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UNIVERSITY OF COPENHAGEN
DEPARTMENT OF FOOD AND RESOURCE ECONOMICS

RCR – A Danish textbook for courses in Responsible Conduct of Research

Fourth Edition

Karsten Klint Jensen, Martin Marchman Andersen,
Louise Whiteley and Peter Sandøe (eds.)

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in Responsible Conduct of Research

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About this book

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1. Introduction

The Danish Code of Conduct for Research Integrity, issued in 2014, recommends that all researchers receive teaching and training in the responsible conduct of research (RCR). Since 2011 it has in fact been mandatory for all new PhD students at the University of Copenhagen to take a course in RCR. PhD students in the Faculty of Science and the Faculty of Health and Medical Sciences have attended courses with the same content and roughly the same structure. For the first few years, course participants were given a compendium of texts to read. This involved inevitable overlaps and a lack of terminological consistency. In addition, many of the texts originated in the US, where the regulatory framework on RCR differs from that found in Denmark. A number of the people involved in teaching the two courses have therefore joined forces to produce a more complete, consistent and concise text. This book, which now is in its fourth edition, is the result.

The aims of this book are to present the RCR course content in an accessible form; to set out and encourage the use of clear and consistent terminology; and to describe the way RCR is dealt with in Denmark and at the University of Copenhagen. The intended readers are from two faculties where the great majority of research projects fall under the umbrella of the natural sciences, broadly construed. The book therefore deals with 'research' as it is typically understood and practiced in the natural sciences. Researchers from the social sciences and humanities may not always feel comfortable with the way we describe research, but we hope that the book will enrich the reflections of students from all disciplines – many of the issues are shared across disciplines, and in any case identifying interdisciplinary differences can be illuminating. We also hope that PhD supervisors and other researchers will find the book useful as a common meeting point for discussion between students and their supervisors.

So we had a course that needed a textbook, but why have the course in the first place? In other words, what do we hope to achieve by teaching the subjects presented here? This is the first question we will address in this brief introductory chapter. We will then consider the scope of the textbook, and finally we will say a little about the book's structure and use.

2. Why RCR teaching?

The University of Copenhagen was the first university in Denmark to introduce RCR courses for all PhD students. The immediate cause of this was a scandal in 2010 involving Professor of Biomedicine Milena Penkowa and centred on alleged research misconduct dating back about 10 years. It led to criticisms and complaints alleging that senior management at the University and in the Faculty of Health and Medical Sciences had not responded in a timely and adequate manner to a number of warnings over the years (read more about this case in Chapter 3).

Following the scandal, a number of initiatives were taken, first at the University of Copenhagen and later nationally, to prevent research misconduct and promote RCR. The first of these initiatives was to require courses in RCR for future researchers, i.e. PhD students. Due to national guidelines, the requirements for RCR teaching have later been expanded to cover PhD supervisors and students at BA and Master's level.

This raises the questions: Are mandatory courses in RCR effective in combating research misconduct? Will they prevent cases like that of Milena Penkowa in the future? The short answer is "no". Cases of serious research misconduct seem to have occurred at regular intervals historically and are often closely linked to the personalities and specific circumstances of the researchers involved. There is every reason to think that such cases will continue to occur.

What then is the point of the course? First, it may provide knowledge and tools to deal in a more timely way with cases of serious misconduct when they occur. Although mandatory courses in RCR would have been unlikely to prevent the Penkowa case, they might have enabled university management and concerned fellow scientists to effectively investigate and deal with the case at a much earlier stage. Secondly, it is important to underline that although a case of serious research misconduct was the immediate reason

for establishing the course, RCR also focuses on wider and much more common issues in the grey zone between research misconduct and acceptable scientific practice – in other words, on everyday issues that all researchers face.

For instance, authorship issues are very important in RCR, but only in serious cases would they lead to cases of research misconduct. Questions about authorship include: Who should be co-authors of a publication? How should the order of the authors be decided? Who should be the corresponding author? In what ways should co-authors be consulted before the final version of a paper is submitted for publication? What kind of information and/or documentation about the relative contributions of the respective authors should be provided? It is important for all PhD students to be clear about the answers to these questions, particularly those whose theses are composed of journal articles. If authorship issues are not managed well, they could lead to authorship disputes, delays in publication or detraction from scientific quality. However, most issues of these kinds amount to questionable research practices (QRP, see Chapter 2) rather than serious research misconduct.

It is our hope that the course's teaching sessions, together with this textbook, will help young scientists to maintain high standards of research integrity in their early career; that they will become better at dealing with authorship issues as well as other key areas where questionable research practices can arise, such as data management, intellectual property rights, conflicts of interest, and communication with the wider society. It should also be noticed that Danish researchers are not alone in having to learn about RCR. Researchers in countries such as the US have for some years had to pass exams in RCR to hold federal grants and to be appointed to faculty positions. Moreover, an understanding of RCR principles, reflection, and regulation are increasingly required as a precondition of international research collaboration.

3. The scope and limits of the book

In some cases, there are clear principles of responsible conduct that students should know: for example, that you must obtain the explicit consent of all co-authors before submitting a paper. But in many instances we cannot give clearly defined answers as to the right way to behave. This is not because we are uninformed or vague; rather it is because there are grey zones where rules and established norms do not give clear answers. For example, as will become clear in Chapter 4, there is no precise, objective and universally applicable rule setting out what contribution one must have made to qualify as a co-author. Minimum requirements are set out, e.g. in the University of Copenhagen's Code for Authorship, that relies on both national and international guidelines. Here it is stated that to qualify as co-author you must make a significant (substantive) contribution to the content, but what it means for a contribution to be "significant" or "substantive" is itself difficult to define and differs across disciplines, institutions, and research groups.

Where clear rules and guidelines cannot be given, we instead aim to enable the reader to become better at reasoning about the issues; to find her or his own stance. This is a critical part of learning to be a scientist, but it is often conducted ad hoc, in private, and alone. We hope to promote a growing climate of openness about what it is to be a responsible researcher, and about the boundary between acceptable shortcuts and irresponsible conduct.

The demands of RCR are not static – quite the contrary. What is considered good practice is constantly shifting. Take, for example, data management. Until recently there were no rules about how researchers at the University of Copenhagen should keep and share research data. Now GDPR regulates the processing of personal data relating to individuals in EU Member States. Various faculties are developing detailed rules and policies, and international norms regarding data sharing are developing rapidly. Another aim of the course and this textbook is therefore to inform researchers about recent developments, whilst also encouraging them to keep themselves up to date.

It should be noted that some subjects that are typically covered by RCR courses in other countries are not covered here. In particular, ethical issues raised by the use of human

subjects and animals in research are not part of the RCR courses in Denmark.

4. The content and structure of the book

Following this introductory chapter, two chapters provide a general framework for understanding RCR, and how it has developed and been institutionalized.

Chapter 2 explains how interest in RCR has developed since the 1980s, starting in the US and then spreading across the world. Key terminology in RCR is then set out and defined. Most importantly, we explain the distinction between *research misconduct* and *questionable research practice*. The former is fraudulent research behaviour involving *falsification*, *fabrication* and *plagiarism*. The latter covers the many 'grey zone' issues that are ubiquitous in scientific life.

In Chapter 3 we describe how the regulation of RCR has developed in Denmark and specifically at the University of Copenhagen. We explain how a series of dramatic cases of research misconduct led to the development of new institutions and codes, including the Danish Committee on Research Misconduct, the Practice Committee at the University of Copenhagen, the Named Person, and the Danish Code of Conduct for Research Integrity. We conclude the chapter with an overview of how to handle issues in responsible research conduct.

The remaining five chapters cover a number of specific issues that we consider likely to be of relevance to young researchers. Thus, in Chapter 4 we look at issues regarding publication and authorship which are often a young researcher's first explicit encounter with questions of research integrity. In Chapter 5 we deal with another dimension of RCR that most readers will need to understand: data management. In what way, and for how long, should we store research materials and data, and when and how should we share them with other researchers? Chapter 6 examines an issue that is a mandatory part of the course but will be relevant only to some readers, namely patenting and other methods of commercialization of research results.

In Chapter 7 we discuss conflicts of interest. As researchers we should attempt to be objective and value-free, ignoring personal factors in our scientific conduct. But sometimes our interests in other matters, such as our financial interests, seem to conflict with responsible conduct of research and when they do there is a conflict of interest. However, some conflicts of interest are unavoidable and some are even harmless. But some conflicts of interest, particularly those regarding financial interests, are a serious threat to responsible conduct of research and should therefore be taken very seriously.

In the final chapter we look at communication between science and the wider society, discussing why, when, and how public science communication work should be undertaken. This subject may seem a little remote for some PhD students, and it is true that it is primarily the responsibility of the institution rather than the individual researchers. However, even PhD students who decide not to get involved in public communication are required to write a popular article based on their thesis which may be quoted by media sources.

Each chapter starts with a summary. Information about rules, institutions and cases appear in text boxes, and links to useful documents and further reading are provided. Finally, at the end of each chapter there are "test yourself questions", which in some cases remind you of the key points and in others encourage you to consider complexities which may not have a simple answer.

Finally, we add an appendix of key guidelines, policies, and legislation (9), a short introduction to GDPR (10), and a list of what to remember and consider when you submit your PhD thesis and papers to scientific journals (11).

The subjects covered by this book are developing all the time. We therefore foresee regular updates to the present text, and we hope that our readers will offer feedback that can be used to improve future versions. Comments can be sent to Karsten Klint Jensen at kkj@ifro.ku.dk, Martin Marchman Andersen at mma@ifro.ku.dk, Louise Whiteley at lowh@sund.ku.dk and to Peter Sandøe at pes@sund.ku.dk.

2.
General introduction to responsible conduct of research

Karsten Klint Jensen and Mickey Gjerris*

* This text grew out of a draft by Hanne Andersen ("Responsible Conduct of Research: Why and How?", *RePoSS: Research Publications on Science Studies*, 29, Aarhus: Centre for Science Studies, Aarhus University (2014)). The authors are grateful to Hanne Andersen for permitting her text to serve as source for the present version with the minor overlaps this might involve. Thanks are also due to Peter Sandøe, Louise Emma Whiteley and Mathias Willumsen for valuable comments. Finally, thanks are due to Teresa D´Altri from the Office of Science and Innovation at The University of Copenhagen for contributing with the section and case box on Image Integrity.

Summary

This chapter describes how the field of research misconduct management developed, first in the US and later elsewhere in the world, driven by a number of spectacular cases. It goes on to ask why researchers engage in misconduct, and this leads to a short discussion of the modern institution of science. The competitive nature of contemporary science incentivizes not only serious misconduct, but also much more widespread questionable research practices. The chapter concludes by describing recent initiatives to promote research integrity, internationally as well as in Denmark

1. Introduction

In Denmark, research integrity has been summarized under the headline features of honesty, transparency and accountability (see the Danish Code of Conduct for Research Integrity (Ministry of Higher Education and Science, 2014), and see more in Section 5 below).

Research misconduct may have serious consequences for patients or consumers, who may experience harmful effects from a treatment or a marketed product which is made available on the basis of false and misleading information in the name of science. Alternatively, as happened in the Wakefield case (see Box 1) individuals may suffer as a result of *not* using a product, after being exposed to fraudulent claims about negative effects, again made in the name of science. In the bigger picture, the worry is that science as an institution may lose credibility, and as a consequence diminish in importance, leaving society vulnerable to more irrational decision-making.

Following several spectacular cases of research misconduct, there has been a gradually increasing focus on promoting *responsible conduct of research* (RCR). This development started in the US, but has now spread across the world. Most countries have set up regulatory mechanisms for institutions to deal with cases of *research misconduct*, a category generally defined internationally by the three notions of *fabrication, falsification, and plagiarism* (FFP, see more below). Within the scientific community the importance of promoting responsible conduct of research has also been increasingly acknowledged, with the goal of discouraging less serious but far more widespread questionable research practices, which may not amount to serious misconduct but nevertheless threaten the integrity of science. Thus a number of international and national codes for *research integrity* have been formulated.

RCR and its failure, i.e. research misconduct and questionable research practices, have become notions which no researcher

BOX 1: WAKEFIELD AND THE VACCINATION SCARE

In 1998, the British medical doctor Andrew Wakefield together with 12 co-authors published a study in the journal *The Lanc*et of 12 children with diagnoses of developmental disorders including autism or autistic spectrum disorder, in which they suggested a possible link between the triple MMR (measles, mumps, rubella) inoculation and what they identified as developmental regression and bowel disease. Before the paper was published Wakefield called for the suspension of the MMR vaccination programme at a press conference. This fuelled an MMR vaccination scare, which was followed by a decline in vaccination rates in the US, the UK and Ireland. The paper, and Wakefield's later warnings, also seemed to produce more general mistrust of childhood vaccination. However, other studies failed to reproduce Wakefield's findings. In 2007 a hearing began to examine charges of misconduct against Wakefield and two of his co-authors, and in 2010 the 1998 paper was declared dishonest because it involved deliberate falsification of data. This led to a retraction of the paper by *The Lancet*. Although he claimed to be innocent, Wakefield was then barred from practicing in the UK. However, he continued to do research in the US, and to this day he defends his claims and continues to warn against the MMR vaccine. It is believed that the vaccination scare is responsible for serious illness and deaths in thousands of children.

Main sources: Godlee et al. (2010), Editors of The Lancet (2010).

can afford to ignore. Thus, in the wake of the Penkowa case, the University of Copenhagen found it necessary to focus more energetically on how to deal with deviations from RCR. Among other things, it set up mandatory courses for PhD students and senior researchers. A similar tightening up has occurred in universities all over the world, and many journals are now enforcing stricter requirements which their authors must meet.

BOX 2: THE SOMAN CASE

In 1978, Helena Wachslicht-Rodbart submitted a manuscript to *New England Journal of Medicine*. One reviewer, Professor Philip Felig of Yale, passed on the paper to his junior, Vijay Soman, and they recommended rejection. However, two other reviewers recommended acceptance subject to revision. During her work on the revision Wachslicht-Rodbart was asked by *The American Journal of Medicine* to review a paper written by Soman and Felig. The paper looked very similar to her own. Some paragraphs and an equation were identical, and it appeared that the authors had been the very people to recommend rejection of her own paper. Wachslicht-Rodbart complained about plagiarism to *New England Journal of Medicine*, and she also expressed doubts to Yale about whether Soman and Felig had conducted a study at all. However, no investigations were initiated. On the contrary, all parties seemed to prefer a quiet cover-up; even Wachslicht-Rodbart's superior, who happened to be an old friend of Felig's, tried to silence her and threatened to dismiss her. The Soman-Felig paper was published, but new problems with the paper appeared, and finally an investigator was appointed. Soman then admitted to having fabricated the data and agreed to resign. Further investigations uncovered fraud in 12 other papers by Soman, on most of which Felig was a co-author. Felig was fired from a prestigious new position at Columbia, but returned later to Yale. Wachslicht-Rodbart decided to leave research.
Main source: Hunt (1981).

The need for open discussion and teaching in RCR is underpinned by the fact that in many cases it is not clear where the line should be drawn. Between the clear-cut cases of responsible conduct, on the one side, and research misconduct, on the other, there is a grey zone within which *questionable research practices* remain a problem, and this zone has vague boundaries. It is therefore necessary for researchers to understand the concepts which lie on either side of, and delineate, this grey zone, and to reflect on the implications for their personal practice.

The remainder of this chapter introduces the key concepts for RCR. It defines and describes the concepts of *research misconduct* and *questionable research practice* through a series of illustrative cases, and explains the concepts of *responsible conduct of research* and *research integrity*, and places them all in context.

2. What is research misconduct?

The Soman case (Box 2) illustrates several aspects of research misconduct. For one thing, there appears to be a great unwillingness to accept that a scientist has intentionally engaged in fraud. The prestige attached to certain persons or their positions, and efforts that have been made to promote certain researchers or results, typically add to this difficulty. In addition, the case demonstrates that research misconduct concerns not only the individual researchers involved, but also the institutions at which they work, and the journals in which they publish. There might be a temptation to conceal a case of research misconduct, to make light of its importance, or even to shoot the whistleblower, in order to shield the university or journal from negative publicity. However, this is a gamble, as once a cover up is revealed the university or journal is likely to lose even more credibility.

Universities were traditionally viewed as self-regulating academic communities, and until the 1980s it was more or less left to universities themselves to deal with cases of research misconduct and questionable research practice. No universities had formal systems for doing this. Even in a very serious case, like the Soman incident described in Box 2, it was often a long while before the university involved reacted by setting up *ad*

hoc investigations; and whistleblowers were often put under pressure to dismiss their case or even threatened with sanctions – in the Soman case the whistleblower was a young scientist without a permanent position.

During the 1970s and 1980s, several spectacular cases of misconduct in the US painted a picture of widespread incidents similar to the Soman case. The perception was that in many cases institutions were closing their eyes in the face of fraud to protect old friends and discredit whistleblowers. Where investigations were initiated, they appeared to be dragged out over very long periods and not to reach clear verdicts; and in many cases perpetrators were able to continue in their questionable practices at other institutions. The cases appeared to show the public that the scientific community was unable to deal effectively and convincingly with research misconduct itself.

In 1981 the first of a series of congressional hearings threw light on the problems and put more pressure on institutions to set up systems to deal with research misconduct, and to teach staff and students norms of responsible conduct of research. In the late 1980s, despite protests from the scientific community, the US was the first country to implement regulations that required universities receiving public funding to establish clear policies and procedures for handling misconduct.

Hence, a system developed in the US in which the main universities and other leading research institutions set up rules for RCR and appointed people to deal with offences. At the same time, large public funding agencies like the National Institute of Health and the National Science Foundation set up offices, including the Office of Research Integrity, to monitor and coordinate action. During this period the leading journals in medicine and science also gradually developed codes of conduct for responsible authorship practices and started to retract papers based on documented research misconduct (see the Wakefield case described in Box 1).

Thus, the first definition of misconduct was developed in US regulation. The current definition is known as the FFP definition, because it focuses on **F**abrication, **F**alsification and **P**lagiarism (see Box 3).

BOX 3: US OFFICE OF RESEARCH INTEGRITY DEFINITION OF RESEARCH MISCONDUCT

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) *Fabrication* is making up data or results and recording or reporting them.

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

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

Research misconduct does not include honest error or differences of opinion.

(Source: Office of Research Integrity, n.d.)

Of course, the US was not the only country to encounter problems with research misconduct which called for regulation. Similar developments have occurred in many other countries and have spread from the medical and natural sciences to social sciences and the humanities.

The Hwang Woo-Suk case (Box 4) emphasizes the international character of much research and demonstrates that misconduct may have consequences all over the world. It also shows, like the Wakefield case, how hype about expected results can create strong expectations among not only patients and other potential beneficiaries, but also among funders. Strong expectations can create incentives to cheat in order to meet those expectations. And experience of success and hero status can sometimes seem to impair scientists' ability to maintain a critical perspective on the integrity of their practice.

The Stapel case (Box 5) is an example from the social sciences. It shows the importance of openness in the handling of data and in particular allowing others access to raw data. Once again in this case, a senior researcher's success and status were instrumental in silencing critical questions for a very long time. Maybe there is an indication here that the fear of losing one's status may be an even stronger temptation to cheat than the original gain of advantage without costs. The case also illustrates the importance of an environment in which procedures are transparent and there is ample space for questions and critique.

The Annette Schavan case (Box 6) is an example from the humanities. It is a case with many ironies. A person who writes about the way conscience is formed, and its necessity in education, does not appear to have been troubled by her own conscience when it came to plagiarizing the work of others. Also, as a government minister Schavan was responsible for

BOX 4: THE HWANG WOO-SUK CASE

Hwang Woo-Suk is a South Korean researcher who became known as the King of Cloning. He appeared to be the answer to the South Korean hope of achieving industrial progress though biotechnology in spite of limited investment and a rather narrow scientific base. Following his claim to have cloned some cows (without providing verifiable data), media hype about the great promise of his research developed. He became a central figure in South Korean science governance and attracted a lot of Government funding. After Hwang's team claimed to have obtained stem cells from one out of thirty human embryos (published in *Science* 2004), and later, that it had established 11 embryonic stem-cell lines derived from the skin cells of individual patients (published in *Science* 2005), Hwang became the pride of South Korea. When the Bioethics and Biosafety Act came into force on 1 January 2005 it contained a clause that effectively exempted Hwang from the regulation.

Ironically, Hwang was charged with unethical conduct for having used eggs from paid donors and a junior member of his team. He admitted this and resigned, but he intended to continue his research. Then the Seoul National University opened an investigation into his research which concluded that both Science papers were based on fraudulent data. Science retracted the two papers, and Hwang was later sentenced to two years in prison (suspended) for embezzlement and bioethical violations. Apparently, he is still active as a researcher. Main source: Gottweis & Triendl (2006).

BOX 5: THE DIEDERIK STAPEL CASE

Diederik Stapel is a former Dutch Professor in social psychology. At the height of his career he was famous for several outstanding publications on human behaviour and considered a star member of faculty at Tilberg University. However, in 2011 three young researchers started to develop doubts about his activities, and eventually a committee was set up to investigate his work at three universities in The Netherlands. He was suspended in 2011.

A final report (Tilburg Univerity, 2012) concluded that Stapel had fabricated or manipulated data in at least 55 publications, dating back to as early as 2004. Early in his career, he manipulated data, but later he simply pretended to have run experiments and sent processed data to colleagues or PhD students for further analysis. No one was ever allowed to see the raw data. In all 19 PhD theses were prepared with data from Stapel, but the investigators advised that the PhD degrees should not be retracted, because Stapel had acted alone in the fraud.

In 2013, Stapel agreed to perform 120 hours of community service and to return income from his former position (at 1.5 x annual salary) in order to avoid further criminal prosecution. Main source: Tilburg University (2012).

research integrity across the entire country, with her own integrity somewhat impaired. Finally, research misconduct did not damage Schavan's standing as a Catholic, and in particular her capacity to represent Germany to the Catholic Church itself.

Not just text, but also images, are susceptible to research misconduct, because images are interpretations of data. Rossner & Yamana (2004) highlighted the image-related misconduct problem and described general rules for correct image processing and became a pillar in the field. Subsequently, several journals have implemented guidelines for authors, describing image handling standards and rules to be followed in preparing images for publication (Rossner, 2012). Fraudulent manipulation refers to alteration of images that affects the interpretation of the data. Inappropriate manipulation refers to adjustments that violate the guidelines but do not affect the interpretation of data. Several journal editors stress that such problems should be spotted before

BOX 6: THE ANNETTE SCHAVAN CASE

Annette Schavan is a German politician and member of the Christian Democratic Union. She studied education, philosophy and catholic theology, earning her doctorate at Düsseldorf University with a dissertation entitled *Person and Conscience*. In 1995-2005 she was Minister for Culture, Youth and Sport in Baden-Wüttenberg, and in 2005-2013 she was federal Minister for Education and Research.

In 2012, a blog (Schavanplag, n.d.) claimed that 94 pages of Schavan's 325-page dissertation were copied without reference to sources. Schavan asked the university to examine the allegation. In an interview, Schavan said that she could not claim never to have made mistakes out of carelessness, but she refuted the claim that she had plagiarized or cheated. However, the faculty concluded in 2013 that, throughout the dissertation, she had wilfully committed fraud by plagiarism, and her degree was revoked. Schavan announced immediately that she would file a complaint over the verdict to the Court of Administration (Verwaltungsgericht). A few days later, she stepped down from her post as a federal minister.

