable practices may have detrimental consequences for research, there is a difference between serious and less serious forms of poor research behaviour. Similarly, the consequences for proven poor research behaviour can also be more or less serious, but in each case, consequences and sanctions must be proportionate to the severity of the violation. Although some forms of poor research behaviour and following sanctions can be defined in advance in institutional policies and laws, those in charge of conducting investigations must make decisions about sanctions on a case-by-case basis. This ensures that investigations are conducted thoroughly, as well as that the principle of fairness is respected. Besides the sanctions imposed by research organizations, funders and scientific journals and publishers may also impose sanctions from their sides. Funders and publishers/journals are important stakeholders in the research process, and play an important role not only in promoting good research practices but also in discovering and sanctioning poor research behaviour. Research funders may impose sanctions such as the withdrawal of funding or obligation to pay back project funds, while publishers and journals may retract research articles in which misconduct was proven or correcting research articles in which honest errors were detected. However, to be a functional system in which misconduct will be discovered and properly sanctioned, all stakeholders (research organizations, funding

agencies, and journals/publishers) must communicate and work together on research misconduct investigations.

Good research practice from the European Code of Conduct for Research Integrity:
Appropriate restorative action is taken when researchers are exonerated of an allegation of misconduct.

It is important to exonerate researchers who are proven not to commit research misconduct or other poor research behavior. If the researcher is exonerated of an allegation of misconduct, appropriate restorative actions must be taken by research institutions, but also other stakeholders such as funding agencies and journals/publishers. In these cases, they must ensure that researcher is cleared of blame and restorative actions that they may implement could include re-employment, public apology, republishing a retracted article, providing funds for continuing research projects, etc.

Good research practice from the European Code of Conduct for Research Integrity:
Anyone accused of research misconduct is presumed innocent until proven otherwise.

As mentioned previously, the allegations of research misconduct can be made in bad faith and they can be untrue. They can also be made in good faith but also be proven to be untrue due to an honest error or another mistake. That is why the presumption of innocence is so important. No one should suffer any consequences for any allegation until it is proven upon investigating that the allegations were true. While the investigation is ongoing, researchers working in the institutions where allegations were made can also contribute to upholding the presumption of innocence and fostering the principles of fairness and no detriment. For example, researchers should refrain from excommunicating those against who allegations were made from the community, and should refrain from any types of retaliation.

If You Want to Learn More

The Embassy of Good Science

Misconduct & Misbehaviors
Institutional dealing with scientific misconduct

Misconduct and fraud in clinical research
Whistleblower protection/rights
Facts and Figures: How do different countries support good science?

Published Articles

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Guidance

European Network of Research Integrity Offices. Recommendations for the Investigation of Research Misconduct.

European Network of Research Integrity Offices. Codes and guidelines from ENRIO members.

Other

Office for Research Integrity (ORI) interactive videos:
The Lab
The Research Clinic

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