Safeguards

4

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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