Her complaint was rejected by the Court of Administration in 2014. But in the same year she received an honorary doctorate from the University of Lübeck, and later in 2014 she became German ambassador to the Vatican.

Main source, which among other things contains all the official documents: Schavanplag (n.d.).

BOX 7: THE CATHERINE VERFAILLIE CASE

Catherine Verfaillie was a researcher at the University of Minnesota when she in 2002 published a widely celebrated paper in *Nature*, where her group described a new type of pluripotent cells. Some years later, reporters found problems related to some of the images contained in several of her publications. Some image panels were duplicated – the same images were used multiple times while claimed to represent separate results obtained from independent experiments.

The University of Minnesota conducted an investigation and concluded that Verfaillie's graduate student had committed research misconduct, while Verfaillie herself was blamed for insufficient oversight. Some of her publications were retracted, while the famous *Nature* paper only had to undergo corrections.

Despite the controversy about her work, Verfaillie continued her career as a prestigious researcher and today she is member of several editorial and advisory boards and since 2005 the director of the Stem Cell Institute at the Catholic University of Leuven (Belgium). However, more concerns have recently been expressed about at least 10 additional papers from Verfaillie's group as other images appear to be manipulated and/or re-used. A total of 18 papers from 1997 to 2014 have been questioned. Remarkably, the student who was accused of research misconduct in the Minnesota University investigation is author of only a minority of them. The case is gaining new media coverage, especially in Belgium, even though no new investigation has been opened up to date.

the publication level and efforts should be done to possibly prevent them.

Initially, the US definition of misconduct contained, in addition to fabrication, falsification, and plagiarism, a fourth clause: "other practices that seriously deviate from those that are commonly accepted within the scientific community". However, this clause was criticized by many scientists and scientific bodies, including the National Academy of Science, because the formulation was so vague that it could be used to accuse honest researchers pursuing creative or novel science of research misconduct. It was therefore later removed, leaving us with FFP.

The fact that research misconduct does not include differences of opinion has been explicitly confirmed in Denmark. This happened as a result of the case against Bjørn Lomborg (see Chapter 3). However, in contrast with the US definition, which only mentions FFP and excludes "honest error" from research misconduct, Denmark, like many other countries in Europe, and like Australia, previously adopted a wider definition. The Danish definition (termed 'scientific dishonesty') was open-ended; it included a clause on "other serious violations of good scientific practice" and also included acts that are "grossly negligent". However, the new law (Ministry of Higher Education and Science (2017), see Chapter 3) has adopted the FFP definition. It should be noted that aligning national definitions and regulation is a difficult task, as different traditions have developed in different countries concerning e.g. what is considered a rightful authorship. Nonetheless it is an important task as science becomes increasingly globalized, thus leaving researchers in international collaborations in muddled waters.[1]

3. The competitive nature of today's science

Why do people engage in misconduct? The many spectacular cases of misconduct have forced the scientific community not only to set up institutions and procedures to handle cases of misconduct, but also to look at the causes. Perhaps unsurprisingly, the usual motive behind research misconduct is self-interested pursuit of an advantage over others in the competition for funding, positions and overall recognition "without incurring the cost of effort" (Fang & Casadewall, 2013).

Back in 1942, the sociologist of science Robert K. Merton tried to describe the values adhered to by the scientific community (Merton, 1973). He identified what later became known as the CUDOS norms: **C**ommunalism (new results are the common property of the scientific community), **U**niversalism (scientists can all contribute to science regardless of their race or gender or social background), **D**isinterestedness (scientists are not driven by personal interests in their pursuit of science), and **O**rganized **S**kepticism (scientific claims are critically scrutinized by the scientific community before being accepted). Merton's description was influential for the scientific community's perception of itself.

Interestingly, Merton did not attribute the norm of disinterestedness to the scientific community because he believed scientists to be morally better than ordinary people; rather, he found that the frequency of severe fraud in science was lower than that in other areas of human endeavour and concluded that an institutional norm actively deters scientists from research misconduct. Outside of explicit research misconduct, Merton also considered that the norm of disinterestedness could be violated by misusing science for various political purposes (e.g. in making claims about race or history not driven by the pursuit of truth).

At the end of the twentieth century the physicist John M. Ziman described the institution of science rather differently using the PLACE norms (Ziman, 2000): **P**roprietary (results are proprietary rather than communal), **L**ocal (researchers focus on local puzzles rather than general understanding), **A**uthority (there is a hierarchical structure of authority rather than the equality implied by Merton's universalism), **C**ommissioned (research is often commissioned and therefore

1 The account in this section is mainly based on LaFolette (2000) and Steneck (1994).

not disinterested), and **E**xpert (scientists are valued as experts who can give advice on action rather than for their originality; Merton later included 'originality' in the CUDOS norms). Clearly, the shift from CUDOS (Merton, 1973) to PLACE (Ziman, 2000) signals a dramatic development in the perception of how science works, how it is organized and how it relates to society. This raises questions about how science can retain its integrity if its traditional norms, as described by Merton, are indeed this deeply challenged. However, a closer look at the actual development of science between the 1940s and today gives a more nuanced picture.

One aspect of the development of science is the *sheer increase in volume*. Already in 1963, the historian of science Derek John de Solla Price had argued in his book *Little Science – Big Science* that the amount of scientific activity, measured by the number of journals and results etc., had been growing exponentially, doubling every 10-15 years (De Solla Price, 1963). Solla Price warned that this growth could not proceed indefinitely, but the expansion still continues. A more recent follow-up study of the number of journals (Olesen Larsen & von Ins, 2010) has concluded that "[t]here are no indications that the growth rate has decreased in the last 50 years" (p. 600).

Another aspect is the increasingly prominent *role in society* that science has gained during the twentieth century and the first years of the twenty-first century. Following WWII, it became clear to politicians and the general public alike that science-based inventions and technologies had the potential to create prosperity and solve problems for society on a large scale (whilst of course also raising anxieties about the destructive potential of science and technology). Society has come to expect that 'expert' scientific knowledge will guide governments, public and private bodies, and individual citizens in making informed decisions on almost any issue in modern life, from dietary choice and medical treatment to energy saving initiatives and computer safety.

With high expectations about the advances science can bring, governments all over the world allocate substantial amounts of money to scientific research and to the education of scientists. Public funding agencies have thus been created in many countries, and across national borders, most notably perhaps in the EU. Governments then expect returns from their investment. In order to optimize quality and the efficient use of resources, many governments allocate large parts of public research funding through free competition between applicants. Many, moreover, have encouraged collaboration and co-funding between universities and industry, hoping to see greater economic returns from research investment. As a result, researchers have become much more dependent on proving scientific success, not least in terms of publications, and they increasingly collaborate with the private sector, where financial and other interests may conflict with the traditional values of academic freedom and disinterestedness (see Chapter 7).

Another development, sometimes described as the move from Mode 1 to Mode 2 Research,[2] is the funding of large, temporary, interdisciplinary projects designed to address specific problems. These problems are defined not by academia (as in Mode 1), but by a wider group of stakeholders in society, often including representatives of industry. Contemporary research is also characterized by greater internationalization. This is typically encouraged by funding agencies in the hope that synergies across borders will increase the quality of outputs and promote capacity building. In order to meet the evolving demands of governments and other funders, it has been necessary to organize science in increasingly large units with a high degree of specialization and division of labour.

Science has no doubt over the years developed higher scientific standards and more rigorous methods. Current requirements on clinical trials and statistical rigor are important examples of this. Also, the increasing demands for openness and accuracy in reporting across large, often international consortia have halted some of the research misconduct practices that big scientific names in the past managed to get away with.

2 These terms were coined in A. Gibbons et al. (1994).

Clearly, however, the developments describes above raise some challenges. The modern scientist has left the ivory tower and has become a member of ordinary society, subject to its demands and trends in a way that may conflict with the pure pursuit of scientific knowledge. Funders of research make strong demands on researchers, and obtaining funds from a variety of sources places the modern scientist in a field of competition and conflicting interests that have to be managed.

Conflicts of interest are discussed in more detail in Chapter 7. Increasingly, patents are the expected outcome of today's collaborations, which means that some scientific results are no longer common property as Merton (1973) insisted. The issue of intellectual property rights (IPR) is discussed in Chapter 6.

Again, scientists are not only providing the public good of shared knowledge; they are also involved in fierce competition

FIGURE 1: A TABLE INDICATING THE PREVALENCE OF VARIOUS BEHAVIOURS IN THE US (FROM MARTINSON, ANDERSON, & DE VRIES (2005))

Percentage of scientists who say that they engaged in the behaviour listed within the previous three years (n=3,247)

Top ten behaviours	**All**	**Mid-career**	**Early-career**
1. Falsifying or 'cooking' research data	0.3	0.2	0.5
2. Ignoring major aspects of human-subject requirements	0.3	0.3	0.4
3. Not properly disclosing involvement in firms whose products are based on one's own research	0.3	0.4	0.3
4. Relationsships with students, research subjects or clients that may be interpreted as questionable	1.4	1.3	1.4
5. Using another's ideas without obtaining permission or giving due credit	1.4	1.7	1.0
6. Unauthorized use of confidential information in connoection with one's own research	1.7	2.4	0.8***
7. Failing to present data that contradict one's own previous research	6.0	6.5	5.3
8. Circumventing certain minor aspects of human-subject requirements	7.6	9.0	6.0**
9. Overlooking others' use of flawed data or questionable interpretation of data	12.5	12.2	12.8
10. Changing the design, methology or results of a study in response to pressure from a funding source	15.5	20.6	9.5***
Other behaviours			
11. Publishing the same data or results in two or more publications	4.7	5.9	3.4**
12. Inappropiately assigning authorship credit	10.0	12.3	7.4***
13. Witholding details of methodology or results in papers or proposals	10.8	12.4	8.9**
14. Using inadequate or inappropriate research designs	13.5	14.6	12.2
15. Dropping observations or data points from analyses based on a gut feeling that they were inaccurate	15.3	14.3	16.5
16. Inadequate record keeping related to research projects	27.5	27.7	27.3

Note: Significance of X^2 tests of differences between mid- and early-career scientists are noted by **(P<0.01) and *** (P< 0.001)

for funding and positions. With such keen competition, researchers are highly dependent on proving their continued success. Since most funders employ various bibliometrics (e.g. journal rankings and citation indices) as a measure of quality in scientific performance, researchers often feel they are under increasing pressure to publish as much as possible, as quickly as possible, and in as high-ranking journals as possible. The competitive environment provides an incentive for each individual to gain advantages relative to others; and in this climate some people are likely to be tempted into misconduct. Or, as stated in an editorial in Infection and Immunity: "It is not difficult to surmise the underlying causes of research misconduct. Misconduct represents the dark side of the hyper-competitive environment of contemporary science, with its emphasis on funding, numbers of publications, and impact factor. With such potent incentives for cheating, it is not surprising that some scientists succumb to temptation." (Fang et al., 2011, p. 3857)

4. Questionable research practices

Just how widespread is research misconduct? Clearly, this is difficult to assess accurately, in part because underreporting is highly likely. Martinson et al. (2005) (see more below) estimate that 1%-2% of all scientists have been engaged in misconduct. These figures indicate that very many cases go undetected when compared to the number of reported cases. Thus, institutions and procedures need to be in place to bring cases to light and handle them when they do occur. Moreover, universities need to develop a culture which provides access and protection for whistleblowers and at the same time offers protection from false accusations, which may also be part of a competitive environment.

Compared to the more serious cases of research misconduct, *questionable research practices* are much more widespread (Martinson et al., 2005; Fanelli, 2009). Such practices are defined as research which undermines research integrity – breaching principles of honesty, transparency, and accountability – without amounting to research misconduct, and commonly arise within some of the areas discussed later in this book, like authorship and publication (Chapter 4), data handling and management (Chapter 5) and conflicts of interest (Chapter 7), as well as within image handling as mentioned above. To the extent that questionable research practices are much more widespread, they may have serious consequences for both the reliability of scientific results and public trust in them.

Some people wish to bring failure to live up to accepted standards for scientific methodology under the umbrella of questionable research practices. For instance, there has recently been a debate over reproducibility that evolved in the medical sciences, but it is likely to spread to other areas. There is evidence to suggest that much basic and clinical research does not meet the fundamental requirement of reproducibility (e.g. see Begley & Ioannidis (2015) and The Lancet, (2014) for further discussion). Failure of reproducibility is, of course, a very serious problem. But whether it should be counted as a questionable research practice, as these are described above, is controversial. There is a distinction between being in good faith but failing to live up to standards (because these have developed), and failing to live up to standards with the intent of cheating. Clearly, scientific standards develop over time, so it is arguable that historical research that would now be conducted differently need not have involved wilfully breaches of honesty, transparency or accountability. Hence, these questions are kept apart in this chapter.

On the basis of a meta-analysis of available studies of the prevalence of research misconduct, Fanelli (2009) found that almost 2% of researchers admitted to having "fabricated, falsified or modified data or results at least once" (p. e5738), while a much larger proportion, 33.7%, admitted to other questionable research practices. When participants were asked about the behaviour of their colleagues, the numbers rose, and 14% reported that they had witnessed colleagues engaging in falsification and 72% reported that they had witnessed colleagues engaging in questionable research practices.

One of the studies include in Fanelli's (2009) meta-analysis was the survey by Martinson et al. (2005), which was

completed by over three thousand US researchers (see Figure 1). The "top ten behaviours" in their table are behaviours that are likely to be sanctionable. The "other behaviours" are less serious or careless.

Martinson and his colleagues found that 0.3 % of the scientists who replied to the survey had, by their own admission, engaged in the falsification of data, and that 1.4 % had used the ideas of others without obtaining permission or giving due credit (plagiarism). However, a number of behaviours in the domain of questionable research practices had far higher frequencies. Of the respondents, 6% reported that they had failed to present data that contradicted their own previous research, 12.5% had overlooked others' use of flawed data or questionable interpretation of data, and 15.5 % had changed design, methodology or results in response to pressure from a funding source. Bias in the face of pressure from funding is examined in more detail in Chapter 7, authorship and publications issues are examined in Chapter 4, and the handling and storage of data is discussed in Chapter 5.

These behaviours can make research results look more credible than they really are. Policymakers, companies, clinicians or other stakeholders who make decisions on the basis of this kind of exaggerated credibility may then end up making unwarranted and in some cases damaging decisions. Scientists who base their research on misplaced confidence in others' results may waste their time, and are at risk of producing further connected errors.

One of the drivers of questionable research practices is the intense competition for funding, positions, and so on, with researchers under constant pressure to 'improve' their CVs. Martinson et al. (2005) suggest that bad practice by some researchers trying to 'get ahead' may in turn encourage wider adoption of questionable practices, because people who see others appearing to get away with such practices without sanction (and who therefore see a skewed distribution of positions, publications and funding) may follow suit so as not to lose out in a competition perceived as unfair.

It is worth noting that questionable research practice (and misconduct) is not just a matter of individuals with "bad traits", or of local contexts (departments, laboratories) with a "bad culture". Widespread questionable research practice appears to be associated with general institutional and structural features of the research environment. As outlined above, recognition of this distribution of responsibility for both good and bad scientific practice has gradually led to a stronger focus on research integrity.

5. Research integrity

The notion of *responsible conduct of research* refers to conduct conforming with published rules or guidelines. This notion looks at behaviour from the outside, so to speak: did the individuals perform the right actions? Did they, for example, report findings accurately and objectively?

Research integrity is a notion which expresses, and emphasizes, the importance of the underlying values and norms of research – norms which the whole research community should not only display through their behaviour, but internalize as ideals they believe in. The hope is that when researchers sign up to norms in this way, they become motivated to comply with rules and guidelines, and to take responsibility for the trustworthiness of their and colleagues' research.

As will become apparent throughout this book there are many grey zones where one can stay within "the letter of the law", but move against "the spirit of the law". For instance in cases of authorships and conflict of interests. If the motivation to act responsibly is to avoid punishment or other repercussions, one can ask the question: "What can I get away with"? Research integrity on the other hand implies that one is motivated to act responsibly out of an understanding of the intention behind the various codes and rules. The question is not: What can I get away with? It is rather: How can I realize the values underlying the relevant codes and rules?

Within the last decade, agencies around the globe have worked towards international dialogue on how to understand

and promote research integrity, and how to eventually harmonize standards and regulations.

A series of World Conferences on Research Integrity, from 2007 onwards, has been prominent in this work. The 2nd World Conference in 2010 produced the Singapore Statement on Research Integrity (World Conferences on Research Integrity, 2010). This international statement outlines "the principles and professional responsibilities that are fundamental to the integrity of research wherever it is undertaken". These are summarized as:

- Honesty in all aspects of research
- Accountability in the conduct of research
- Professional courtesy and fairness in working with others
- Good stewardship of research on behalf of others

BOX 8: PRINCIPLES OF RESEARCH INTEGRITY IN THE DANISH CODE OF CONDUCT FOR RESEARCH INTEGRITY

Honesty

To ensure the trustworthiness of research, researchers should be honest when reporting objectives, methods, data, analysis, results, conclusions, etc.

This requires accurate and balanced reporting when:

- presenting and interpreting research
- making claims based on findings
- acknowledging the work of other researchers
- applying for research funding
- reviewing and evaluating research

Transparency

To ensure the credibility of scientific reasoning, and to ensure that academic reflection is consistent with practice in the relevant field of research, all phases of research should be transparent.

This requires openness when reporting:

- conflicts of interest
- planning of research
- research methods applied
- results and conclusions

Accountability

To ensure the reliability of research, all parties involved should be accountable for the research carried out.

This requires that researchers and institutions accept responsibility for the research they are conducting, in terms of:

- accuracy and reliability of research results
- adherence to all relevant regulations
- fostering and maintaining a culture of research integrity through teaching, training, and supervision
- taking appropriate measures when dealing with breaches of responsible conduct of research

This statement was followed, at the 3rd World Conference, by the 2013 Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations (World Conference on Research Integrity, 2013). This outlines the responsibilities of individual and institutional partners in cross-boundary research collaborations, including general collaborative responsibilities, responsibilities in managing collaboration and in collaborative relationships, and responsibilities for the outcomes of research. The statements acknowledge that there are many national and disciplinary differences in the way research is organized and conducted, but they nonetheless seek to formulate basic principles and professional responsibilities that are fundamental to the integrity of science in general terms. Detailed interpretation of the general principles and their specific legal implications are often spelled out, however, in national and local regulations.

All existing Danish guidelines refer to these international statements. In a collaborative operation initiated in 2013, the Ministry of Higher Education and Science and the organization Universities Denmark worked together on The Danish Code of Conduct for Research Integrity (Ministry of Higher Education and Science, 2014), which was published in 2014. This Code now serves as the primary point of reference for researchers working in Denmark. It will of course need to be implemented by the universities, at which point it will be elaborated in more detailed local policies. According to the Code, three basic values should guide all research, inspired by the Singapore Statement (see Box 8):

The Code goes on to specify in detail the responsibilities of individuals and institutions across a wide range of areas, including research planning and conduct, data

BOX 9: HOW TO HANDLE SUSPICION OF RESEARCH MISCONDUCT?

You learn that a senior colleague has discarded several observations from a data set that you both use as they do not support his hypothesis. When you ask him about it you are presented with a rather unsatisfactory explanation on why he has done this and you strongly suspect him of falsifying the data to strengthen his paper. What do you do?

A: Nothing – this is somebody else´s problem.
B: Confront him again and go deeper into the discussion to show him that you suspect something – but leave it up to him to decide what to do.
C: Without informing him, you inform the professor who is supervising you both and leave it to her to do something.
D: Confront him with your suspicions at the next internal seminar in front of the whole group.

It seems obvious that A is not an expression of research integrity as part of being a good researcher is to intervene when others conduct research misconduct or questionable research practices. B is to address the problem without escalating the conflict unnecessarily and keeping the option open that you might be mistaken. But if you are still suspicious, you probably ought to move on to C, and possibly inform your colleague that this is what you will do. If C results in you still being suspicious as it seems to you the professor is part of the falsification, D is an option. But D could carry costs for you – both if you are right and if you wrong. An option not mentioned is to contact "the named person" (see chapter 3) for anonymous advice before moving into D.

As can be readily seen it is not easy to find your way in such a situation, both because it is under-described here, but also because doing the right thing, having research integrity, might entail problems for you depending on the culture that you work in.

(Case based on Erasmus University Rotterdam (2016))

management, publication and communication, authorship, collaborative research, and conflicts of interest. It also outlines principles for research integrity in teaching, training and supervision. Finally, it states: "Institutions and researchers share a responsibility for addressing and taking appropriate measures when encountering breaches of responsible conduct of research", and this includes research misconduct as well as the broader range of questionable research practices.

It seems appropriate to end this chapter with the statement: "**Researchers** and **institutions** are responsible for creating and maintaining an environment where it is acceptable to bring forward well-founded suspicions of breaches of responsible conduct of research in good faith." This helps to bring out the idea of a shared, personal *and* institutional, duty to create an environment for research in which the incentives to indulge in questionable practices are minimized because individuals regard the system as fair, and because it is hard to gain an unfair advantage without cost to oneself. In Chapter 3, we move on to discuss how breaches of responsible conduct of research are handled in Denmark.

6. Test yourself questions

- How do "research misconduct" and "questionable research practices" differ?
- What are the main reasons why people engage in scientific misbehaviour?
- How do "responsible conduct of research" (RCR) and "research integrity" differ?
- What are the basic values underlying research integrity?

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3.
How are breaches of RCR handled in Denmark?

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Summary

This chapter describes Danish procedures for handling breaches of RCR as they have developed over the years and explains how researchers encountering problems with RCR can navigate in the system. The following institutions, regulations, and official recommendations are covered by the chapter: the Danish Committe on Research Misconduct (DCRM) – until 2017 called the Danish Committees on Scientific Dishonesty (DCSD), the Practice Committee at the University of Copenhagen, Named Person arrangements, and the Danish Code of Conduct for Research Integrity.

1. Introduction

What can and should you do if you come across colleagues or collaborators who engage in scientific practices you find problematic? If you decide that you need to act, what are the possibilities and where can you seek guidance? The answers to these questions to a large extent depend on answers to the following questions, to be addressed in this chapter: What systems are set up in Denmark to deal with research misconduct and questionable research practice? And what official rules and norms apply within these systems?

Over the last few decades, following the developments in the US as described in Chapter 2, most Western countries have set up systems to deal with research misconduct. Most countries have followed a model in which the primary responsibility for investigating and dealing with allegations of research misconduct lies with the individual research institution. However, in Denmark, a system for dealing with cases of research misconduct at the *national* level was developed from the start of the 1990s. This system was later supplemented with institutional procedures for dealing with less serious cases of questionable research practice at the university level. Since 2012 this has been further supplemented with so-called Named Persons who serve as the point of contact for researchers and students who are unsure about how to handle alleged cases of research misconduct or questionable research practice. At the University of Copenhagen, there are two Named Persons appointed at the Faculty of Health and Medical Sciences and at the Faculty of Science, and there is one for each of the other faculties.

In the following sections we describe the Danish system for handling violations of RCR, as it has developed over the years. We give some key pieces of information and pointers to help researchers who are facing problems with RCR to use the system. We begin by looking at the DCRM, the central national committee handling Danish cases of research misconduct. The body from which the Committee developed was first established in 1992, and the Committee is still the backbone of the system for handling cases of alleged research misconduct in Denmark.

2. The Danish Committee on Research Misconduct – Outline of the system

The committee system grew out of an initiative taken by the Danish Research Council for Medical Sciences. In 1992, an initial committee of eight members was established, including seven medical scientists and a high court judge as Chair. This committee covered health and medical sciences only and was established as a temporary initiative. In many ways it served to define the later terms and workings of the system.

In 1998 a permanent system with a committee system covering the full spectrum of scientific enquiry was established by an executive order issued by the Minister of Higher Education and Science. (This system is currently based on *Lov om videnskabelig uredelighed m.v. (Research Misconduct etc.), Act no. 383 of 26 April 2017* passed by the Danish parliament). This meant that from 1998 onwards the committee system was founded on Danish legislation, and that the definition of research misconduct was now laid down in law. For a reference to the current rules, see Box 1 and Box 2; and for a description of the 1998 rules see the 1999 report (in Danish) issued by the DCSD (2000).

The Committee is chaired by a high court judge and the other 8-10 members must be recognized scientists representing different research areas. All the scientific members of

the Committee are appointed by the Minister of Higher Education and Science, based on an open call followed by a consultation with the Independent Research Fund Denmark.

The starting point of a case is normally that someone files a written complaint. Complaints can be filed by an individual or an institution. With the procedural setup introduced by the new law from July 2017 all individual complaints must be filed at the relevant research institution. The institution will then screen the case to see if some formal requirements are met (is there a scientific product, is the person complained about a researcher, and does the compliant concern research misconduct) and forward the case to the Committee for processing. The Committee can raise cases at its own initiative, but typically cases rely on someone being willing to come forward and make the complaint. Here it is important to notice that according to the law, every Danish university or other public research institution is obliged to raise cases for the Committee if there is a grounded suspicion of research misconduct committed at the institution in question. So the managament of the University of Copenhagen is under the legal obligation to pursue and report cases of research misconduct. The name of the person who makes the complaint will be issued to the person(s) complained about: the system does not allow for anonymous whistleblowers.

When someone makes a complaint it will in most cases be about alleged research misconduct by another researcher.

BOX 1: THE DANISH COMMITTEE ON RESEARCH MISCONDUCT

The Danish Committee on Research Misconduct is a national committee consisting of a high court judge and 8-10 recognised researchers and it operates under the Ministry of Higher Education and Science.

The Committee deals with written complaints about research misconduct. It cannot punish offenders but may inform the institutions to which an offender is attached and the institutions may then invoke disciplinary actions. A complaint cannot normally be sent directly to the Committee but must be sent to your own research institution which will then pass it on. At the University of Copenhagen a complaint about research misconduct should be sent to the Practice Committee at the University of Copenhagen (see box 5).

You can read more about the Commitee on its webpage (DCRM, 2017a) where it is also possible to read anonymized decisions taken by the Committee. You can also find an overview of the current regulatory framework (DCRM, 2017b).

BOX 2: THE DANISH DEFINITION OF RESEARCH MISCONDUCT

Lov om videnskabelig uredelighed m.v. (Act on Research Misconduct etc.), Act no. 383 of 26 April 2017, § 3:

"3.-(1) For the purposes of this Act:

1) Research misconduct shall mean: Fabrication, falsification and plagiarism committed wilfully or with gross negligence when planning, performing or reporting on research.
2) Fabrication shall mean: Undisclosed construction of data or substitution with fictitious data.
3) Falsification shall mean: Manipulation of research material, equipment or processes as well as changing or omitting data or results, thus making the research misleading.
4) Plagiarism shall mean: Appropriation of other people's ideas, processes, results, texts or specific concepts without giving due credit."

Excluded from the definition are

1) cases of fabrication, falsification and plagiarism which have only had minor importance when planning, performing or reporting on the research;
2) matters relating to the validity of scientific theories; and
3) matters relating to the research quality of a scientific product.

According to the remarks of the law authorship issues and so-called self-plagiarism are not normally considered cases of research misconduct.

However, sometimes cases are raised by researchers who want to be cleared of allegations of research misconduct against themselves. For example, in 1994 the newly elected rector[3] of the University of Copenhagen, Kjeld Møllgård filed a case to exonerate himself of allegations of research misconduct going back more than 20 years. In this case the Committee, based on a report from a subcommittee with external members, concluded that the allegations were baseless.

The wording describing what counts as research misconduct has changed since the rules for the first committee were defined, but the substance is more or less the same – see Box 2 for the latest version.

When a case is presented to the Committee, the first thing it should do is to decide whether or not to deal with the case. For the Committee to accept a case, it must fall under its remit, as defined by the rules set out in Box 2, i.e. by concerning "fabrication, falsification or plagiarism in planning, performing or reporting research". The case also has to concern research conducted with full or partial Danish public funding or research conducted at a public research institution in Denmark. If the research in question is strictly privately funded and does not involve a public research institution the Committee can only deal with the case if the enterprise etc. consents. A number of formal requirements must then be satisfied. First, the case must concern a scientific product, i.e. a product generated by means of scientific methods applied in research typically in the form of a research paper or funding application. Secondly, the person concerned must be a researcher which is defined as any person who is a PhD student or who has a PhD degree or similar qualifications.

For the Committee to deal with a case it must be one of alleged research misconduct, not just scientific disagreement. From the beginning, the committee system has drawn a distinction between scientific disagreement over the validity of scientific theories or the quality of the research being conducted, and claims about research misconduct. The Committee only deals with the latter. Disagreements about what constitutes good science and the validity of specific scientific claims are left for the scientific community itself to deal with through peer review and via public critique of others' work.

Many of the cases put before the committee system so far have been rejected during the initial phase, typically because they do not concern a scientific product. For example, if a researcher engages in a public debate and makes claims that are not supported by facts, this is usually not covered by the rules.

If a case is complicated and requires expertise not found among the members of the Committee, it may decide to obtain expert assistance as specifically required, e.g. by including an external expert in the Committee's processing of the case. In other cases, the Committee may obtain an external statement from an expert giving an opinion on (parts of) the case.

When the Committee finds that a case meets the formal requirements and therefore should be taken under active consideration in the Committee, the next step is to procure all relevant information for processing the case. This will always involve a hearing of the person subject to the complaint, so

3 These were the days when rectors were elected by university staff and students.

BOX 3: REQUIREMENTS THAT MUST BE MET FOR THE ACTIONS OF A RESEARCHER TO BE DEEMED A CASE OF RESEARCH MISCONDUCT:

1) It must be a case of falsification, fabrication, or plagiarism.
2) It must be done wilfully or with gross negligence.
3) It must be about a researcher's product brought forward by means of scientific methods as part of research.
4) It must be about research related to a Danish public institution or based on public funding.

that she/he gets a chance to bring forward his view on the matter in question.

After this, the case is investigated by the Committee. In the process of investigation additional material going beyond that originally submitted by the complainant, the relevant research institution, and the person being complained about may be asked for. If the material contains factual information, the person subject to the complaint will be given an opportunity to comment on this information.

In Box 4 below is a sketch of a case dealt with by the committee system.

BOX 4: A CASE OF RESEARCH MISCONDUCT HANDLED BY THE DANISH COMMITTEE SYSTEM

The committee system was contacted by a Danish university which filed a plagiarism complaint. A member of a hiring committee, set up for recruiting candidates for a scientific position, suspected that an applicant had enclosed an article which they had not written. The hiring committee confirmed its suspicion by tracking down the original article.

During the hearing of the facts in the case, the respondent admitted having enclosed an article which he had not written although he had supplied it under his own name. The respondent then stated that the plagiarized article should be regarded as a test of whether the university was sufficiently thorough in its processing of applications for scientific positions.

The Committee did not find the respondent's argument to be credible and found the respondent to exhibit misconduct by intentionally plagiarizing the results of others and wrongfully alleging to be the author of a scientific publication which the respondent had not written …

The case can be retrieved from the 2009 annual review of the activities of the DCSD (2010).

This case was simple. Others are much more complicated – they have often been protracted and prolonged as a result of numerous hearings and complaints from the parties. As a result, one of the ideas behind the procedural setup in the new law is to give the research institutions a bigger role in treating individual cases while simultanously diminishing the role of the person bringing forward the complaint and not automatically make this person a party to the case.

In recent years there has been, on average, around one case a year where a researcher has been found guilty of research misconduct. The Committee is not able to punish offenders, but it can do a number of things which may have serious consequences for a researcher who is found to have acted dishonestly. The most important thing it can do is inform the researcher's employer. Using this information, the employer may choose to apply sanctions, the most drastic of which would be to terminate the researcher's employment. Also, if the case concerns an application for a grant from a public funding body, the Committee may inform the funding body. The Committee may also inform the editor of a scientific paper or book about its decision.

In the case described in Box 4 the effects on the convicted researcher are likely to have been minimal. Since the decision is only made public in an anonymous form, the name of the researcher will not be publicly announced, and the case will therefore not affect the person's possibility to apply for future jobs. However, the activities of the Committee fall under Danish legislation on access to public information, so the press and other interested parties may seek access to non-anonymized versions of the Committee's decisions. The researchers most affected by a verdict of research misconduct are those who already have a strong public profile, and hence a reputation that can be badly damaged. A bad reputation may, among other things, affect the researcher's ability to attract funding and obtain invitations to give lectures at conferences and the like.

So it is no small thing for an established researcher to be found guilty of research misconduct. This is why the Committee is headed by a high court judge, and why

safeguards based on public administrative law are in place. In many cases the Committee reaches a conclusion that research misconduct has not occurred, either owing to lack of evidence or because the practice involved, although questionable, does not qualify as research misconduct.

During their first ten years, the committee system would adjudicate on both research misconduct and questionable research practices. In other words, they could reach the conclusion that a person was not guilty of research misconduct, but was still open to criticism for questionable research practice. In this way the system was to some extent able to deal with the grey zones lying just beyond the borders of what had been defined as research misconduct. However, this came to a dramatic end in 2003 following the case of Bjørn Lomborg.

3. The Lomborg case and the establishment of the Practice Committee at the University of Copenhagen

In 1998 Bjørn Lomborg, who was then Associate Professor at the Department of Political Science, Aarhus University, published a series of short pieces in the Danish newspaper *Politiken,* in which he accused many of the scientists dealing with environmental risks, not least concerning global warming, of overstating the case and creating unnecessary fear. He also claimed that many of the solutions offered to deal with environmental problems were not optimal from a cost-benefit perspective. Later he turned his ideas into a book entitled *The Skeptical Environmentalist*, published in English by the prestigious academic publisher Cambridge University Press. His claims and arguments had a wide uptake both in Denmark, where in 2002 he was made director of the newly established Environmental Assessment Institute, and internationally.

Many of the scientists accused of scaremongering by Lomborg were unhappy, and some of them reacted by writing critical responses to Lomborg's claims and arguments. Thus Lomborg's views gave rise to a huge debate which took place both in popular media and in scientific circles. For example, the *Scientific American* invited four experts to comment on different aspects of *The Skeptical Environmentalist*, and Lomborg then provided responses to these commentaries. A number of the frustrated scientists also reacted in the beginning of 2002 by filing three separate complaints against Lomborg to the committee system. Here it was claimed that in *The Skeptical Environmentalist* Lomborg was guilty of, among other things, falsification of data, deliberately misleading use of statistical methods, and deliberately skewed representations and reports of other people's scientific findings.

From the start, the allegations gave rise to disagreement among the members of the committee system. Some members believed the case should be rejected at the initial phase because, as they saw it, *The Skeptical Environmentalist* was not a research publication and therefore did not meet the third of the three requirements listed in Box 3. Other members disagreed, and in the end a decision was made to establish an ad hoc working group to review the case.

The working group delivered its report in September 2002. The report presented the strongly critical comments on *The Skeptical Environmentalist* made by other scientists in *Scientific American* and indirectly used these as evidence. It also referred to a number of highly defamatory statements about Lomborg made by prominent scientists in an issue of *Time Magazine.* Furthermore, it criticized Lomborg for not submitting his controversial claims to international journals for peer review. The report claimed that it was not in accordance with the norms of good scientific practice for a researcher to communicate research results to a wider public before these results have been reviewed by scientific peers.

On the question of whether *The Skeptical Environmentalist* could be considered a research publication, the working group delivered a divided decision. This disagreement continued when the report from the group was discussed in the commitee system. However, an agreement was reached that the complaints should not be dismissed simply on the grounds that the work complained about was not a scientific

publication (see Chapter 9 for further discussion about the relationship between scientific and popular publication).

In the final decision, which was accepted unanimously, it was decided that Lomborg satisfied the first of the three requirements of research misconduct (at the time called 'scientific dishonesty') in that his book misrepresented the scientific content of the studies reviewed to such a degree that it could be classified as a case of falsification. However, the committee members also agreed that it was not possible to prove that the falsification was wilful or grossly negligent – in other words, that they could not prove that Lomborg had intended to falsify results, and thus the second requirement for a case to count as one of research misconduct was not fulfilled. At the same time the Committee chose to leave the question whether *The Skeptical Environmentalist* should be classified as a research product unanswered.

On this basis the Committee decided on the following wording of its decision:

> "*Objectively the publication falls under the concept scientific dishonesty. Viewed in light of the subjective requirements regarding wilfulness or gross negligence Bjørn Lomborg's publication cannot be said to fall under this term. However, the publication is clearly seen to violate the norms of good scientific conduct."* (DCSD, 2003)

Although Lomborg was formally acquitted of research misconduct, in practice the Committee's conclusion could be, and was, viewed as a serious attack on his scientific credentials. The decision was controversial and divided the scientific community, with strong reactions from groups of Danish researchers who were both for and against the decision made by the committee system. On the critical side, there was an outcry among many social scientists, who felt that norms of good scientific conduct originating in medical science were being superimposed on social science and the humanities. Thus many argued that it is common practice in large parts of social sciences and humanities to publish books without basing these on prior publications in international journals with peer review – which was one of the points of criticism underlying the decision.

Lomborg himself complained to the Ministry. It was not possible to appeal the full decision of the Committee, but it was possible for him to complain that the relevant legal procedures had not been complied with. Some of his key points were: a) 'Objective dishonesty' cannot be treated as a separate entity in a decision from the Committee. b) The Committee cannot base its assessment of research misconduct simply on the decisions of others, as it did here by referring to the papers in *Scientific American,* but must assess the publication in question itself. c) The Committee cannot make a decision on violations of the norms of good scientific practice (as distinguished from research misconduct). d) The book was not a scientific publication, as defined by the law, and it therefore did not fall under the remit of the Committee to assess it.

The Ministry accepted Lomborg's complaint on all four counts and made it clear that the Committee should only consider the scientific activities of scientists, not their communication with the wider public. The Ministry also said that the assessment must be undertaken by the Committee, possibly with the help of expert members of ad hoc groups, and that the Committee's decisions should only conclude whether or not an accused scientist is guilty of research misconduct in the full sense of the word; it may not draw conclusions on the issue of whether an acquitted scientist is nonetheless guilty of improper or questionable research practice.

Following the Ministry's decision, the Committee decided not to re-consider the case. But after the Lomborg case the committee system changed its practice, and it no longer includes possible violations of the norms of good scientific practice that do not strictly qualify as research misconduct in its decisions – something which has also been written into the latest version of the legislation regulating the committee system where the Committee now has explicit legal basis for refering such matters to the relevant research institution.

This left a hole in the system. It meant that the Committee could no longer adjudicate on matters lying in the grey zone between responsible conduct of research and research misconduct. To rectify this situation, it was decided by the Minister that questionable research practices should be dealt with at university level, and indeed it was written into the contracts between the Ministry and the universities that universities should ensure that good scientific practice is promoted and protected. As a consequence of this, in 2004 the University of Copenhagen established a Committee for Good Scientific Practice, also known as the Practice Committee. This additional Committee was set up to deal specifically, and only, with potential cases of questionable research practice. (For more details of the remit of the Practice Committee, see Box 5.) The new law on research misconduct from July 2017 specifically obliges research institutions to have a system in place and published guidelines for handling questionable research practice at the institution. With the law the Danish research misconduct system has a clear distinction of task: All cases of research misconduct are handled at the central level by the DCRM and all cases of questionable research practice are handled at the institutional level.

Another outcome of the Lomborg case was a change in the regulatory framework which made the decisions of the DCRM final, i.e. not subject to appeal to the Ministry. The reasoning was that the committee members are experienced and recognized researchers led by a High Court judge as chairman. With this level of legal and academic expertise, it was felt that there was no need to allow decisions to be appealed at ministerial level.

In its first decade the Practice Committee examined one or two cases a year, but since 2014 the number of cases has gone up. Most cases have involved disputes over authorship (see Chapter 4).

4. Recent developments

Since 2010 there have been significant changes in the handling of RCR in Denmark and at the University of Copenhagen. These changes were made in response to a spectacular case, involving the University of Copenhagen: the Penkowa case. This case led to general strengthening of the mechanisms supporting RCR, including mandatory courses for PhD students, as mentioned in Chapter 1. It also led to the establishment of Named Person arrangements at the University of Copenhagen. Around the same time, a Danish Code of Conduct for Research Integrity was issued. The latter appears to have influenced recent efforts to limit and clarify the remit of the committee system, and to draw a clear distinction between research misconduct and questionable research practice resulting in the new law on research misconduct etc.

Milena Penkowa received her degree as medical doctor at the University of Copenhagen in 1998 and then began a stellar research career at the same university. She received her PhD degree in 2000, and less than a year later she handed in her doctoral thesis (a thesis for a second doctoral degree beyond

BOX 5: THE PRACTICE COMMITTEE AT THE UNIVERSITY OF COPENHAGEN

The Practice Committee was first established in 2004. It consists of associate and full professors at the University of Copenhagen who are appointed by the academic councils, with two from each of the Faculty of Health and Medical Sciences and the Faculty of Science, and one from each of the other faculties.

The Committee deals with written complaints about failure to adhere to good scientific practice (questionable research practice). It does not deal with complaints about research misconduct, which should be referred to the DCRM (see Box 1).

The Committee is also responsible for helping to clarify the existing norms of good scientific practice, and it may propose rules and guidance. Finally, the Committee takes steps to ensure public discussion of different aspects of good scientific practice, typically by means of a yearly meeting for all employees and students at the University of Copenhagen.

the PhD). However, this doctoral thesis was rejected, and suspicions were raised about research misconduct. After an internal review, part of which was conducted by the then Dean of the Medical Faculty and later Rector of the University of Copenhagen, Ralf Hemmingsen, it was concluded that there was no basis for raising a case about research misconduct at the committee system.

Penkowa continued her career at the University of Copenhagen. She became associate professor in neuroanatomy in 2004, and later the same year she submitted a revised version of her doctoral thesis on the basis of which she received her doctoral degree. In 2009 she received the prestigious EliteForsk Prize from the Ministry of Research, and later that year she was given the title of full professor.

However, in 2010 Penkowa was suspended following a conviction for financial fraud. Around the same time, and in large part as the result of investigations pursued by a journalist from the national newspaper *Weekendavisen*, it became clear that Penkowa had probably been involved in research misconduct dating back to her doctoral thesis of 2001. A series of investigations were conducted at the University of Copenhagen, and a number of cases concerning research misconduct were presented to the committee system. In some of these cases Penkowa was convicted of research misconduct; in others it was not possible to prove misconduct. In 2016 Penkowa was acquitted of 'document forgery of a serious nature'. The High Court judges deciding the case agreed that documents had been forged, but only three of the judges considered it document forgery of a serious nature. The remaining three judges held that the conduct, though questionable, could not be considered document forgery of a serious nature. This meant that the case was subject to the statutory period of limitation regarding less serious forgery and statute-barred. Since Penkowa could not be convicted of document forgery of a serious nature she was acquitted.

The conclusion of the Penkowa case was that research misconduct and other forms of fraud had taken place, that this had been going on for more than a decade, and that despite a number of warnings and signs that there were problems, things had been allowed to go on. So there was a feeling, both at the University of Copenhagen and nationally, that more needed to be done to prevent research misconduct and to deal with issues of questionable research practice.

Two of the many initiatives taken in the wake of the Penkowa affair have had a direct impact on the way breaches of RCR are handled and should therefore be mentioned here.
The first is that new arrangements in which so-called Named Persons are nominated were established at the University of Copenhagen, in the Faculty of Health and Medical Sciences in 2012, and then in the other faculties in 2014. The Named Person is a professor or associate professor in the relevant faculty to whom employees or students at the university can apply for advice and help, and for mediation in disputes. The Named Person is not part of the management, and she or he does not take initiatives alone. Rather, the main role of the Named Person is to assist people who are concerned about activities in their faculty which may involve questionable research practice or research misconduct.

There are small differences between the Named Person systems in different faculties; we shall describe the system as it works in the Faculty of Health and Medical Sciences. Here, whenever the Named Person is contacted, she or he must make a record of the contact. If allegations are raised about a specific person, that person must be informed. When contacting the Named Person, it may therefore be advisable not to mention any names initially and start by describing the problem in general terms. If it turns out there is no reason to pursue the issue, the accused person will not know about it. But if a name is mentioned, the individual in question may be informed about the inquiry even if it doesn't lead any further.

If accusations relate to issues that fall within the mandate of the DCRM or the University of Copenhagen Practice Committee, the Named Person can advise the complainant on how to present a case there. However, in reality many cases concern matters which can be dealt with through mediation, and here the Named Person plays a central role.

The current (in May 2020) Named Person at the Faculty of Health and Medical Sciences Nils Billestrup reports that from October 2016 to April 2020 he has received a total of 303 inquiries from scientist at SUND by phone or email. The majority (50-60 %) dealt with authorship issues asking for advice about authorship requirements or the order of authorship. In about 40 of these cases the Named Person acted as a mediator in order to solve conflicts. Many inquiries dealt with data ownership in addition to authorship issues. In about 20 cases advice concerning how to report suspicion of research misconduct or questionable research practice was requested. In the majority of these cases he was engaged in many discussions with the person making the accusations and other relevant stakeholders.

The second development following the Penkowa case was that the Danish Ministry of Higher Education and Science and the organization of Danish Universities decided, in 2013, to develop a Danish Code of Conduct for Research Integrity (Ministry of Higher Education and Science, 2014) (see also Chapter 2). A working group led by a representative of the Ministry and with representatives from major Danish research institutions drafted the Code. After revisions based on a broad hearing process the Code was published in November 2014. The main aim of the Code is "to support a common understanding and common culture of research integrity in Denmark". The Code is intended to guide both individual researchers and institutions. Institutions are expected not only to promote the principles and standards of RCR found in the Code, but also to develop policies that will integrate these principles and standards in their daily work.

BOX 6: THE NAMED PERSON

Since 2012 there has been a Named Person in the Faculty of Health and Medical Sciences, and since 2014 there have been Named Persons in all faculties in the University of Copenhagen. The role of the Named Person is to serve as an advisor and point of contact for people who are concerned about possible research misconduct or questionable practice at their faculty.

The Named Person must inform the individual accused if she or he is named. However, it is possible to obtain advice from the Named Person on the basis of a general description of a case in which no names are provided.

The Named Person can advise on the procedure for passing on cases to the relevant Committee, but she or he is also authorized to mediate in less serious cases.

The Named Person also promotes awareness of RCR in her or his faculty.

For more information about the Named Person in the Faculty of Health and Medical Sciences you can visit the faculty's web page.

For more information about the Named Person in the Faculty of Science you can visit the faculty's web page.

BOX 7: DANISH CODE OF CONDUCT FOR RESEARCH INTEGRITY

The Code sets out principles of research integrity and makes recommendations on the standards defining RCR. It is not a legally binding document, but it aims to provide a framework within which institutions and researchers can further promote research integrity.

The Code outlines standards in the following six areas:
1. Research planning and conduct. 2. Data management.
3. Publication and communication. 4. Authorship.
5. Collaborative research. 6. Conflicts of interest.

Together these standards address the most common areas where questionable research practice may arise. In most cases the Code recommends that more specific policies must, where relevant, be defined by universities and other research institutions.

The Code also gives advice on teaching, training and supervision relating to RCR, and it emphasises the need for a system to handle research misconduct and breaches of RCR. (Ministry of Higher Education and Science, 2014)

The Code has received widespread support throughout the research community. All universities, including the University of Copenhagen, all of the major public and private foundations, and all research councils and institutions have signed up to the Code. These signatories are in the process of implementing the Code's recommendations by defining policies on various aspects of RCR. At the University of Copenhagen, the Practice Committee assists University management in developing such policies. The policies will eventually cover most of the issues presented in the following chapters of this book. A final development worth emphasizing is the new Danish law on research misconduct etc. which came into effect on July 1. 2017. The new law aims to create a Danish system with an adequate and effective framework for handling both cases of research misconduct but also questionable research practice.

5. How to handle RCR issues

When a researcher at the University of Copenhagen has questions about research, and is in doubt as to how to behave, or about the behaviour of colleagues or students, there are a number of things she or he can and should do:

1) A good starting point would be to look at the Danish Code of Conduct (see Box 7), to look through the present book, and to consult the web-page of the Practice Committee, for guidance.
2) If doubts remain, a logical next step would be to contact the Named Person in the relevant faculty. The Named Person can give advice, and in cases of disagreement she or he can try to mediate. It is also possible to seek advice from colleagues, the head of section or head of department.
3) If the case concerns questionable research practice, and if the Named Person is not able to mediate, the next step may be to file a written complaint to the University of Copenhagen Practice Committee.
4) Finally, if the case is about research misconduct a complaint should be submitted to the Practice Committee, cf. Box 1. For younger researchers, it may be a good idea to ask a senior colleague, the head of section or the head of department, to file the complaint.

So the key to dealing properly with issues regarding RCR is to seek information and help in deciding where, when, and how to bring forward your concerns.

6. Test yourself questions

- What requirements must be satisfied if the actions of a researcher are to amount to a case of research misconduct?
- In a collaborative project you become aware that a colleague reporting results has omitted a number of data points which, if they were retained, would affect the statistical validity of the study. How should you handle this situation?
- Can you approach the Named Person with allegations about a colleague and remain anonymous?
- If a case similar to the Soman case (see Chapter 2) were to occur today in Denmark, how would the Danish system for handling violations of RCR make a difference?

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4.
Authorship and other publication issues

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Summary

In this chapter we describe the Vancouver Recommendations' requirements for authorship in detail. We also mention some alternative guidelines and address some of the issues authorship raises. After this, we discuss various ways in which authorship can be wrongly claimed. We explain the consequences of different forms of undeserved authorship, indicate how widespread they are, and highlight some other publication issues. The chapter concludes with some recommendations to PhD students on how to manage publications and minimize problems and conflicts.

1. Introduction

In most scientific fields peer-reviewed publications are the primary means of communicating research results. It is fundamental to science that new findings are shared with the scientific community, both to enable critical assessment and, if the findings stand up to scrutiny, so that others can learn from them and build on them in their own research (see Chapter 2 and Chapter 9 for more discussion). At the same time, publications have become one of the primary measures by which scientists are ranked – e.g. when they apply for positions or for research funding. Scientists are compared via bibliometric measures based on the individual researcher's number of publications and citations The commonly used phrase "publish or perish" reflects how crucial this is to scientists careers, meaning that they are always striving competitively to have the most, and the most influential, publications.

Hopefully, you have not been in a situation like the one described in Box 1. But crediting authorship to someone who does not qualify as an author is unfortunately not a rare practice. In this chapter, we shall present the most influential international and Danish guidelines on authorship and explain in detail what they mean for researchers. We also discuss various other publication issues of importance for the PhD student. In the final section, we discuss what one can do to avoid engaging in questionable authorial practices.

2. Requirements for authorship

2.1 The Vancouver Recommendations

There are no globally accepted rules on academic authorship; different disciplines and different cultures have varying perspectives and traditions. However, in 1978 an influential group of editors of medical journals known as the International Committee of Medical Journal Editors (ICMJE) met in Vancouver and formulated a set of recommendations now widely known as the "Vancouver Recommendations" (ICMJE, 2015). Originally, these recommendations were called *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication*. They have been updated several times since, most recently in 2018. The official title is Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical journals, but are widely known as the "Vancouver Recommendations" (ICMJE, 2018).

BOX 1

Imagine that you are about to finish the first article for your PhD thesis. Together with your main supervisor and one of your co-supervisors, who works at another university, you decided on the subject area and methodology.. You gathered the data, though a postdoc at the other university performed some measurements for you. You wrote the first draft of the paper, and you have discussed possible interpretations of the data with your supervisors. Both have commented in detail on the first draft. Having revised the manuscript, you have circulated it again, and then received an e-mail from your co-supervisor who declares it ready for submission – but who also requests that you add the postdoc as a co-author. You ask your supervisor what to do, and he advises you to do as requested, as the co-supervisor is coordinator on a research application that your research group needs to be involved in if they are to obtain a share of the grant. Declining the request will just antagonize the co-supervisor, whom your main supervisor knows very well.

Although the Vancouver Recommendations were formulated in the medical sciences, the principles they express are widely adopted today across the natural sciences and, to a lesser extent, beyond. In Denmark, they have become highly influential because various guidelines refer to them. Thus The Danish Code of Conduct for Research Integrity states in section 4.1: "Attribution of authorship should in general be based on criteria adapted from the Vancouver guidelines" (Ministry of Higher Education and Science, 2014). Further, the University of Copenhagen – Code for Authorship developed by the Practice Committee reiterates The Danish Code of Conduct for Research Integrity by stating that: "Attribution of authorship should generally be based on criteria a-d from the Vancouver rules and all persons that satisfy these criteria should be acknowledged as an author" (University of Copenhagen, 2017).

BOX 2: THE VANCOUVER RECOMMENDATIONS (ICMJE, 2015, P. 2)

The ICMJE recommends that authorship be based on the following 4 criteria:[4]

1. Substantial contributions to the conception or design of the work; OR the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their coauthors.

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged […].

These authorship criteria are intended to reserve the status of authorship for those who deserve credit and can take responsibility for the work. The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion #s 2 or 3. Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.

We shall now discuss each of the four Vancouver requirements in more detail.

1) Contributions to the research process

The first requirement is to have provided a substantial contribution to the research process, anywhere from the conception of the idea to the analysis of the data. As the term 'substantial' is vague and open to interpretation the ICMJE list a number of examples of contributions that are *not* sufficient to merit authorship: acquisition of funding, general supervision of a research group, and general administrative support.

The Danish Code of Conduct for Research Integrity also lists a number of contributions that are insufficient for authorship. In section 4.1 it says: "Participation solely in the acquisition of funding, in the collection of data, or in general supervision of the research group does not justify authorship." (Ministry of Higher Education and Science, 2014) It is worth noting that here "collection of data" is included as it is in many fields a practice that sharing of data is followed by a co-authorship. The University of Copenhagen – Code for Authorship takes this into consideration when stating that: "The most important factor in describing authorship is for the author to have provided a significant (substantive) contribution to the research on which a publication is based. When establishing the criteria for this factor, the traditions of the individual scientific areas must be respected." (University of Copenhagen, 2017)

4 We have used capital-lettering to emphasize the logical connectives.

Thus, the requirement of a significant (substantive) contribution is not easy to interpret, even less when one should further take into consideration the traditions of the scientific field one works in. As discussed in chapter 2, this points to the importance of the motivation for following the different codes. If one simply seeks to stay within the letter of the law, the interpretation of "significant" will probably be more inclusive than if one seeks to incarnate the spirit behind the codes: That only those who have been part of the scientific part of a research project and made an intellectual contribution to this specific project should be merited with an authorship. But what exactly counts as significant or substantive is still up for discussion and should be so when assigning authorships, taking the traditions of the scientific field into account. This becomes even more important in interdisciplinary collaborations where different traditions might clash.

2) Contributions to the written text
The second requirement states that all authors must have participated in producing the written text. This may be through participation in preparing a draft manuscript or through critical revisions of important intellectual content in the final text. As a minimum this will require a careful reading of the manuscript where comments and suggested amendments are added. As examples of contributions that are *not* sufficient to merit authorship, the ICMJE group lists: writing assistance, technical editing, language editing, and proofreading.

3) Approval of the final manuscript
To claim an authorship it is necessary that all authors have read and approved the final version of the manuscript.
The formal way of claiming this is typically by signing a co-authorship statement required by the publishing journal. Often it will also be required to state which parts of the article the different authors are responsible for or have contributed to. By signing one confirms that the work to the best of one´s knowledge fulfills the demands of responsible conduct of research and is a valid scientific work. The importance of this is further explicated in the fourth requirement.

4) Agreement to be accountable
The fourth requirement was added in 2013. The ICMJE (2013) explains it this way:

> *Authorship involves not only credit for the work but also accountability. The addition of a fourth criterion was motivated by situations in which individual authors have responded to inquiries regarding scientific misconduct involving some aspect of the study or paper by denying responsibility ("I didn't participate in that part of the study or in writing that part of the paper; ask someone else"). Each author of a paper needs to understand the full scope of the work, know which co-authors are responsible for specific contributions, and have confidence in co-authors' ability and integrity. When questions arise regarding any aspect of a study or paper, the onus is on all authors to investigate and ensure resolution of the issue. By accepting authorship of a paper, an author accepts that any problem related to that paper is, by definition, his or her problem. Given the specialized and myriad tasks frequently involved in research, most authors cannot participate directly in every aspect of the work. Still, ICMJE holds that each author remains accountable for the work as a whole by knowing who did what, by refraining from collaborations with co-authors whose integrity or quality of work raises concerns, and by helping to resolve questions or concerns if they arise.*

The new element introduced here is the duty to help in resolving issues of potential misconduct if they arise. It is not possible for an author to deny responsibility for this by claiming that she or he is not responsible for the parts of the paper he or she did not participate in. A further implication is that authors need to assess the integrity and trustworthiness of all of their co-authors. This helps to ensure that authors who engage in questionable practices will end up in a position where others refrain from collaborating with them on publications.

The *Danish Code of Conduct for Research Integrity* (Ministry of Higher Education and Science, 2014) states: "In addition to being accountable for the parts of the work he or she has

done, an author should be able to identify which co-authors are responsible for other specific parts of the work." However, it is later clarified that responsibilities may be variable among co-authors:

> *All authors are responsible for the content of the publication. However, the responsibility of each author should be assessed subject to their individual role in the research by considering their area of expertise, their experience and seniority, a possible supervisory role, and other relevant factors. Thus, in some cases an author may have a wider responsibility than others for ensuring the integrity of the publication or specific parts of the publication.*

2.2 Deviating Practices

In some fields, particularly those involving very large teams of researchers, the Vancouver Recommendations are not considered adequate. Alternative guidelines, not least for these areas, are used by the journal *Neurology* (2017) and have been accepted, among others, in an editorial in the *British Medical Journal* by Baskin and Gross (2011), and these also seem to be echoed in *The European Code of Conduct for Research Integrity* (ALLEA, 2017, 2.7).

BOX 3: *NEUROLOGY'S* AUTHORSHIP POLICY

Criteria for qualification (intellectual contributions):

- Design or conceptualisation of the study
- Or analysis or interpretation of the data
- Or drafting or revising the manuscript

All authors acknowledge all versions.

Those who do not qualify as authors are listed as co-investigators or contributors.

Any paid medical writer who wrote the first draft or responded to the reviewers' comments must be included in the author byline.

All authors must complete and sign authorship forms with roles and contributions, disclosure forms listing all sources of potential bias, and copyright transfer agreements; author contributions and disclosures are published in the journal.

These requirements are less demanding than the Vancouver Recommendations. The crucial difference is that a co-author does not need to be involved in the actual writing of the text. In a large team, it is accepted that one or just a few authors may do the writing. Moreover, taking part in the writing is considered a sufficient intellectual contribution, in line with the Vancouver Recommendations. However, the requirement of full transparency about the role of each author is more demanding than the corresponding accountability rules in the Vancouver Recommendations.

Since the *Danish Code of Conduct for Research Integrity* (Ministry of Higher Education and Science, 2014) refers to the Vancouver Recommendations as its standard, one might think it would be a violation of the *Code* to follow *Neurology*'s authorship policy. However, the foreword of the *Code* says: "The Recommendations of the Code should always be understood in accordance with established practices predominant within the individual fields of research". This also echoes the previously quote from the University of Copenhagen - Code of Authorship that the traditions of individual fields should be respected. We see this as an indication that substantiated reasons based on practices within a certain research field may be justified as exceptions to the general policy. The Vancouver Recommendations should therefore be seen as exactly that: Recommendations. They are not a set of rules that can be followed blindly, but guidelines that require interpretation.

2.3 Order of authors

When submitting a manuscript for publication, it is necessary to decide not only who is to be listed as authors, but also the order in which order the authors should appear in the by-line. In some fields, authors are ordered according to the importance of their contributions, and special academic merit is therefore indicated by the authorial positioning. The author listed first (the 'first author') is selected for having contributed most significantly and for drafting the first manuscript. The last position on the by-line (often referred to as the 'senior author') is reserved for the (typically senior) principal investigator who had overall responsibility for the

project. The remaining authors are ordered according to the estimated significance of their contributions. Both first authorship and last authorship can be allocated to two people if their inputs were comparable; this should then be noted in the paper and can later be recorded in an explanatory footnote in the authors' CVs. However, again, these principles are not observed universally. In some fields, often with large teams of researchers, authors are simply ordered alphabetically. See Marusic et al. (2011) for a review of the meaning and practices of authorship across different disciplines. Typically, either the first author or the last author will be responsible for internal communication among all authors. Likewise, one of them will serve as the corresponding author who makes sure that the journal's guidelines are properly followed and communicates with the journal about responses to referees' reports and revisions of the manuscript. In some fields the senior author is normally expected to assume a special responsibility for the validity of the work, and he or she should therefore take extra care in reviewing the contributions of the other authors.

The ordering of authors in the by-line, especially where the positions of first and last author are concerned, can of course create conflicts. It is therefore advisable to prepare a draft statement when initiating a collaboration that specifically addresses this issue (see Box 4).

2.4 Authorship declarations

As previously mentioned, an increasing number of journals require all co-authors to submit a signed statement that they have read and approved the final version of the manuscript before it will be considered for publication. Some journals also require contribution statements that specify what each author has contributed, and some even ask to know what percentage of the work was done by each author.

For PhD students enrolled at a Danish university, the Ministerial Order #1039 of August 27 2013 on The PhD Degree Programme at the Universities and Certain Higher Artistic Educational Institutions (Ministry of Higher Education and Science (2013), sometimes referred to simply as "the PhD Order") specifies that where a dissertation includes articles written in collaboration with others, a written declaration, or co-author statement, describing the PhD student's contributions to the work must be submitted. Standard forms for these declarations can be found on Danish university websites. The co-author statements must be submitted with the dissertation, and if they are not completed correctly, the university may not accept the dissertation. At the University of Copenhagen, the Faculty of Science requires: "The co-author statement should always be signed by the first author, the corresponding-/senior author and the PhD student. If there are two or three authors the statement must always be signed by them all." At the Faculty of Health and Medical Sciences, where there are six co-authors or fewer, all must sign. If there are more than six, the corresponding author, the senior author and the principal supervisor must sign as a minimum.

These co-author statements are not to be confused with the co-author statements that journals require researchers to fill out when they are submitting papers for publication. Where the latter are concerned, specific requirements may differ from one journal to another.

2.5 Acknowledgements

If other researchers have contributed to the article in ways that do not merit co-authorship, their contribution can still be noted, and appreciated, in the acknowledgement section of the article. Admittedly, there is limited formal academic recognition in such an acknowledgement, but it nevertheless serves important functions. First of all, it is a question of expressing gratitude where it is due and thus increasing the likelihood that people will be willing to assist again in future. In some institutions the ability to demonstrate that one has assisted in a piece of research, even if not as a co-author, may itself be treated as a parameter of success. Finally, acknowledgements also help to make transparent who actually contributed to the work presented in the paper.

Acknowledgement does not imply responsibility for the content of the publication, but it may still be seen as an

endorsement of the paper; and on some occasions a person who qualifies for acknowledgement may not want to be seen as endorsing the work. The ICMJE group therefore recommends that "[b]ecause acknowledgment may imply endorsement by acknowledged individuals of a study's data and conclusions, editors are advised to require that the corresponding author obtain written permission to be acknowledged from all acknowledged individuals" (ICMJE, 2015, p. 3).

3. Undeserved and ghost authorships

In cases of undeserved authorship, a paper's author by-line will name an individual whose contributions do not merit authorial status. This questionable research practice can arise in a number of ways. The *Danish Code of Conduct for Research Integrity* (Ministry of Higher Education and Science, 2014) states (4.1 viii): "Guest authorship (i.e. listing authors who do not qualify as such) or ghost authorship (i.e. omitting individuals who should have been listed as authors) should not take place."

3.1 Gift authorship

Gift authorship (also sometimes known as *honorary authorship*, or, when asymmetric power relations are involved, *coerced authorship*) is an authorship that has been granted to, and accepted by, a person who does not fulfil the requirements for authorship. The reasons for granting gift authorships vary. At some institutions, and in some fields, the head or director of a unit (e.g. a department, laboratory or research group) has traditionally been added routinely as co-author of all articles published by the unit. However, if he or she does not satisfy the requirements of authorship described above, this is gift authorship and therefore undeserved.

Sometimes authorship is granted to a person who does not satisfy the requirements for authorship because one of the other authors owes him or her a favour; or authorship may be granted in order to strengthen a relationship through the exchange of a gift. Sometimes, however, this exchange can involve coercion – e.g. when a lab whose assistance is needed for some routine services request co-authorship in return, even though this is not merited by their contribution.

Gift authorships are also sometimes swapped among researchers as a way to artificially inflate their publication lists. But note that, according to the Vancouver Recommendations, in receiving a gift authorship one becomes accountable for work that one has not been involved in – and may not even know about.

3.2 Planted authorship

A planted authorship is a gift authorship that the recipient was not informed about. In such cases, the intention is normally not to benefit the recipient, but to strengthen the impression that the article has a good pedigree (and perhaps also to facilitate passage through the peer-review process) by including a highly ranked or well-known scientist as co-author. This is problematic for several reasons. First of all, it obviously gives a false impression of the real authorship, and thereby of who is responsible for the content of the article. And, unknown to him or her, the recipient of the gift may end up being held responsible for research which turns out to be of low quality or perhaps even an example of misconduct. To the extent that journals require signed co-authorship statements from all authors, planted authorships are likely to become extinct.

3.3 Ghost authorship

Ghost authorship is the opposite of gift authorship. In it, despite deserving authorship, one or more authors are hidden by being omitted from the by-line. This may be done to hide a possible conflict of interest. A typical case is an author from a private company who fears that a paper will lose in credibility if she or he appears as author, thereby signalling that the research involved a collaboration with industry. However, the Vancouver Recommendations state clearly that authorship is not only a right, but also a duty. If a person satisfies the criteria of authorship, she or he should figure as an author. More and more PhD projects are undertaken in close collaboration with industrial partners who have a direct commercial interest in the results. In these cases, transparency about authorship and funding is very important. For more on conflicts of interest, see Chapter 7.

A number of cases have been uncovered in which medical companies have managed to get drug studies published with

the authorship of seemingly independent researchers who downplayed the risks or overstated the benefits of a drug, but did not in fact participate in the research. This is of course highly questionable practice, as it makes someone responsible for research they didn't conduct and at the same time can hide commercial interests. Wislar et al. (2011) found that more than 20% of the articles in six high-impact medical journals had gift authors, ghost authors, or both.

4. Negative impacts of undeserved authorships

4.1 How widespread is undeserved authorship?

According to the International Association of Scientific, Technical and Medical Publishers (Johnson et al., 2018), in late 2018 there were about 33,100 English-language (plus a further 9,400 non-English) journals in the fields of medicine, science, and technology. Together these journals were publishing more than 3 million peer-reviewed articles a year. It has also been found that the number of authorships has increased at a much higher rate than the number of articles (Plume & van Weijen, 2014). In the decade from 2003 to 2013, the number of articles grew from 1.3 to 2.4 million; in the same period, the number of authorships went from 4.6 to 10 million.

A study of research misconduct and questionable research practices in general (Martinson et al., 2005) based on anonymous self-reporting by several thousand early- and mid-career researchers funded by grants from the US National Institute of Health (NIH) showed that 12.3% of mid-career and 7.4% of early-career researchers had engaged in "[i]nappropriately assigning authorship credits" within the last three years. In another study, this time of German universities, Böhmer et al. (2011) found that by far the most common questionable research practices related to authorship. More than half of the respondents reported that they had experienced such issues.

A smaller Danish study recently looked at attitudes towards and experiences with research misconduct among PhD students affiliated with the Department of Clinical Research or Department of Regional Health Research at the University of Southern Denmark. 165 of 330 PhD students completed a questionnaire (anonymous self-reporting) on whether they had been involved in or heard of colleagues being involved in a number of behaviors expressing research misconduct or questionable conduct of research. 22% stated to have felt an unethical pressure (within the past year) regarding the inclusion or the order of authors. (Jensen et al., 2018)

Yank and Rennie (1999) examined contribution statements published with articles in the medical journal *The Lancet*. Analyzing descriptions of the contributions of individual authors, they found that 44% of authors did not satisfy the Vancouver Recommendations.

Focusing specifically on authorship, the study by Wislar et al. (2011) mentioned above surveyed six general medical journals with high impact factors. Corresponding authors of a randomly selected sample of articles were asked about the contributions and roles of all authors. On the basis of the replies, it was investigated whether all of the authors of each article had complied with the Vancouver Recommendations on authorship. The results showed improper authorship affected 21% of the articles. Comparing the results to those of a similar study from 1998 by Flanagin et al., which had found improper authorship in 29% of articles, Wislar et al. concluded that increased efforts by both journals and academic institutions would be important for maintaining integrity in scientific publishing.

Thus, although the Vancouver Recommendations are widely accepted, authorship issues remain widespread. This is confirmed by the fact that most of the cases handled by the Practice Committee and the Named Persons in the University of Copenhagen's Faculty of Health and Medical Sciences and Faculty of Science concern authorship issues.

4.2 What's the problem?

The reasons why undeserved authorship and ghost authorships are considered a questionable research practice or, in very serious cases, research misconduct relate to the impact of these practices on colleagues, science as an institution, and society.

For one thing, boosting your publication list with false authorship gives you an unfair competitive advantage. You are simply cheating or, as it is sometimes put, participating in "academic doping". Secondly, incidents of guest, planted and ghost authorship may harm science as an institution. For one thing, they make it unclear who is responsible for what in the scientific literature. Knowing who is responsible for what is important when questions or criticisms relating to methods, data or the interpretation of results are raised. Further, public knowledge of undeserved authorship practices damages the reputation of science and scientists, and may in the long run undermine society's trust in results. Finally, from the perspective of society, a practice of crediting undeserved authorships, and not crediting qualified authorships, implies that resources may not be being allocated optimally. Many countries invest a great deal in scientific research in the hope that this will help us to solve the grand challenges facing the global community today (from climate change, to cancer, to famine), or simply to promote economic competitive advantage. Since authorship is the most important parameter for obtaining academic positions and funding, its mis-representation means that the resources spent on science will not necessarily end up with the best-qualified scientists, but rather with those who are best at appearing to be strongly qualified, perhaps via undeserved authorship, false citations and the like.

Given these impacts of undeserved authorship, it is not surprising that increasing attention is being given to it – both with respect to how authorship can be made more transparent through better implementation of, for example, the Vancouver Recommendations, and with respect to the question of how to evaluate the qualifications of individual scientists more accurately and thereby discourage the negative consequences of a "publish or perish" climate.

5. Other publication issues

5.1 Prepublication

Different disciplines operate very different practices of pre-publication. In physics, mathematics and related disciplines, where peer-review may take several years, it is common to submit papers to a publicly accessible pre-publication archive. For example, www.arXiv.org holds papers from physics, mathematics, computer science, quantitative biology, quantitative finance and statistics. When the paper is finally published, the author should notify arXiv; the arXiv publication should at this point be deleted from the author's publication list and give way to the journal version.

In complete contrast with this approach, many journals in other fields will *not* publish results based on data that have already been presented publicly – e.g. in conference proceedings. This is especially common policy in biomedical sciences. Before engaging in prepublication, it is therefore wise to check whether it would preclude later publication in the relevant journals. It is also necessary to be careful about when and where to present data and results at conferences. A PhD student should check with his or her supervisor before presenting work in any public forum, to avoid problems of this kind.

Secondary publications – republishing data in a different journal – is generally considered an acceptable way of reaching different audiences (e.g. a national audience, or researchers from different fields), but they normally require the agreement of both the original and secondary journal, and must be made fully transparent by inserting a cross-reference to the original version of the article. As a general principle, the *Danish Code of Conduct for Research Integrity* (Ministry of Higher Education and Science, 2014) states (3.1 ii): "Publishing the same results in more than one publication should only occur under particular, clearly explained and fully disclosed circumstances."

The guardians of the Vancouver Recommendations, the ICMJE (2018), lists the following conditions:

1. *The authors have received approval from the editors of both journals (the editor concerned with secondary publication must have access to the primary version).*
2. *The priority of the primary publication is respected by a publication interval negotiated by both editors with the authors.*

3. *The paper for secondary publication is intended for a different group of readers; an abbreviated version could be sufficient.*
4. *The secondary version faithfully reflects the data and interpretations of the primary version.*
5. *The secondary version informs readers, peers, and documenting agencies that the paper has been published in whole or in part elsewhere—for example, with a note that might read, "This article is based on a study first reported in the [journal title, with full reference]"—and the secondary version cites the primary reference.*
6. *The title of the secondary publication should indicate that it is a secondary publication (complete or abridged republication or translation) of a primary publication.*

Undisclosed duplicate publication is in general discouraged, and is likely to be treated as questionable research practice (so-called "self-plagiarism"). It may distort the scientific record by giving undue weight to the results, as they are reported several times. For example, if the same data from a study of the side-effects of a medical treatment are published several times, review studies will be skewed and ultimately, this may place patients at risk (see Tramer (1997) for a case study).

5.2 Inappropriate recycling of material

When sections of the same text appear in several of an author's publications, this is referred to as "text recycling" and is another form of self-plagiarism. Attitudes to text recycling have developed within disciplines over time and vary from field to field. Unfortunately, there is no well-defined boundary indicating when a textual overlap between two articles is so substantial as to be classified as a case of recycling. See, for example, Bretag and Mahmud (2009) as well as Bruton (2014) for more detailed discussions of the definition of text-recycling.

The Danish Code (Ministry of Higher Education and Science, 2014) has the following policy (3.1 iii): "Recycling or re-use of primary materials, data, interpretations or results should be clearly disclosed." In some fields, a certain degree of recycling is difficult to avoid, especially in sections such as methods and materials. In these cases, recycling may even be encouraged to ensure a precise and easily recognizable description of, for example, a technique. However, such recycling should be made transparent in a cross-reference to the earlier article in which the material, method or technique was first described. Similarly, previous work may be recycled to serve in the introduction to a new article, but again such recycling should be made transparent in cross-references.

5.3 Manuscripts based on the same database

With regard to multiple publications based on the same dataset, the ICMJE (2018) states that:

> *Editors might consider publishing more than one manuscript that overlap in this way because different analytical approaches may be complementary and equally valid, but manuscripts based upon the same dataset should add substantially to each other to warrant consideration for publication as separate papers, with appropriate citation of previous publications from the same dataset to allow for transparency.*

Lack of transparency is problematic because readers can be led to believe that the reported results derive from different studies or samples, distorting the scientific record.

Data fragmentation occurs when available data is partitioned so as to produce multiple articles, where they could instead have been published together. Sometimes, this is done deliberately with the purpose of creating more publications – a ploy known as "salami publiation". In some cases, data fragmentation is considered a questionable research practice because it gives the author an unfair advantage in building his or her list of publications and citations, and because it wastes time and resources, e.g. the time of the researchers who peer review or revise the papers. However, it is difficult to pin down exactly when the practice is dubious, because word limits and other restrictions imposed by journals may actually prohibit publication of the material in one paper. In all cases, transparency and the ideal of contributing to the scientific record with as much value as possible should be the guiding principles.

5.4 Plagiarism versus proper attribution

In science, researchers almost always draw on previous work by others, whether data, results, or other text. Unless this work has become so established that it is considered common knowledge, the use of another researcher's work should always be clearly attributed, and references to the original work should be sufficiently detailed to enable readers to find the relevant passage. Verbatim text taken from the work of others must always be marked as quotation, and paraphrases as well as translations must always be accompanied by a reference to the original. Failure to do this is plagiarism, which may be considered a form of scientific misconduct (see also Chapter 2).

Authors writing in a language other than their native tongue may find it tempting to use phrases they have read in the publications of native speakers (see Yilmaz (2007), for such a case). However, while this may be a good strategy for language learning in everyday conversation, it is a questionable practice in academic publications, where it counts as plagiarism. Software developed to detect similarities between multiple texts, including programs that compare a submitted text to all publications available in a particular corpus (e.g. arXiv, MedLine abstracts, etc.), has revealed many cases of plagiarism in the literature (e.g. see VroniPlag (n.d.) or Déjà vu (n.d.)). In addition, more and more journals are now running new submissions through plagiarism detection software like iThenticate or Turnitin. All PhD dissertations at the Faculty of Health and Medical Sciences, University of Copenhagen, are routinely checked by iThenticate before being accepted for further assessment.

5.5 *Publication of negative results*

It can be difficult to get negative results published. To attract readers, journals generally seek to publish new and exciting findings, and grant-giving agencies and foundations have a similar leaning, since they need to demonstrate that their money is being well spent. This has led to an environment where positive results are much easier to publish than negative ones, even though negative results can be of high scientific value. Just imagine the time that you could save if you did not have to go through a laborious research process to find out that your hypothesis is wrong, but could rather read that others had already provided the relevant disproof. In recognition of this, journals specifically aimed at publishing negative results have appeared, such as *The Journal of Negative Results in Biomedicine*. Such journals are very valuable to the scientific community, but usually they have a low impact factor and are thus less attractive to publish in.

Plainly, failure to publish negative results may lead to publication bias. If it is easier to publish studies with positive than negative results, there is a risk that reviews of the literature will show a false picture of the world, with the positive results being given disproportionate weight. However, as is stressed in the *Danish Code of Conduct for Research Integrity* (Ministry of Higher Education and Science, 2014), researchers have a responsibility to be transparent about their results, which must imply being open about negative results as well as positive.

5.6 Predatory journals

As mentioned above, publishing papers is part and parcel of a career in the academic world and especially important early in your career. It can therefore be exciting to receive almost daily offers to publish your work in your inbox. It can be very flattering to hear that other researchers and editors find your work so interesting that they have written directly to promise you a smooth peer-review process and swift publication. However, if you read the e-mails closely, you should become skeptical. Many of the offers are from journals whose titles do not connect to your work, the name and address of the organization behind the sender does not ring any bells. If the offer seems too good to be true, it probably is.

With a growing number of PhDs, and the "publish or perish" culture within academia, a number of so-called "predatory journals" have arrived. They are journals that pretend to be outlets for academic research, but in reality are only interested in money. They have no scientific merit, and publishing in them will typically cost you money and bring no academic credit. It may be hard to figure out whether these invitations are relevant for you and whether they come from a real, new

and upcoming journal that would be relevant for you. As with scams everywhere, some are very convincing. The library at The University of Copenhagen have therefore developed some guidelines to help you distinguish between predatory and real journals. Here are the most important advices:

- Check if the journal is indexed in Web of Science and/or Scopus.
- Find the homepage of the publisher/journal and see if it looks trustworthy.
- Who are the editors, where do they work, and what is their e-mail address? Can you find independent evidence of these details online outside of the supposed journal homepage, and are they based at credible institutions?
- How is the peer-review process structured, does it follow a standard path?
- Is there a list of reviewers, and where do they work? Again, can you find independent evidence of these details online outside of the supposed journal homepage, and are they based at credible institutions?
- Look at a couple of recently published articles and assess their quality and the trustworthiness of the authors.
- Use Curis to check if other researchers from The University of Copenhagen have published in the journal.
- Check journal ranking, but be sure that it is a widely accepted ranking.
- Ask your supervisor or ask the library.

By following these guidelines you should be able to avoid wasting your research and time publishing in a predatory journal, thereby securing that your research will be properly peer-reviewed and contribute positively to the scientific community. You can find the guidelines and additional information on predatory journals at KUnet.

5.7 Non-academic publications

The Vancouver Recommendations apply to academic publications only. These include peer-reviewed articles in journals, but also chapters in collections and monographs published by academic publishers, as well as publications without peer-review that are nevertheless research publications. However, most scientists also publish other kinds of writing, such as popular articles for the general public. Often such non-academic publications are based on previously published academic papers.

There are no formal academic guidelines for non-academic publications, but the general rules and guidelines covering publishing apply to them – e.g. copyright regulations. Although the Vancouver Recommendations ignore non-academic publications, it may still be wise to consult others and discuss how their contributions should be recognized when you are considering non-academic publication.

6. How to manage your publications as a PhD student

As a PhD student you will need to manage your authorship and publication issues yourself, since you cannot expect anyone else to take responsibility. However, this may involve difficult situations. On the one hand, you are responsible (in part) for decisions about who is added as a co-author to the by-line of your articles. On the other hand, you might work in an environment where you come under pressure to accept a questionable practice; and whistleblowing may give rise to conflict with your collaborators.

To minimize the risk of unpleasant conflict we suggest that you follow the advice given in the "Guide to minimizing authorship issues" (see Box 4) below.

If you ever come under pressure to grant co-authorships in return for access to technical equipment or routine services, you should ask your supervisor to assist you in the negotiations. In the unfortunate circumstance that your supervisor turns out not to be helpful, you may contact the Named Person designated for your faculty and seek advice.

In the last resort, after consulting the available guidance, the question is: Do you want to make a complaint because you cannot agree to engage in a questionable practice? Or is the prospect of repercussions by making a complaint so serious that, under the circumstances, you would prefer to accept a

questionable practice? This is not an easy choice, since both alternatives may lead to negative consequences. But in the end, only you can decide.

7. Test yourself questions

- What are the Vancouver Recommendations' requirements on authorship?
- What should you do if you observe someone being credited with unwarranted authorship?
- What should you do if someone requires to be a co-author of your paper?
- Who can you approach for help with conflicts over authorship?
- Should a researcher who participates in data acquisition and analysis, but who lacks the skills in English to engage in the writing process, be credited as a co-author?

BOX 4: GUIDE TO MINIMIZING AUTHORSHIP ISSUES

Arrange a meeting with your supervisor on publications for your PhD. One of the items on the agenda should be authorship issues.

If it is relevant, make it clear that you intend to follow the Danish Code of Conduct for Research Integrity or The Vancouver Recommendations. Discuss at the meeting how you will manage your publications in the light of these documents.

When you are initiating collaboration with others on an article, always make a draft statement that specifies who is to be included as a co-author and how the workload will be distributed, and seek to ensure that the parties involved accept and sign up to it. Encourage people seeking co-authorship to make suggestions as to how they can contribute to qualify as co-authors – this applies equally to heads of department and fellow PhD students. Keep a record of agreements to consult in cases of doubt. Of course, initial agreements may need to be revised as the work progresses, and initial agreements may include a list of areas where the relative contributions are yet to be determined, but changes and clarifications should be recorded explicitly. Make sure to have the co-authorship statements that are required for submitting your dissertation ready and signed by all relevant parties before submitting a manuscript.

If a co-author wants to withdraw because of disagreements over the final manuscript, the guiding value should be transparency. For example, it might be advisable to briefly explain the withdrawal in the acknowledgements.

See more in Richard et al. (2014)

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5.
Research Data Management

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Summary

Good research data management is a crucial foundation of transparent, trustworthy research. Therefore, research institutions, funding agencies, scientific journals and policy-makers – led by the European Commission – have been investing increasingly in efforts to improve practices for the management of research materials and data. But what is 'good' research data management, and how do we define 'research data' in the first place? In this chapter, we provide an overview of research data management throughout the research process. We illustrate the various benefits of establishing best practice in research data management for the individual researcher, including higher levels of efficiency and security during the project and improved visibility and impact of results.

1. Introduction

With a few exceptions – for example, mathematical and philosophical studies – almost all research activities revolve around the description, interpretation and analysis of some kind of primary material or data, defined in The *Danish Code of Conduct for Research Integrity* as follows:

> *Primary material is any material (e.g. biological material, notes, interviews, texts and literature, digital raw data, recordings, etc.) that forms the basis of the research.*
>
> *Data are detailed records of the primary materials that comprise the basis for the analysis that generates the results.*

For an anthropologist, primary material could be videos or interviews, and the corresponding data could be the transcripts of these videos or interviews. For a geneticist, primary material could be tissue samples, while data could be the digital DNA sequences obtained from these samples. Please note, that unless we specifically state otherwise, we will collectively refer to the abovementioned primary material and data as '*research data*' (or in short: '*data*') in this chapter. Thus, research data will include any qualitative or quantitative information used for research purposes – for example, transcriptions, translations, digitized copies, output from analyses and intermediate results. Countless types of research data exist, depending on the discipline, the format, the purpose for which the data are used, and the collection method (e.g. via measurement, observation, simulation or aggregation from public or commercial sources).

Besides producing or using research data, there are of course also other elements in a research project: the formulation of a research question, the reviewing of existing findings, and critical discussion and dissemination of the results. However, if the research data are not in order, then all other components will usually have little scientific merit. Two of the three main forms of research misconduct presented in Chapters 2 and 3 relate to the way researchers obtain, process and record their research data. Falsification and fabrication occur when data are wholly made up, or partly supplemented with fictitious information, or when some data are deliberately omitted to skew the results. Here, the entire project or research product must be deemed fraudulent. It is easy to see why such practices are to be condemned and policed: they waste precious time and funding, threaten to undermine the reputation of science and the public's trust in research, and in some cases may even cause harm to those whose actions are guided by spurious research findings (e.g. the Wakefield case, Chapter 2, Box 1). However, when it comes to setting out exactly what good research data management looks like, numerous questions present themselves. Such questions may include: what permissions are required before the research data are collected? How will the data be recorded, and measured, or compiled? What needs to be digitised, transcribed, translated or treated in a particular way? What information is needed to document data management methods? Where will the physical material and digital data be stored, and who will be responsible for them? How will access to data be secured? What information will be shared with others, and when? How will valuable research data be archived and for how long?

The above questions are to a large extent methodological, and most answers can be found within existing practices of the relevant field of research. However, the questions also touch upon wider ethical issues that go beyond a technical discussion of methodology, as is for example evident when

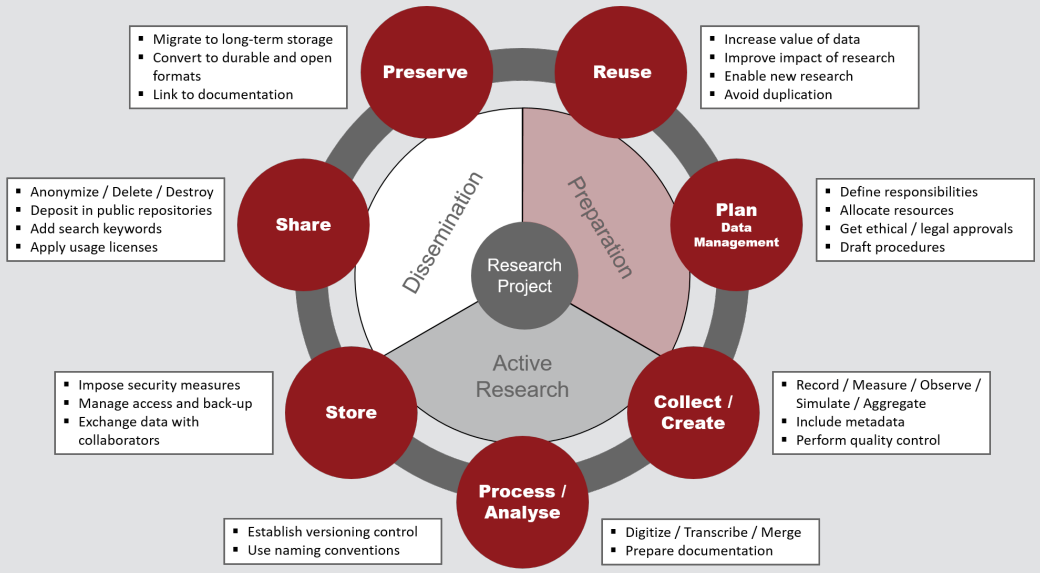
it comes to sharing of data with the broader research community. A publication in *Nature* in 2019 observes that:

> *Science is moving towards a greater openness, in terms of not just data but also publications, computer code and workflows. Yet researchers who are learning to navigate the open-science arena face a thicket of thorny issues. Many scientists — especially early-career researchers who are building a publication record — worry that sharing their data too early could lead to their getting scooped by a competitor. They must also decide whether to spend valuable time curating and sharing data sets...*
> *However, opening up data can yield benefits: it can catalyse new collaborations, increase confidence in findings and generate goodwill among researchers. (Popkin 2019)*

The example above, like others that could be given, illustrates that data sharing is not necessarily straightforward. Despite an increasing number of requirements imposed by funders, journals and institutions, data sharing practices and other aspects of research data management are clearly up for discussion, and views on appropriate conduct will likely continue to change. What today may be seen as part of a burning cultural debate requiring seemingly unmanageable changes, may in the future be a normal part of what is taught as responsible and ethical conduct of research.

In the rest of this chapter, we will take a closer look at some of the main actions taken to manage research data. The chapter is structured according to the 'research data lifecycle', which illustrates the typical phases of a research project, shown below in Figure 1. In short, we will discuss how to best plan your research data management, how to collect, process, store and secure your research data during the active phase of the research project, whether and how to share your data with others after your project has concluded, what to consider when preserving research data, and what documentation to generate and maintain along the way. The aim of this chapter is to outline general norms of good research data management and to discuss the ways in which these norms can be implemented across disciplines.

FIGURE 1. THE RESEARCH DATA LIFECYCLE, ILLUSTRATING DIFFERENT ASPECTS OF RESEARCH DATA MANAGEMENT THROUGHOUT THE COURSE OF A RESEARCH PROJECT



2. Planning research projects

Research data management starts before any research data are collected in the form of project planning. This is an essential part of every research project; in this phase you define the experimental design and set-up your protocols. You determine who has a right of access to the data you will generate or collect during and after the project, and who will be responsible for the data in the future (which may mean when you are no longer employed at the university). If you work with big data sets it is important to plan where you will store them; if you work with sensitive material or data, it is essential to plan how you will secure them.

2.1 Data Management Plans

A good tool to help you plan your research project is a data management plan (DMP). A DMP is a document in which you describe actions to be taken during all steps of the research data lifecycle (Figure 1), based on a number of questions. Increasingly, DMPs are required by funders in Denmark and abroad (e.g. the European Commission) as a component of funding proposals, and more and more institutions are asking their employees and students to produce DMPs at the start of research projects.

If you are a PhD student, it is a good idea to discuss the DMP with your supervisor before you start collecting data, to see whether your expectations align when it comes to managing your research data. For example, it is important to know the answers to the following questions: Are there any standards for data formats in your discipline? What is your strategy for describing the research data, and for preventing data loss? If you need to collect quantitative or qualitative data in the 'real world', how can you store it securely whilst travelling? What should be done with any physical material and data after your project has ended? Discussing all of these issues beforehand will save you time (and possibly trouble) once you have started the project. The process of making and discussing a DMP will likely be useful in any discipline that collects new research material, or reuses existing data, even if some of the questions in a DMP seem not to be directly applicable to your project and have to be rephrased a little – for example, to match more qualitative studies.

You can design your own data management plan. Alternatively, you can use an existing template for example one provided by the funder from which you have received or expect to receive funding, or by your own institution. To show you how a DMP might look, we have collected information from three real plans, with the consent of their creators. Excerpts taken from these DMPs are presented in the appendix at the end of the chapter, together with links to the plans themselves.

2.2 Ethical and legal approvals

One part of the planning process involves obtaining approvals of various sorts. If you are working in a field where the collection of physical material and data, or other aspects of research data management, require ethical or legal approval, it is your obligation to acquaint yourself with the relevant legislation and ensure that all of the required permissions are obtained before you start the project. An overview of approvals you may need is provided in Box 1. Please be aware that this list is not exhaustive, and that the requirements may change over time. Also, if you engage in international collaborations, you should be aware that requirements may vary across countries.

Ethical and legal approvals are most likely to be needed when projects involve human subjects, human material and/or personal data.

- *Personal data* are defined as data relating to persons who can be identified directly or indirectly using those data. Examples are (references to) CPR numbers or other unique identifiers. The management of personal data in research projects must comply with the General Data Protection Regulation (GDPR), and failure to comply with this could lead to economic penalties for the institution at which the researcher is employed.
- *Pseudonymous data* (or pseudo-anonymous data) are data from which individuals can only be (re)identified indirectly

BOX 1. CHECKLIST OF APPROVALS AND REGISTRATIONS THAT MAY BE REQUIRED BEFORE PROJECT START

Please note that the list may not be complete.

Does your study involve human participants?

- Approval from the Regional or National Committee on Health Research Ethics.
- Approvals from an institutional ethics committee at UCPH (institutional review boards) for projects that are not covered by the Regional/National Committee. This can e.g. be a requirement from journals for research including surveys and interviews.
- Registration of your clinical trials in databases like clinicaltrials.gov.
- Informed consent from study participants a) for their participation in research projects, and b) for the processing of their personal data during and possibly after the project.

Does your clinical research project include test of drug(s) and/or medical equipment?

- Approval from the Danish Medicines Agency.

Is your research based on information from hospital records?

- Approval from the Danish Patient Safety Authority.

Does your research involve gene technology or therapy?

- Approval by the Danish Working Environment Authority.

Does your research involve radiopharmaceuticals?

- Approvals by the Danish Medicines Agency.

Does your study involve animal testing?

- Approvals by the Animal Experiments Inspectorate.
- Evidence of the necessary qualifications in animal handling according to Danish law. For more information, see the webpages of SUND Department of Experimental Medicine.

Does your study involve personal data, including biobanks?

- Registration of your project at the university, via the Faculty Secretariat and with approval by the head of your department.

Do you want to publish your research findings?

- Evidence of approvals by the committees, boards, agencies, authorities listed above, at the request of the publisher.

using supplementary information, such as an ID key. As long as this supplementary information exists, even if it is stored by a different organisation or a person who is not associated with the research project, the data should be treated as personal data, and extreme care should be taken to manage them in accordance with GDPR. However, when personal data are fully anonymised, they can be managed in the way any other non-sensitive data are.

- *Anonymous data* are data where the individual is not, or is no longer, identifiable, and could not be identified by further processing of the data. In determining whether your data are anonymous, you should take into account the possibility that a combination of metadata or variables may potentially permit re-identification of individuals.

Box 2, and appendix 2 on GDPR at the end of this book, provide an overview of the data management actions to be taken, and of the considerations to be taken into account when you are planning and carrying out projects involving human subjects, human material and/or personal data. For more information you should consult the University of Copenhagen's intranet pages on personal data, or contact a member of staff with expertise in supporting those conducting research involving personal data, and human subjects or material.

BOX 2: OVERVIEW OF DATA MANAGEMENT ACTIONS IN PROJECTS THAT INCLUDE HUMAN SUBJECTS, HUMAN MATERIAL AND/OR PERSONAL DATA

When working with human subjects, human material and/or personal data (including pseudonymous data) at the University of Copenhagen, there are some additional actions to take and/or to consider. A summary of these actions is listed below and in appendix 2 at the end of the book. You can find more information on UCPHs intranet pages (Research Portal on KUnet), including details of who to go to for support.

1. The requirements for the ethical and legal approvals necessary before project start are outlined in Box 1.

2. Whenever personal data and/or human material moves from one institution to another, this must be fixed in an agreement, for example:
   - A data processing agreement: when data for which UCPH is responsible are to be processed by other institutions or by Master or Bachelor students during the project.
   - A data disclosure agreement: when data for which UCPH is responsible are to be transferred to others outside the university after the project's end. You will need permissions from the Danish Data Protection Agency if 1) personal data are to be sent to countries outside the EU, 2) when human biological material is to be transferred, and 3) when personal data are to be published in scientific journals.
   - A cooperation agreement and an agreement on shared responsibility for data protection: when UCPH shares responsibility for the data with an external collaborator.

3. You must create an ID key as the only way of connecting the subject's personal data or biological samples with his or her name or other identifiers. The ID key should be stored separately from the data, and all other documents or biological samples, in order to restrict access to the identity of the subjects.

4. You must anonymise data as soon as possible in the project. This includes destroying the ID key.

5. You must keep personal data, including pseudonymised data, ID keys, informed consent forms and any physical material in secure locations and under lock and key. By default, digital files should be kept on your personal university drive, or on the S drive if you collaborate with other UCPH employees.

6. Data should be anonymised when you share data with externals. If anonymization is impossible, pseudonymous data should be encrypted before sending with secure solutions such as the Bluewhale plug in for email, or Microsoft OneDrive for Business. The ID key must remain at UCPH.

7. At project end, either 1) anonymise data sets, 2) destroy data sets that cannot be anonymised and where (legal) obligations dictate destruction, 3) transfer data sets to the Danish National Archives, or 4) transfer data to a secure database if the participants have consented to this.

8. You must immediately report any breach of security (e.g. disclosure of personal data to unauthorised persons) to your department's information security representative, the IT Service Desk and Information Security Unit, and obtain guidance on how to respond to the breach.

2.3 Rights to, and responsibilities for, physical material and data
Before starting a research project, you should clarify the rights to, and responsibilities for, the data and materials collected or generated by the project. This helps you to prepare for, and ideally avoid, many of the issues that can arise in collaborations. It also clarifies who will do what with the research data during and after the project, and can also help to avoid certain forms of authorship dispute. Unfortunately, determining rights and responsibilities is not always straightforward. For one thing, rights to research data are defined by a number of legal rules (e.g. personal data law, law protecting patients, copyright law, design law, property law, and general contract law). In this chapter, we cannot cover all of the relevant legislation. We therefore recommend that you talk to your supervisor(s) and/or project collaborators before embarking on your project, and as a starting point determine:

1. *To what extent you will have access to, and be permitted to obtain a copy of, the data and/or materials collected.* For example, if you obtain data and materials from other sources, it is important to know what you can and cannot do. There may be agreements in place that regulate access, such as material transfer agreements. If you work with industry partners, there may be contracts with these partners defining how materials and data can be used.

2. *To what extent you may (re)use the materials and/or data – for example, in other projects and for other purposes.* This includes agreeing on which rules apply if you or your collaborators leave the project prematurely, when you complete the project, or finish your employment at the university. At that point, would it be acceptable for you to use the data and/or materials in the new project even if you are working in a different team, lab, or university? Physical materials, such as tissue samples, geological samples and paper laboratory notebooks are subject to common property rights, which means that by default they belong to the institution at which you are employed. Thus, you cannot remove them at the end of your employment or project without seeking permission first. Please note, that at the University of Copenhagen researchers must leave a copy of their digital data sets at the university, unless legislation precludes it, or it has been otherwise agreed upon.

3. *Whether there are regulations that cover the above, and what disciplinary measure will be taken if the terms of these regulations are violated.* For example, if you work with personal data, you should be aware of the rules concerning data confidentiality and how these rules limit access to data by you, your collaborators, and others. How will you ensure these rules are followed, and what penalties might you expect if they are violated?

4. *Intellectual property rights* (see Chapter 6).

5. *All data management and sharing requirements of funding bodies and partner organisations.* For example, many funders require data to be made publicly available at the end of the project ('Open Access' to data, also called 'Open Data'). Check your funder's requirements and recommendations carefully and discuss what they mean for your data management.

6. *Any local regulations on rights to research data*. It is important to note that the University of Copenhagen has a policy on research data management. This must be followed. Additional regulations and guidelines may exist within your faculty, department or research group. Also be sure to check the (PhD) contract you signed at the start of your employment.

3. Collecting and processing physical materials and research data

It is essential that you provide a thorough and clear description of the research data you collect, and the way they are being, or were, processed. Doing this as you go along will save you a lot of time and effort later on. Please note that you should aim to provide records of your research that are transparent to, and useable by, others; your supervisor may wish to replicate your study, or one of your peers may be

enthused by your work and ask to use your sampling design or protocols in their own research. In the following section, we describe good practice and methodological consistency when recording and processing research data.

3.1 What should you record

Your research plan

Apart from describing your data management in your DMP, it is a good idea to set out the background of your research project in more detail in a research plan that is kept with the research data for the duration of the data's existence. A research plan may be referred to as the project 'description', 'proposal', 'protocol' or 'investigation plan', and can be part of your PhD plan. In the research plan, you outline what the project is about, the background, the aims, methods, research questions, expected results, any collaborations, time schedule, resources, dissemination, risks and approvals. By describing the background of your research project in detail, you will be able to demonstrate the importance of your topic and the knowledge gap the research will address. It is important to be specific. Keep the plan relatively short, focus on the major themes, and ensure the language is understandable to others. Be aware that different research fields, communities, institutions and funders may have templates for research plans and requirements for preregistration of these plans in specific databases such as PROSPERO (health, welfare and social care), ClinicalTrials.gov (medicine), WHO registry Network (health), AEA registry (economics) or EGAP (governance & politics). The benefits of preregistration include the prevention of publication bias, ensuring that negative results and failed projects see the light of day, and committing researchers to a fixed plan to make them think harder about a project before it begins (Kupferschmidt, 2018). Of course, a summary of some of the research plan can be included in the data management plan and vice versa. Here, a little repetition is unavoidable, but the one does not replace the other.

The nature, quantity and location of research materials

You should keep clear records of any materials used in your project to generate research data. It is the duty of the research institution to provide proper storage facilities, such as freezers and secure storage cabinets, and instructions on how to use them. It is your responsibility to draw up a storage/documentation plan in collaboration with your supervisor or project partners. This plan could be recorded in the DMP and should describe informed decisions on what to keep in storage, where, and for how long, in line with best practice in your field and in accordance with legislation, regulations and agreements. What is most important is that you provide thorough records which allow data to be traced back to the physical material they were generated from. You should therefore ensure that your physical materials are labelled properly (e.g. with a sample ID, date of collection, a short description, the name of the person in charge of the project), and that this information is recorded in your data file together with your digital research data.

Research data generated or collected

If you work in a laboratory, you will probably use a paper or electronic lab notebook to record research data. These notebooks have been used as the basis of claims to intellectual property (e.g. rights to patents), and to show who invented something first. They can be offered as evidence to defend against accusations of research misconduct (e.g. Nickla and Boehm 2011, Ledford 2016). It is therefore important that you use lab notebooks appropriately, by recording data directly in a way that cannot be altered at a later stage, as well as adding dates to your records and signing the pages. Researchers in other disciplines may not use a lab notebook. Instead they may use field notes, or code books and annotated files generated by software for statistics, or software for qualitative and mixed methods research, such as Nvivo or Altas.ti.

Another consideration is the format of your digital data. Data should be accessible and readable for a suitably lengthy period after the project ends. Is the data format you are using accessible by others using standard programs and equipment? Is it reasonable to expect that the computer program you are using will still be available ten years from now? If your data were generated, or processed, with specific software or code (e.g. a commercial Electronic Laboratory Notebook), you

should always keep information on these with the data, and you should save an additional copy of the data in an accessible format (e.g..csv,.rtf,.tif,.mp3,.mp4,.pdf,.nvp,.gexf, or see the UK Data Services' recommended formats).

Once you start to gather and work with your data, they can easily become disorganised. To prevent errors later on, and to improve accessibility, create a logical and consistent file structure from the start of the project, and be aware of when these structures need updating. Useful file names are consistent and meaningful, and allow you to find your data easily. Structure your folders hierarchically, starting from broad topics and descending to more specific topics within these folders. Think carefully about what will make most sense to you five years from now (e.g. *Fig1B.ai* versus the more explicit *Fig1B_EffectSleeponMood_PeterPetersen_Jan16.ai*)? The same goes for versioning. Version control can avoid duplication and accidental overwrite, and it ensures that your data are backed up and that you are working in the most recent copy of the file. How will you keep track of multiple versions, the changes made in these versions, and the members of the team who made these changes? What titles will work best: for example, *Finaltext.doc*, *absolutelyfinaltext.doc*, *reallyabsolutelyfinaltext.doc*, or *2020-1-16_tabacco exp__V1_Susanne.doc* and *2020-1-22_tabacco exp_V2_Asger.doc*? Assess your files regularly, and at the end of the project, to ensure that you are not hoarding data needlessly. A range of resources can help you to establish good documentation practices (e.g. TILS Document Naming Convention, 2009).

Metadata

Metadata are data that are used to describe and add context to your physical material and digital data. Adding metadata enables you and others to identify, search through and understand the work you have created, both in the short term and in the longer term. This can then facilitate further analysis, replication, and other follow-up work.

Metadata can be embedded in the data or dataset itself – for example, within text documents or as file headers. Digital images are a good example here: in these, technical specifications of the camera, resolution, shutter speed, timestamp, location, and other recording information are stored in the file properties. This ensures that the metadata do not become separated from the digital file. Metadata can also be supportive, which means stored in a separate file that accompanies the data. Examples are lab books, ReadMe files, interview guides, bibliographic data and catalogue data.

Metadata can be divided into a number of categories (Riley and Niso 2017):

- *Descriptive metadata* describe the content and context of a dataset or document for discovery and identification. This includes elements such as title, creator/author, subject, keywords, and description/abstract.
- *Structural metadata* indicate the internal structure of a dataset or document (e.g. page number, chapter, and table of contents). Structural metadata can also tell you something about the relationship between elements (e.g. 'Figure Z is part of Article B' and 'PhotoB_FilterX was created using original PhotoA').
- *Administrative metadata* provide information needed to manage a resource. Examples are creation date, file type, copyright permissions, software required to manage the data, provenance (history) and information on who can access the data.

Ask yourself which metadata are best suited to describe your research data. A good starting point is to gather metadata commonly used in your research discipline and check for discipline-specific metadata standards (e.g. see the UK's Digital Curation Centre's website on Disciplinary Metadata). Remember to outline your metadata planning in your DMP.

4. Storing research data and materials during the project

Losing research data can be disastrous, especially when they have been generated over a very long period, were costly or difficult to collect, or cannot easily be replaced. Every researcher has probably gone through a 'data storage scare' at some point: a misplaced USB stick or laboratory notebook, a laptop that crashed before a back-up was made, or a camera

that was stolen. It is easy to imagine how this can have severe consequences if valuable research data generated during a PhD project are lost, or if sensitive personal data are accessed by persons not authorised to do so.

To prevent problems, you should plan for the storage and security of your research materials and data, and detail this in your DMP. It is strongly recommended that you make a separate assessment for each project, tailoring your storage and security plan to the specific materials and data that you will work with. Are they sensitive, or not? Are there any rules and regulations governing these data types? Do you need to share them with others, and are any other agreements, intellectual property or commercial interests that you need to take into account?

4.1 Storage & back-up

The risk of loss of digital data needs to be considered when you are choosing the method and location of data storage. How stable is the storage solution? Could it easily be damaged or misplaced? Is the process of backing up data straightforward? Portable devices such as USB sticks and external hard drives, or personal laptops and computers, are not the best storage solutions. One way to prevent data loss is to store the master copy of your data on your personal drive on the university's network, because data stored there are automatically and regularly backed up. If you are looking for ways in which data can be shared with your research group members, consider setting up a project-specific secure drive, or use the research group's shared network drive. The latter may become especially important at the end of your employment: your personal drive is not accessible by others, so crucial data may disappear from the research group if you do not migrate them.

4.2 Information security

You will also need to ensure that materials and data are secure, and cannot be accessed or manipulated by unauthorised persons. This should be planned carefully from the very start of the project, especially when you are one of several researchers collaborating on the same project and you need to share datasets. All employees should adhere to UCPH's information security guidelines, and if you use private IT equipment (e.g. mobile phones, tablets, and so on) during your work, bear in mind that the security guidelines apply to these units as well – perhaps especially so.

Information security can operate on various levels:

Security of data files

Questions you should ask yourself include the following: Are my computer and data files password-protected? How can I guarantee the secure removal or destruction of data? Will collaborators have controlled access to the data? Are changes made by my collaborators logged somewhere? Will I be able to see whether unauthorised persons have tampered with my data? If you need to share data in an ongoing research project with collaborators at the University of Copenhagen, you can request password-protected folder sharing from your faculty's IT department. Alternatively, you could set up a group room on KUnet in which you deposit copies of your files. Care should be taken when distributing data by email. Such transfers should only be made via the university email system (not Gmail and the like), and personal or sensitive information should always be encrypted. This could be done, for example, by using UCPHs email add-in Bluewhale, which is also suitable for large files.

Security of storage networks

If you cannot avoid storing data outside the university's servers, you should investigate whether the service you use sufficiently protects your data from viruses, malicious software, hacking attempts, etc. Commercial cloud-based file sharing services such as Dropbox, Amazon Web Services and GoogleDrive can be used as backup, but they should never be used for the master copy of your data. In addition, they should never be used when the data are confidential, sensitive or valuable. These services are very popular because of their ease of use, but they may store the data in countries with privacy and data protection laws that differ from those in Denmark (or the EU), and you might need additional permission. Instead, it is strongly recommended that you use

the university's secure access to Microsoft OneDrive, after you have encrypted your data and have set up the appropriate legal agreements to allow transfers of personal data (see Box 2).

Security of physical materials

You should also consider the security of your materials, such as tissue samples, notebooks, soil samples, and photographs. Can someone simply walk into your office and take them or tamper with them? Do you store your computer in a locked cabinet? Have you set up an alarm in case the freezer holding your samples breaks down? If you do not take these precautions, you might discover that a laptop has been stolen from the office, that samples have accidentally been defrosted, or that coffee has been spilled over a notebook rendering it unreadable. Where it makes sense, consider making (digital) copies of your research materials at regular intervals.

BOX 3: WHY SHARE RESEARCH DATA?

There are many reasons why research data should be shared with the wider research community whenever possible:

Impact on your research profile:

- It may lead to new research collaborations.
- It may increase the impact and visibility of research.
- It provides credit for the researcher.

Impact on the (scientific) community:

- It enhances scientific enquiry and debate.
- It enables innovation and new data uses.
- It increases the efficiency of research due to reusability and replication studies.
- It provides a valuable resource for education and training.
- It encourages the improvement and validation of research methods.
- It enables scrutiny of research results.
- It facilitates transparency and accountability.

Compliance with requirements:

- It meets journal, institution and/or funder requirements for data sharing.
- It meets standard practices within the research community.

5. Sharing research data outside the project

In the previous section, we considered the sharing of research data with collaborators within an on-going research project. In this section, we address the sharing of data with the wider scientific community after a project has concluded. As mentioned in the introduction to this chapter, sharing data with peers has become more and more common and is likely to become standard in most disciplines in the near future, as part of a broader open access movement (Federer et al. 2018). Below and in Box 3 we discuss why the sharing of research data should be considered, and how to go about it. Please note that legislation, regulations and/or agreements sometimes exclude or limit sharing.

5.1 Why share research data?

Why would you share research data? Many papers have investigated attitudes to sharing of research data in different disciplines – for example, in biomedical research (Federer et al. 2015), (bio)chemistry (Bezuidenhout 2019), astrophysics (Zuiderwijk and Spiers 2019), the arts, humanities and social sciences (Curty et al. 2017) and cultural heritage (Modolo 2017). All of the studies agree that barriers currently hinder sharing, and that these barriers are more cultural, social and professional than technical. For example, researchers are concerned that they might lose their competitive advantage in getting future papers accepted for publication, or in obtaining funding, if they share data before publication. They may also fear that others will scrutinise, or misuse, their research data, or find errors in the published results that they themselves did not uncover. Curty et al. (2017) discuss researchers' concerns about not knowing how to share research data and credit appropriately. As these concerns exist in all research disciplines, how can it be that there is a general shift towards data sharing?

In the next two sections we give an overview of the incentives for sharing research data (see Box 3 for a summary).

Reasons for sharing research data – the carrot

There have recently been significant improvements in the infrastructure supporting data sharing. The effort required to share data is not the barrier it once was (Kim 2017). For example, when you deposit a dataset in a research data repository, a permanent identifier (e.g. a digital object identifier, or DOI) is generated automatically. This identifier allows others to refer to, and cite, the dataset properly, and thus it ensures that you will receive appropriate credit for your work. Previous studies (Piwowar et al. 2007, Piwowar and Vision 2013) found that articles for which supplementary datasets were deposited in public repositories received more citations than those for which datasets were not available. These studies also show that 20% of the deposited datasets are reused at least once within four to eight years of being deposited. In many cases, reuse can lead to invitations for co-authorship on new articles, with the original authors being asked to collaborate on a new project based on the available dataset. Sharing research data also benefits the research community as a whole: it increases the likelihood that research will be discovered by others (Niyazov et al. 2016), improves the reproducibility and transparency of research (Ascoli 2015, Sturges et al. 2015), and stimulates collaborative efforts in which massive datasets are analysed effectively (Ferguson et al. 2014).

Reasons for sharing research data – the stick

Another reason to share research data is the fact that stakeholders demand it. This includes funding agencies, publishers and universities. Funding agencies naturally seek to maximise their 'return on investment'. They are increasingly requiring research data to be made publicly available, both to increase transparency and replicability, and to encourage reuse and thus generate more results from a single funded project. Publishers (including PLOS, Springer Nature, Wiley, Science, Elsevier and Taylor Francis) are enacting policies that focus on making supplementary data available to readers. This can be required on various levels of increasing rigour (Mellor 2018): 'disclosure' (authors state simply how to access data underlying the published results), 'mandate' (authors must make supplementary data available in a public repository, or state access conditions and procedures for restricted datasets) and 'verify' (supplementary data must be made fully available and reproducible). Some journals even specify requirements on the format of supplementary data, and where and how the data must be deposited. Therefore, always check the publisher's policies carefully, including the publisher's Copyright Transfer Agreement (CTA), to ensure you understand which rights to the data you are transferring to the publisher, and thus the restrictions or potentials that accordingly apply to your data.

5.2 How to share research data: the FAIR principles, data repositories and licences

The FAIR principles

To improve the potential for reuse of research data, an expert group consisting of researchers and representatives from journals, funders, universities and the European Commission, introduced the 'FAIR principles' (Wilkinson et al. 2016). The FAIR principles are a set of recommendations to make digital data Findable, Accessible, Interoperable and Reusable:

- *Findable:* Make information about your data available online in a searchable resource, so that others can discover that the data and study exist. A persistent identifier (e.g. DOI) should be used as permanent link to this information.
- *Accessible:* Provide access to your research data and documentation thereof. This can be done, for example, by depositing data in a data repository as described below. Access does not have to be open, but the conditions for access to restricted data need to be well-defined (Who may access the data, and when? Who can give access and how?).
- *Interoperable:* Apply commonly understood and preferably open formats and standards for data and metadata, allowing them to be easily exchanged, linked and combined with other data.
- *Reusable:* Document your research data in a way that supports their interpretation and reuse across disciplines. This means that a thorough description of the context in which the data were created (data provenance), such as a ReadMe file or the project protocol, should always be provided. In addition, a reuse licence could be added to datasets explaining how others may reuse the data.

It is important to stress that the FAIR principles can also be followed for data sets that are not made openly available through a data repository. Legal or contractual restrictions may exist that prevent the open sharing of data. However, you might still be able to share these data in a FAIR way on an individual basis, or through a specialised and secure database.

Research data repositories

As stated above, one step towards making your research data 'more FAIR' is to deposit your dataset in a public repository for research data. Examples are provided in Box 4, and the online database re3data is a good place to start if you want to find a suitable repository. *Discipline-specific* repositories may have the largest outreach and impact in your field. However, *generalist*, *institutional* or *national* repositories may also be suitable. Your research funder or publisher may make recommendations on repositories to use. If you want to ensure that your datasets are discoverable, citable and reusable by others, you should check that the repository allows you to enter meaningful metadata (keywords, links to related publications and documentation, etc.). You should also make sure the repository allows you to generate a persistent identifier to reference the data set, and that you can attach an appropriate usage licence.

Usage licences for research data

When you are making research data available to others, be sure to describe the terms and conditions of reuse. May others make changes to the data? May they redistribute the data, or parts of the data? Are they permitted to use the data for commercial purposes? Will you request proper attribution or citation from those who reuse your data? You can describe the terms and conditions yourself or choose a standard licence – for example, one of the Creative Commons Licenses. The 'CC-BY' licence permits unrestricted reuse, including distribution and reproduction in any medium, and

BOX 4. EXAMPLES OF RESEARCH DATA REPOSITORIES

Discipline-specific repositories

Advantages: Will have collections of similar types of data, using the same metadata schemes and vocabulary, which makes it easier to combine different datasets. It is likely also to be the place where peers in the relevant discipline will find data to reuse.

Examples: NASA's Space Physics Data Facility, Archaeology Data Service.

Generalist repositories

Advantages: Often free of charge up to a certain storage size. Many have options to add a Digital Object Identifier (DOI), standard metadata and usage licenses. These repositories are usually very easy and convenient to use.

Examples: DRYAD, ZENODO, figshare.

Institutional repositories

Advantages: Include support function for local users, and may help to brand the content. The data are stored 'in-house'.

Example: Data DOI at the University of Copenhagen.

National repositories

Advantages: Often long-term and stable preservation of high-quality research data.

Example: The Danish National Archives. This is the only repository where personal data can be archived without explicit informed consent. It is the most appropriate solution for data that should be preserved indefinitely.

commercial and non-commercial usage, as long as the original author and source are credited. Other licences are more restrictive. For example, the 'CC-BY-NC-ND' license only allows others to download and share your data if they credit you and does not allow changes or commercial use. GNU licences apply similarly for software and coding.

6. Preserving research data after the project

Research data management does not stop with the publication of research results. The last step in the research data lifecycle is the preservation, or archiving, of research data after the project. Unfortunately, this step is often overlooked when, for example, researchers move on to a new place of employment and start on new and exciting research projects. Research groups may not have standard procedures describing what should happen to physical material and data after the project is completed, and it will often be unclear who will have responsibility for them 5, 10 or 25 years later. As a result, research data are often left behind in various storage locations, rendering them inaccessible and difficult to interpret by others. Depositing data in Open Access data repositories, as mentioned in the previous section, can be considered a form of data preservation. However, not all repositories (except for the Danish National Archives) can guarantee the long-term persistence of the data deposited there, especially if you want to preserve data for more than 10 years. In addition, not all data can be deposited in data repositories. This means that other or additional measures may need to be taken to preserve your data long-term. We detail some of the considerations and measures for long-term preservation below.

6.1 Why preserve research data?

As with other aspects of research data management, there are requirements from funders, publishers, policy makers and institutions for retaining research data after a project is completed. For example, the Danish Code of Conduct for Research Integrity states that researchers must retain the data underlying results for *at least* 5 years after publication. Publishers and funders that require open access to research data will also require that those remain available long-term. Vines et al. (2014) showed that despite demands for data preservation, the availability of underlying research data declines rapidly with article age; the odds that a dataset remained available dropped by 22% every year after publication. Choosing a stable storage solution to preserve your data helps if you need to defend yourself against future challenges raised by peers in connection with your published work. Good preservation will also benefit your future work when you archive your research data along with proper documentation and metadata, because this makes them easy to find and understand at a later time.

6.2 What to preserve?

Should every single file containing research data be preserved for years and years? The answer is no. As a starting point, you should always investigate whether relevant legal, ethical or contractual restrictions apply to your project. Some types of research data may need to be destroyed when your project ends – for example, if you are dealing with personal or confidential data and material.

For research data that may be preserved, you should make some informed decisions on what you should retain for at least 5 years. First of all, you will need to preserve all data associated with publications. Second, we recommend that you preserve all data that are costly or difficult to replace. For example, think of research data generated in large collaborative projects, data derived from materials and observations that were difficult to obtain (e.g. in remote locations, at a certain point in time, or under very specific circumstances) and data that were generated with specialist equipment not standardly present in every research group. Remember that it may also be of great value to preserve research data from projects that did not lead to a publication. Often data from studies with a negative result are simply discarded, and this can lead to the repetition of experiments that will give the same negative results.

The preservation of physical objects will only make sense if the quality of the material allows it, and it is feasible financially to do it.

6.3 How to preserve?

When you have a collection of materials or data that should be preserved, you will also need to decide how to preserve them. The preservation of materials and data often involves moving them from one storage medium and format to another. The location at which you stored your data during your research project (e.g. your laptop or the university's network drives) is often not suitable for long-term storage, as it will be inaccessible to others (e.g. project collaborators or your supervisor) when you leave the workplace or project. The file formats may be specific to the equipment and (version of) software used, and therefore not readable otherwise. And storage media change over time; where storing data on CD-ROMs was pretty common 10 years ago, nowadays hardly any new laptop has an internal cd-drive. In 10 years, it may be very hard to find a device that can read CD-ROMs. Therefore, in making decisions that will facilitate interpretation and the reuse of your research data in 5, 10, 25 years, you should ask: Where should the data be stored so that they can be found and accessed when needed? In what format should they be retained? What documentation and/or labels should be associated with the data and materials so that they can be understood in the future? What will it cost to preserve materials and data, and who will cover these costs? Who will be the contact person for preserved materials and data? It is a good idea to decide on a preservation strategy for your research data at the project start – for example, as part of your data management plan.

6.4 Data destruction

Some data and physical material will need to be destroyed after the project's completion, instead of being archived. This may be because they are of low value or quality and not worth preserving, because an agreed retention period (e.g. specified in a collaboration contract) has ended, or because legal or ethical regulations require destruction. As with data preservation, data destruction needs to be carefully considered when dealing with confidential or sensitive data. Use irreversible methods; the 'simple deletion' of files may not destroy the data but merely remove the reference to them at the user-interface. This means that if you lend out your USB stick, or dispose of your old laptop, someone may still be able to access your data. Before doing so you will need, as a minimum, to fully format the USB stick and laptop to overwrite the files.

7. Conclusion

As this chapter has illustrated, there are many things you need to consider when you are planning your data management. It is vital that you ensure your research is carried out in an efficient and secure way. The starting point in deciding on your approach should always be the factors specific to your project. For example, these factors are:

- *Data*
  What types of research data are you going to be working with? Are there any regulations or pieces of legislation that apply to that specific data type? What precautions must be taken when dealing with confidential, sensitive or personal data – for example, in the storing, sharing and preserving these data?
- *Responsibilities and rights to data*
  Who will you be working with? What procedures will you follow in collaborative work – for example, in collecting, documenting and analysing your materials and data? Who will be responsible for the different aspects of research data management? Who will have access to the data and material, when, and under what conditions? And what can everyone do with the data after the project is complete?
- *Outreach & compliance*
  Who, potentially, will be interested in your research data? How will you make the data findable, accessible, interoperable and reusable for them? How will you comply with institutional policies and requirements from funders, journals and your research community – for example, on the provision of open access to your research data?

In summary, there is no one-size-fits-all-solution for data management. You need to plan your research data management based on the nature of your own project. Create an overview of all the factors that will influence how you collect, document, process, store, secure, share and preserve your research data, and design your procedures accordingly.

The best way to do this is to write a data management plan, or DMP, preferably using the template provided by the University of Copenhagen. Use the DMP to align expectations and make agreements with your supervisor and collaborators. The effort that you put into thorough planning will pay off when your project runs smoothly and lives up to the standards of honesty, transparency and credibility in research that we all value.

8. Test yourself questions

- What is the difference between 'personal data', 'pseudonymous data' and 'anonymous data'?
- In your particular research project, what aspects of research data management should you talk about with your supervisor and collaborators, and agree upon at the start of your project?
- What measures can you take to ensure that you yourself and others can find, understand and reuse your research data, now and in the future?
- How can good research data management have a positive impact on your career?

9. Getting help with research data management

For help with any issues related to research data management contact research support at your faculty, or the University's central contact point for research data management (datamanagement@ku.dk). Information about research data management and working with personal data can be found on the Research Portal on KUnet.

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Appendix: Examples of Data Management Plans

Project title	**The Avon Longitudinal Study of Parents and Children (ALSPAC)**	**Critical Heritages: performing and representing identities in Europe (CoHERE)**	**Climatic Limitation of Alien Weeds in New Zealand: Enhancing Species Distribution Models with Field Data**
Project Type	Large collaborative project	Large collaborative project	PhD study
Description	Birth cohort study following more than 14,000 pregnant women ('91-'92) together with their children and partners over two decades.	Study of European heritages, their socio-political and cultural significance and their potential for developing communitarian identities. Including museum, heritage and memory studies, cultural history, education, musicology, ethnology, political science, archaeology, ethnolinguistics and digital interaction design.	Study of the potential distributions of three alien plant species in their introduced ranges of New Zealand, using a combination of correlative species distribution models and observational and experimental approaches.
DMP template	Medical Research Council UK	European Commission (H2020)	National Science Foundation (NSF)
Links	Project website, DMP	Project website, DMP	PhD thesis, DMP
How are responsibilities for data management divided?	Executive Lead for Data: release of data and metadata. Senior Data Manager: surveys of documentation, quality assurance of data sets. Technical Lead: data collection, curation, storage.	Project PI: DMP implementation, long-term preservation of the data. Project partners: day-to-day coordination of data collection (anonymisation, de-identification, file labelling and storage and production of metadata).	The PhD student is responsible for all data management concerning, in agreement with the PhD supervisor.
What data types are collected, generated or used?	1) Quantitative data from questionnaires and interviews; physiological, cognitive, anthropometric measures; analyses of biological samples; images (e.g. MRIs, Liver scans); administrative records (e.g. records of maternity/ birth, cancer/deaths); social media (e.g. Twitter, Facebook). 2) Qualitative data such as interviews, audio recordings and transcriptions. 3) Biological samples, e.g. DNA and lymphoblastic cell lines.	Data are collected using: 1) Mixed ethnographic methods (observations, semi-structured interviews, audience surveys, focus groups, in-depth interviews). 2) Content analysis of textual and audio-visual documents, onsite analysis of museums/sites 3) Textual analysis of heritage tourism blogs and online photographs. The formats of data collected will include: audio (.mp3), video (.mp4), transcriptions of interview (.pdf/a;.txt;.docx), exhibition and display analyses (.pdf/a;.txt;.docx.; png;.jpg2000), survey data (.csv;. pdf/a), literature review (.pdf/a.; txt;.docx.;), academic texts (.pdf/a;.txt;.docx), online text.	1) Compiled data, such as records from online databases, surveys, online records. Data from society newsletters, proceedings, and journal articles. Written notes from communication with local residents, experts and herbaria. 2) Data from measurements and observations, such as species occurrence data, raw temperature data from data loggers, derived climate data, transplant experiment data, Field survey data, model codes (R scripts) and outputs.

How is consistency and quality of data ensured?	1) Assessment of data by logical and range checks in electronic data collection systems, with ambiguous values assessed by an operator. 2) All assessment scales are validated externally with a known reference paper. 3) ~3% of clinic participants will be re-invited to validate earlier measures and test for fieldworker bias or equipment calibration issues. 4) Clinical assessment data are collected according to clear protocols; regular audits of clinic processes will be performed. 5) Molecular analysis of some samples is repeated, using control probes, analysis for batch effects.	Responsibility for controlling accuracy of the data lies with the respective PI overseeing the collection of the respective dataset. Note: This DMP does not describe any specific procedures or protocols for collecting and analysing the data, e.g. on how to conduct interviews and surveys in order to avoid unintentional bias and validate the results.	Note: This DMP outlines detailed procedures for the collection and analysis of each individual dataset, e.g. by listing references for all data compiled from external sources, explaining the applied models and justifying the choice of input parameters, describing experimental protocols, including rules for omitting data, repeating measurements, etc, comparing selected datasets with reference data.
What metadata will be included?	Metadata are collected as an integral process to (i) catalogue and index the data in a searchable manner, (ii) define the assessment tools (validated measures, key reference publication, modifications etc.), (iii) describe the data collection process on an individual basis (age at completion, administration and reminder process) (iv) catalogue laboratory information as captured through LIMS and (v) assign a geographical reference point (at a non-disclosive level) to assist spatial analysis. Published datasets will use the DDI Lifecycle 3.2 metadata standard facilitated through the CLOSER Discovery portal.	Each data collection process creates a template metadata spreadsheet (.csv) including design process, software, and vocabularies. As there is no standard, formal vocabulary in the fields covered by the project, the project partners will generate their own vocabulary as part of the research process. International metadata standards will be applied to describe bibliographic information such as title; description; creator; funder; keywords and affiliation. Social Science metadata standards may be appropriate for some aspects of the data collection (i.e. quantitative surveys).	Species occurrence data, transplant experiment data (e.g. site descriptions, deaths, flowering, growth, seedling counts), field survey data (e.g. seeds per pod). Also, metadata for the results: identifier, creator, title, publisher, publication year, contributor, subject, language, size, format, rights, description (abstract, column names and units), dates, geo-location.
What conventions for file naming, labelling and versioning are used?	Each data item is referenced and stored using a universal indexing and naming convention. Note: The DMP is missing a description of, or a reference to, this convention.	1) Files are numbered in Year-Month-Day format. 2) File names include: project name; work package number; deliverable/milestone number OR research task number; deliverable/ milestone name, OR research task name; draft or final version; version number. File names are spaced with hyphens and underscores.	Not addressed.

What security measures are in place to prevent unauthorised access, removal or alteration of data and material?	1) Research data are stored separately from administrative data (e.g. subject identifiers), accessible only to specified team members. 2) Free text is coded separately from any other data; any identifying information is screened out before being passed to a researcher. 3) Complete dates (birth, clinic attendance etc) are not released to researchers; instead ages are derived. 4) Interview data are collected and validated in real time on encrypted laptops with data routinely transferred to the central repository.	All Digital data created, including master copies, are securely stored and backed up on the university's Filestore Service, accessible only to authorised staff. The Project Administrator manages access to the data. Only the project lead or their nominee have access to the 'key' file. Any pseudo-anonymisation will be replaced with full anonymisation. If the sample size is small enough to enable de-anonymisation, the research team will employ statistical techniques such as differential privacy to further protect participants.	There are no ethical or privacy issues related to the data in the project. All finalised data and metadata will be stored in a private folder in the cloud on figshare until publication. Note: The DMP does not describe how the raw data are stored, secured and backed up.
Which datasets will be shared outside of the project?	Majority of data are available for immediate use on request. ALSPAC is run and encouraged as a resource to be used by the research community. The process for accessing data is the same for all, regardless of research area, institution, location or funding source, provided the proposed research is in the public interest and is not being carried out for personal or commercial gain.	All research outputs (project deliverables) and some 'raw data' will be made openly accessible. Access to sensitive data will be restricted in accordance with the ethics policy of the project, the participating institutions and the Data Protection Act. Anonymised data underlying publications are released with the publication. Within 12 months of the project ending, any appropriately anonymised data will also be made publicly available.	All finalised data and metadata will be made available under embargo until publication of chapters as manuscripts, or 3 years after the PhD has been awarded, whichever is sooner.
FAIR: How will datasets be made findable?	Available data are described on the ALSPAC website, including a dictionary that is fully searchable by keyword. A web portal will be developed that allows for advanced searching of variables. Searchable indexes of ALSPAC variables are also available via the CLOSER Discovery search engine.	Datasets that have been identified as suitable for depositing in a public archive will be deposited in Zenodo, with basic metadata for the archived data. DOIs for each dataset will be automatically created upon uploading. Short films will be made available in the CoHERE Critical Archive, and integrated online digital repository. Project partners generate keywords for use in the CCA. These keywords will be visible to CCA users to search and organise the CCA content.	Research outputs will be searchable through the figshare repository, and will have a DOI to make the outputs citable. Associated information is disseminated publicly on the internet.

FAIR: How will datasets be made accessible?	ALSPAC data are made available to researchers on a supported basis rather than via an unrestricted, open resource. Bespoke datasets of requested variables are provided to collaborators upon completion of a Data Access Agreement.	Data deposited Zenodo will be made open access within twelve months of the completion of the project. Sensitive data will be restricted in accordance with the ethics policy of the project and applicable data protection rules. No specialist methods or software are required to access the data. Should any specialist software become needed to access more complex data (such as film, digital or online apps) instructions will be provided.	All data and metadata will be stored privately in the cloud on figshare until publication, after which point it will be made open-access on figshare, so that others are free to download data sets.
FAIR: How will datasets be made interoperable?	Study protocols, assessment tools, data derivation methods and coding schema are provided as part of the research data documentation available as downloadable content from the ALSPAC website.	Data deposited Zenodo will be in open formats, e.g..pdf/.txt files. Format changes to the data files (e.g. from closed to open formats) will be the responsibility of each institutional PI. Public deliverables and selected, anonymised raw data may be used by third parties, subject to attribution and acknowledgement of intellectual property rights, artistic copyright, etc.	All data files will be saved as CSV or ASCII files for cross-platform compatibility, exchangeability and long-term access. Metadata will be created as separate XML files using DataCite's metadata schema version 3.1.
FAIR: How will datasets be made reusable?	The full ALSPAC data access policy is available online and provides information on data sharing. Researchers wishing to use the ALSPAC resource complete an online proposal form describing the proposed research.	Data in the CCA will be licensed with a Creative Commons License. Data archived in Zenodo will be available for the lifetime of the repository. This is expected to be at least 20 years. Zenodo states that if the repository is closed then they will endeavour to integrate deposited data into suitable alternative institutional and/or subject based repositories.	Data will be free to use under a Creative Commons License, with the expectation that it will be correctly attributed and cited using the DOI provided by the figshare repository.
How will the data and documentation be preserved after the project ends?	ALSPAC maintains an archive of data available to researchers on request. To ensure longevity and availability, ALSPAC reviews data regularly and migrates data formats to newer formats if necessary. Where data are disposed of this will be done securely and in line with University IT information security policies. Primary source material (e.g. questionnaires, clinic data sheets and consent forms) will be preserved as electronic (scanned) copies where practicable.	Archived project data will be securely stored in the University of Newcastle's archive file store.	USB hard drive and paper copies of (meta) data are stored at the university library and archived along with the PhD thesis. Digital copies are stored on figshare which is stable and accessible and provides a suitable and secure option for long-term storage of data.

6.
Commercialization of research results and intellectual property rights

Niels Lysholm Engelhard

Summary

Universities have become increasingly engaged in collaboration with industrial companies, and intellectual property rights (IPR) play an important role in this kind of collaboration. This chapter begins by introducing the legal background to transfers of technology from universities to industry. It then describes the two most important forms of intellectual property right used to regulate this transfer; patents and copyright. There follows a detailed description of how technology transfer works at the University of Copenhagen, through the involvement of the Tech Transfer Office at the University. Finally, a short account of experiences with technology transfer at University of Copenhagen is provided.

1. Introduction

Industry depends on access to the results of university research in order to develop new products and processes, and thereby remain competitive. Mechanisms to support technology transfer from academia to industry have been embedded in innovation policies by almost all governments across the globe. Direct industry participation in publicly funded research projects has become a tool widely used by the various funding bodies to encourage technology transfer, both in national and EU research programmes, especially as part of the EU Horizon 2020 programme. More and more, universities and other public sector research institutions are involved not only in providing education and scientific discoveries, but also in collaboration with industrial companies.

On the face of it, this seems to conflict with the traditional role of publicly funded universities as institutions which provide knowledge as a public good for the benefit of all. The potential conflicts of interest the wider role gives rise to need careful management (see Chapter 7). At any rate, it has become part of life on universities all over the world. Technology transfer can take many forms, but this chapter will focus on technology transfer based on the commercialization of research results protected by IPR.

2. Technology transfer

The transfer of technology from universities to industry really took off with the 1980 Bayh-Dole-Act in the US, which stated that the *universities* have the right to take ownership of inventions made by their researchers. Before 1980, in the US, researchers themselves had ownership to any inventions made as part of their work. This was called "Professor Privilege". Denmark's own "Bayh-Dole-Act" – the Act on Inventions at Public Research Institutions – was passed in 2000 (Ministry of Higher Education and Science, 2009). Before then researchers at Danish universities and other public sector research institutions had ownership of their own inventions.
Why should universities protect inventions, rather than allowing researchers to just publish new knowledge so that anyone can benefit from its application? Imagine having invented a new molecule that could be the key ingredient in a wonder drug for the eradication of HIV or tuberculosis. Would it not be more ethical to publish the findings so that anyone can use them?

The problem is that it takes years, and vast funds, to develop and market a new drug or other high tech product. Therefore, no investor or company would take on the risk of developing and commercializing a new product or technology without the protection offered by a patent to secure a return on that investment. Hence, if technology is to be made commercially available, a property right to the invention may be necessary. Companies also want to invest in products for which there is likely to be a demand – there's no point developing a drug that no-one wants to buy. However, there are also areas which are not commercially interesting, but where new knowledge may be beneficial – e.g. to people living in impoverished parts of the world. Universities also have an obligation to benefit these people, and publish results deemed not to be worth patenting.

Hence, there are important scientific, economic, and societal priorities involved in technology transfer and how it is managed. Governments encourage technology transfer, because it is a way to supply innovation to industry and create new jobs. For universities, industrial collaboration offers

opportunities for extra funding; and for researchers to gain access to otherwise unobtainable knowledge and equipment. However, universities have obligations that go beyond what can be achieved through commercialization – e.g. finding cures for very rare diseases of little commercial interest, or helping people to find healthier ways of living. Therefore, a reasonable balance between research focused on commercial applications and other kinds of research is called for. Where industry collaboration does occur, the freedom of research must nonetheless be protected.

The effective technology transfer process is in essence about people interacting so that innovation can occur. Intellectual property rights may be viewed merely as tools, and legal agreements can be seen as a framework to support collaboration between academic scientists and industry. The process is not always easy, as academia and industry belong to different worlds. Understanding the viewpoint of the other party is the key to success. The primary mission of a university is education, and the creation and dissemination of new knowledge for the sake of knowledge itself, with publishing as a fundamental condition. Industry's mission, by contrast, is to make a profit by providing services and offering products to the market. The knowledge lying behind these services and products is for the most part developed confidentially in-house.

3. Intellectual property rights

Intellectual property rights confer ownership on ideas and creations and grant the inventor/creator exclusivity for a certain period of time. They are instrumental in driving forward the development of technology and innovation. IPR divide into two categories:

1) *Industrial Property Rights* include patents and utility patents, trademarks, industrial designs and geographical indications.

2) *Copyright* covers literary and artistic works such as articles, theses, films, photographs, musical compositions, drawings and paintings, sculptures, and architectural designs. The rights related to copyright include those of performing artists in their performances, and those of producers of phonograms and broadcasters in their radio and television programmes. This chapter will focus on patents, utility patents and copyright, since these are the most relevant types of IPR for public sector researchers.

3.1 Patents

A patent covers the technical aspects of an invention – it is, in other words, a technical solution to a problem. The owner of a patent can block others from commercial exploitation of the invention; at the same time anyone is permitted to perform research on the invention for non-commercial purposes. Patent rights are territorial rights. If a patent has only been granted in Denmark, anyone can exploit the invention in other countries outside Denmark, although they cannot export products or semi-manufactured products that are based on the invention to Denmark. But there is no "patent police" – it is the owner of a patent who must protect his or her rights against infringement.

Criteria governing the issuing of a patent are:

1) Novelty
2) Inventive step
3) Industrial applicability

Novelty means that the invention has to be novel at the date the patent application is filed. Meeting the novelty criterion is an objective and a global matter. If an invention has been presented in a public forum, described in a paper, journal, or on the Internet, or in any other way, it is not possible to obtain a patent unless the patent application is filed before the invention was published. Discussing the invention in a closed circle – e.g. with a supervisor and close colleagues – does not destroy the novelty of the invention, nor will the submission of a manuscript to a journal provided the manuscript is kept confidential during the review process and a patent application is filed at least one day before the paper is published. Thus, patenting will not hinder or prevent publishing – it is only matter of timing.

Inventive step means that the solution presented by the invention must not be obvious to a person with knowledge within the technical field of the invention who has all of the relevant published information at hand. The combination of two or more already published documents, such as a scientific paper combined with a text book or a patent, may not qualify as an inventive step, and render the invention obvious.

Industrial applicability means that it is possible for the invention to be made and used.

A patent provides protection for 20 years from the date the patent application was filed. Anyone can exploit an invention freely after expiry. Twenty years is a long time in some technological areas, but not in the pharmaceutical or pesticide industry, where it takes 10-13 years from initial filing of first patent application to the product's being ready for launch in the marketplace. The long development phase leaves the company with only 7-10 years to get a return on its investment before the patent expires. An annual fee is paid for each country in which the patent is in force. The patent protection will lapse in a country if the fee is not paid.

A patent application can be filed for four types of item:

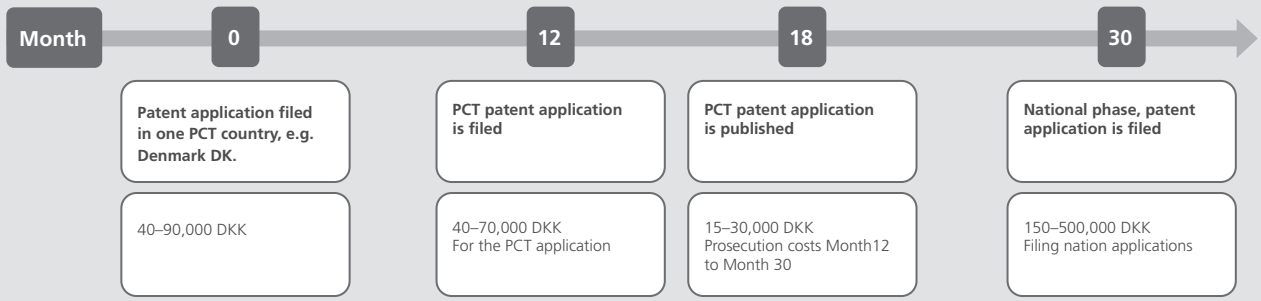
- Subject matter (e.g. a compound, herbicide or drug)
- Process or method (e.g. a process for the extraction of specific compounds, or for manufacturing a product)
- Machine or article of manufacture (e.g. a new tool)
- Use (e.g. a drug developed against one disease may show effectiveness against another disease)

A plant or animal that can be found in the wild is not patentable. However, a transgenic animal such as the Oncomouse may be patentable in certain countries such as US; the same is true of genetically modified (GM) plant varieties – e.g. a GM wheat. Inventions contravening public policy or morality (e.g. a torture instrument) cannot be patented.

It is very costly to file the first patent application in many countries, and this imposes a heavy burden on companies and institutions. This could be detrimental to innovation, either preventing the filing altogether or imposing further delay on top of the frequently long journey between the first filing and the final product. Thus, several regional and global patent treaties make it possible to postpone costs while working to obtain a patent. This allows an inventor or company several years to complete prototyping and business planning before the application process becomes costly, as outlined in Box 1 below. One of the most widely used systems is the Patent Corporation Treaty (PCT) system, which is operated by the United Nations.

It usually takes 3-4 years from the date of the initial filing of the application, for the patent to be granted. The route from patent application to granted patent, including costs in DKK, is outlined below (Box 1):

BOX 1



This overview clearly shows the expense of the route from patent filing to granted patent. The precise cost depends on the complexity of the invention and field of technology.

Inventorship is credited to one or more individuals who have contributed intellectually to the conception of the invention and the technical means of the invention (the "how"). An individual cannot be an inventor if he or she merely follows a protocol designed by others, comments on the text of a draft patent application, provides funding for the research project leading to the invention, or has a senior or management role. Adding people to the list of inventors who are not really inventors, or omitting inventors from the list, can lead to problems for the patent owner and even result in the invalidation of a granted patent. In cases of doubt, inventorship can be determined with the assistance of a patent agent (see Box 2). This has some interesting similarities to questions of academic authorship, where a 'substantial contribution' is usually required (see Chapter 4), but is more formally regulated.

Knowledge created by companies is often not published in journals, but the information is available in the patent literature. Patent applications are published 18 months after the first filing date, and the patent literature offers researchers a rich source of knowledge and "how to" which can be used freely for research purposes as long as the research is *into* the invention and not using the invention as a tool in research project. For example, research into the Polymerase Chain Reaction (PCR) method would not infringe the PCR patent, but using the PCR method as a tool instead of buying the patented PCR product would constitute an infringement. Thus, by a search of the patent literature it is easy to carry out business intelligence on competing groups or companies.

BOX 2

More information on patents can be found here: wipo.org, www.epo.org and dkpto.dk.

There are several free databases available on the Internet. google.com/patents and espacenet.com both excellent databases. lens.org is another free database that offers patent mapping tools and link between scholar work and patents. Lens also offers also free search of biological sequences in patents.

3.2 Copyright

Copyright differs from industrial property rights (patents, trademarks and design registration) in many ways. The copyright symbol © is still widely used, but in fact it is not necessary, as copyright is automatically given by law without any application process. Copyright also differs from industrial property rights in that with it the creator of the copyrighted item, who is always an individual, holds the right to his or her work. Furthermore, a work has to represent "originality" to enjoy copyright protection.

The Danish Copyright Act ("Ophavsretsloven", Danish Ministry of Culture, 2014) regulates the protection of two categories of subject matter (or types of creation):

1) *Literature and artistic works* such as maps, drawings, computer programs, architecture, various expressions of art (fictional or non-fictional), applied art, works of fine art, and graphic works, photographs (artistic).

2) *Neighboring rights* covers photographs – all photographs enjoy protection as neighboring rights, but artistic photographs also enjoy protection as artistic work – movies, sound recordings, and the performance of literary or artistic work such as theatre plays.

Copyright protection lasts for 70 years after the death of the creator in the first category and 50 years in the second category.

The creator has the right to reproduce (copy), alter, disseminate, and perform or show or display his or her work. These rights can be assigned to a third party such as a journal or publishing company. Researchers and teaching staff hold the copyright to any material (except computer programs) that fulfil the criteria for copyright protection.

Computer programs are protected by copyright. The protection relates only to the actual code (the binary sequence of "0" and "1") and to graphical representations such as the layout of the graphical interface, including icons and drawings – not to the algorithm in itself. Who owns a computer program made by a researcher at a public research institution in Denmark? Unlike inventions, the employer (institution) automatically has ownership here.

A work that enjoys copyright may consist of two individual works, e.g. a photo of a sculpture presented in PowerPoint. The creator of the sculpture still has copyright to his work, the photographer holds copyright to the photo, and maker of the PowerPoint holds the copyright to the PowerPoint slide. In this case, the last of these creators would need permission, or a license, from the photographer and artist, or from an organization to which the artist and photographer have assigned their right to reproduce or otherwise use the creation.

It should be emphasized that copyright protection only applies to the work itself, not to the idea or theory presented in the work – e.g. to a new theory in given scientific field. Box 3 presents some practical tips for navigating the complex world of copyright.

BOX 3: TIPS CONCERNING COPYRIGHT ISSUES

- Never use photos, drawings, or other copyrighted material in public without obtaining permission from the rights holders
- Do not assign all your rights to publishing companies or other organizations without having read the guidelines: *Copyright for researchers, students and teachers at University for Copenhagen*
- UBVA (Udvalget til Beskyttelse af Videnskabeligt Arbejde, The Committee for Protection of Scientific Work) offers free guidance, an e-book on copyright (in Danish), and free online courses in copyright

4. How does technology transfer work at the University of Copenhagen?

Collaboration with external partners is often an integral part of working at a university or other public research institution. The collaboration can take many forms and is regulated by different types of legal agreement. Technology transfers are usually organized by specialized Tech Transfer Offices. In order to avoid problems employees should always consult the local legal advisor in their faculty, or contact the Tech Transfer Office for assistance.

The Tech Transfer Office at the University of Copenhagen operates from the Research & Innovation Department, in the university's Central Administration (Fælles Administrationen). All matters relating to the commercialization of IPR at the University of Copenhagen are handled by the Tech Transfer Office, which also assists researchers in entering all types of legal agreement.

As a junior researcher, you are not permitted to sign an agreement between the University of Copenhagen and external partners. The agreement must be negotiated by the Tech Transfer Office and signed by your head of department. If you need more information, there is a booklet introducing the overall principles of the university's collaboration policy at fi.ku.dk. The booklet is available in Danish and English.

Inventions made by researchers at Danish universities, university hospitals and other public sector research institutions are regulated by the Act on Inventions at Public Research Institutions (Lov om opfindelser ved offentlige forskningsinstitutioner, Ministry of Higher Education and Science (2009)). If an employee has made an invention as part of his or her work, the research institution has a right to transfer to itself the rights attached to the invention. All tangible materials – e.g. antibodies, seeds and microbial strains – belong to the institution and can in principle be commercialized under a license agreement or sold. However, the Act only gives the institution the right to inventions falling inside the researcher's field of work at the institution. For example, if a cancer researcher invents a patentable new

kitchen tool, that tool will not be considered an invention subject to the Act.

The inventor must report (disclose) the invention to the Tech Transfer Office by completing an Invention Disclosure Form, but how do you know if you've made an invention? The definition of "inventions" is stated in the The Patent Act (Patentloven, Ministry of Industry, Business and Financial Affairs (2017a)), and The Act on Utility Patents (Brugsmodelloven, Ministry of Industry, Business and Financial Affairs (2017b)). Under the Act on Inventions at Public Research Institutions (Ministry of Higher Education and Science, 2009) the research institution has a two-month period after the date of disclosure to decide whether to assume the rights to the invention. Inventors are not entitled to publish or otherwise disseminate information relating to the invention during this assessment period. If the Institution fails to notify an inventor of their decision within the two-month period, the inventor retains the rights to his or her invention as a private individual.

Where the institution decides to assume rights over the invention those rights become the property of the institution. If the invention is exploited commercially, the employee will be entitled to a reasonable payment from the institution. That payment is described by the Act, where details of how net income is to be calculated are given; but each institution has the right to decide how they distribute net income between the institution, the departments and inventors. Box 4 describes how this distribution is handled at the University of Copenhagen.

Sometimes an invention involves inventors from more than one institution, as well as inventors from a company. In such cases the invention will be co-owned and a patent co-ownership agreement will be signed between the parties. The proportion of ownership will, unless otherwise agreed, be based on the intellectual contribution of each inventor to the invention. It is highly advisable therefore that all inventors agree on the distribution rubric internally as soon as possible, and preferably at the time when the invention is disclosed to the institution.

Bachelor's and Master's students are not subject to the Act on Inventions at Public Research Institutions (Ministry of Higher Education and Science, 2009) in that the Act does not apply to inventions created as part of their studies as private individuals. If a Bachelor's or Master's student becomes a co-inventor by participating in a research project, the institution may enter an agreement with the student under which the student assigns his or her share of the rights to the invention to the institution in return for a share of the net income.

BOX 4: DISTRIBUTION OF NET INCOME FROM INVENTIONS AT THE UNIVERSITY OF COPENHAGEN

Net income is defined as gross income (e.g. royalties received) minus external costs incurred during the commercialization of an invention (including patent costs and travelling expenses). Once the total costs for commercialization of the invention have been recouped, the net income will be distributed in the following manner:

If the University of Copenhagen assumes the rights to an invention before the end of the two-month period:
1/3 to the inventor(s)
1/3 to the department(s) where the inventors are employed
1/3 to the University of Copenhagen

If the University of Copenhagen decides not to assume the rights to an invention within the two-month period and offers the rights of ownership to the inventors:
The University of Copenhagen is entitled to 1/3 of net income.

Where the University of Copenhagen offers the inventors to reclaim the ownership to an invention after having tried to commercialize it:
The University of Copenhagen is entitled to a share of the net income subject to individual agreement on a case by case basis.

If a University of Copenhagen Bachelor's or Master's student becomes a co-inventor through his or her participation in a research project, the Tech Transfer Office will ask the student if he or she wishes to assign his or her share of the invention to the University of Copenhagen as if he or she was an employee of the University of Copenhagen. It is recommended that an assignment and confidentiality agreement with the student should be set up as part of a research project involving industrial partners. Contact the Tech Transfer Office for help and guidance.

4.1 The two-month period

Each institution has its own procedures and forms for the disclosure of an invention. Once formalities are in place, the invention is assessed and evaluated before the institution decides whether to assume the rights to the invention and file a patent application. Essentially, the decision is based on answers to the following questions:

1) Is the invention new and patentable?
2) Does the invention have commercial potential?
3) Can it be commercialized (sold or licensed)?

The first question, relating to patentability, is assessed by an external patent agent who not only understands the specific field of technology, but is also a specialist in IPR and patent law. As outlined above, one of the prerequisites for obtaining a patent is that the invention must be novel. This means that the invention must not have been made available before to the public anywhere in the world. The patent agent conducts a search in the patent literature and the scientific literature to identify documents or other material that may destroy the novelty of the invention and thus prevent the invention from being patented. This process usually requires input from the inventors, who assist the patent agent in fully understanding the technology, defining the invention and setting up a proper search profile. The review and assessment of patentability is stated in a written report.

The Tech Transfer Office reviews the commercial potential of an invention by benchmarking it against similar technologies or products currently available in the marketplace, and by contacting relevant companies and other commercial players (without disclosing the invention) to assess its commercial potential. For some inventions, an examination of the regulatory landscape surrounding the technology may be necessary in order to identify potential barriers to the commercialization of the invention such as industry standards or customs in the trade. The inventors play an important role in assisting the Tech Transfer Office with any technical input needed in the evaluation of commercial potential.

To answer the question of whether an invention can be commercialized it is necessary to consider a number of issues: the stage of development of the invention, the internal resources (funding, capacity of potential inventors, and availability of equipment) it will require, the availability of relevant potential industrial partners, and time and funding constraints, both internal and external. The Tech Transfer Office investigates these issues in close collaboration with the inventors.

Following the investigations outlined above, the Tech Transfer Office will decide to either assume or decline to assume rights to the invention from the inventors. In the first of these outcomes, a patent application will be drafted and filed, and commercializing activities will begin. The patent applications are drafted by an external patent agent in close collaboration with the inventors.

4.2 The commercialization period

After the patent application has been filed commercialization activities begin. There are basically two routes to commercialization for university IPR:

1) License or sell the IPR to an existing company
2) Establish a spin-out company founded by the inventors or a wider group of inventors

Under the Act on Inventions at Public Research Institutions (Ministry of Higher Education and Science, 2009), an

institution may sell or license IPR to industry partners, license IPR to a spin-out company or receive shares in a spin-out company, or both, in exchange for IPR generated at the institutions. Each Danish university has its own business strategy (see Box 5 for the University of Copenhagen's strategy). Some institutions sell IP rights, some only out-license IPR, yet others receive shares for equity in start-up companies originating from the institution as the preferred strategy. Institutions may employ a combination of these strategies.

Although a given technology can in principle be sold or licensed to more than one company, the majority of commercial agreements involve one company obtaining exclusivity for the technology. The commercial partner (or licensee) pays the ongoing patent costs as part of the license agreement and will therefore almost always demand exclusivity in exchange. When commercialization of the invention is unsuccessful the institution will offer to hand back, or return, the rights to the invention to the inventors, including the right to make a patent application which will then no longer be supported by the university's Tech Transfer Office.

Luckily inventions from the University of Copenhagen do find their way to partners in industry. This can mean both some initial income, sometimes modest, for the inventors and an intensified collaboration with the industrial partners, often leading to more funding and greater access to skills and equipment in the industry.

The University of Copenhagen received 45 to 77 new invention disclosures a year between 2010 and 2017, and rights to the invention were assumed in 20-30% of cases, resulting in 18-33 license and sales agreements a year. In comparison, 324 to 471 new invention disclosures were filed across all Danish universities and other research organizations in the same time period, resulting in 103 to 140 license and sales agreements. As shown in Figure 1 below, while the number of invention disclosures and new patent applications has been rising, the number of the license and sales agreements has not gone up to the same extent. This is the result of the time-lag between an invention being disclosed and the license or sales agreement being signed.

Patent expenses are roughly equal to income between 2009 and 2013, but the net profit here does not represent the real value of technology transfer to the university. In most cases a license or sales agreement entails collaboration with the industrial partner that generates more funding and new equipment. In some cases, the inventors have raised double-digit millions in research grants, so it is a win situation for both the university and the individual inventor, even if the industrial partner does not succeed in commercializing the invention.

BOX 5: IPR AND BUSINESS STRATEGY AT THE UNIVERSITY OF COPENHAGEN

The University of Copenhagen:

1) only invests in patent applications with a likelihood of being commercialized
2) does not sell IPR or accept shares in spin-out companies in exchange for them
3) maintains ownership of IPR and licenses rights to external or spin-out companies

Before a potential industry partner is approached, a non-confidential description of the invention and business opportunity will usually be drafted by the Tech Transfer Office and the inventors in collaboration. There are several ways in which to identify the appropriate industry partner. The inventors may be familiar with relevant companies, or the Tech Transfer Office may be able to identify and contact relevant industry partners. Face-to-face presentation of the invention to a potential external partner is headed by the Tech Transfer Office with the assistance of the inventor(s).

5. Further information and sources of assistance

Visit www.fi.ku.dk
Contact the Tech Transfer Office by e-mail: techtrans@adm.ku.dk
Employed within Capital Region of Copenhagen?
Visit www.regionh.dk/til-fagfolk/forskning-og-innovation

6. Test yourself questions

- Who owns innovations created at a Danish university or hospital?
- Is there a copyright to scientific work?
- How can a university innovation be patented?

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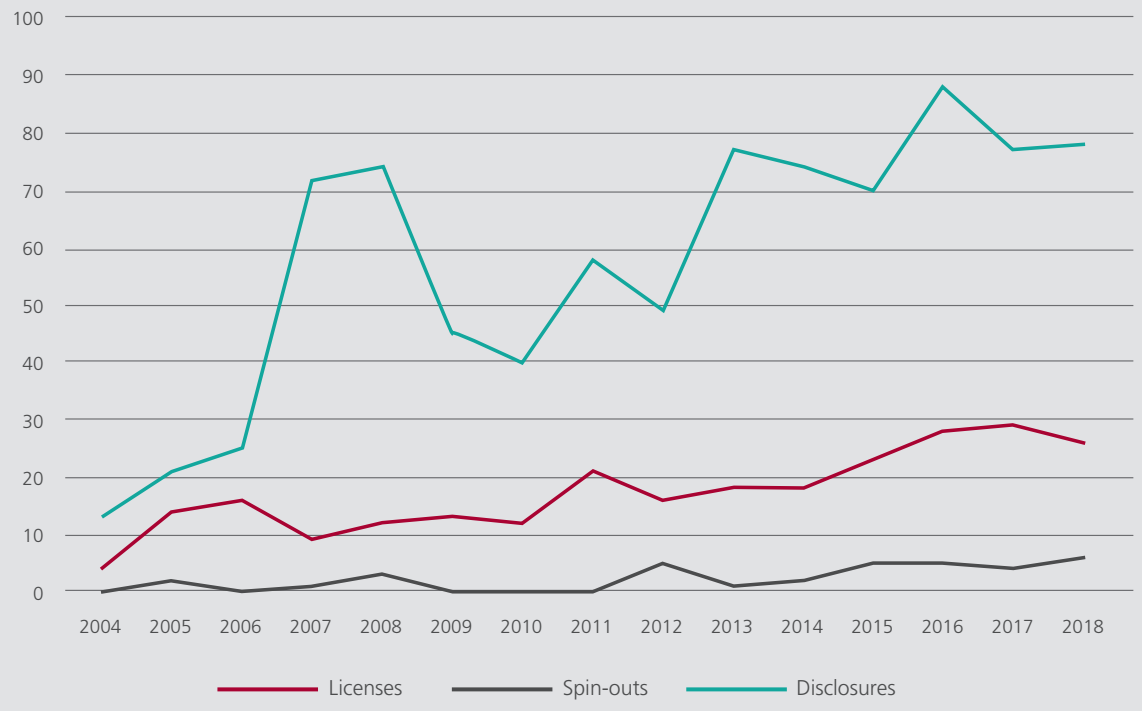
FIGURE 1: COMMERCIALIZATION STATICS, UNIVERSITY OF COPENHAGEN 2004-2018



7.
Conflicts of interest

Martin Marchman Andersen, Jeppe Berggreen Høj,
Louise Whiteley and Peter Sandøe

Summary

It is widely assumed that scientists should be objective and ignore personal factors in their scientific conduct (Douglas 2014). However, scientists are human beings and are therefore also driven by interests other than the advancement of scientific knowledge – for instance, by the pursuit of honour and status, wealth, the desire to support their students, political commitments, morality and other factors. Sometimes scientists' non-scientific interests seem to be in conflict with responsible conduct of research, and when this is the case there is a *conflict of interest*. However, some conflicts of interest are unavoidable and some are even harmless; conflicts of interest do not necessarily lead to questionable research practice and are sometimes an intrinsic part of research itself. But some, particularly those involving financial interests, are a serious threat to the responsible conduct of research and should therefore be taken very seriously. In this chapter we discuss *what* exactly a conflict of interest is, and *why*, *when* and *how* we, as scientists, should actively respond to our conflicts of interest by, for example, disclosing them.

Key take-home points include the following: Take all conflicts of interest seriously. Discuss them with colleagues in all scientific projects you take part in. Disclose all conflicts of interest linked to financial holdings, or other benefits, or linked to collaboration with external partners.

1. What is a conflict of interest and what is the problem?

According to the Danish Code of Conduct for Research Integrity, a conflict of interest is 'a situation in which financial or other interests have the potential to compromise or bias professional judgement' (Ministry of Higher Education and Science, 2014, p. 15). The code also states that 'all parties involved with the research in question should disclose any conflict of interests' (ibid.). Suppose that you are a stockholder in a tobacco company, but also an epidemiologist specialising in studying the impact of tobacco on various forms of cancer. If you publish a paper arguing that the common medical belief about smoking's impact on throat cancer is overstated, the code would require you to disclose your conflict of interest, i.e. to disclose that you hold stocks in the tobacco company.

Initially, one might wonder what the problem really is. Why should others criticise your study just because you hold stocks in a tobacco company? Criticising a study on the basis of the authors' private life seems to be *argumentum ad hominem* – the fallacy of attacking the character, or motive, of the person making the argument, rather than the substance of the argument itself. If scientific conduct is transparent it should be possible for others, at least other scientists, to find the methodological and logical shortcomings of a study and thereby separate the wheat from the chaff. If there is a problem with the scientific conduct behind a scientific paper, other scholars will find it and thus reject the paper's conclusions.

However, the reality of scientific conduct, and indeed scientific communication, is not that simple. For instance, thorough scientific peer review is difficult and time consuming, and the incentive to review with sufficient care is often not very strong in academic life. There may also be methodological uncertainties that one may exploit to approximate a desired conclusion. And perhaps even more importantly, scientific publications are not only read by other scientists, but also by journalists and others who may well lack the necessary training to understand the scientific details and limitations. There is a risk that scientific findings will be widely circulated in public media before they are properly criticized and evaluated by the scientific community.[5] It therefore seems that we cannot merely dismiss conflicts of interest as irrelevant or unimportant. Rather, non-scientific interests seem to affect scientific results in a way that is not easily debunked. For instance, in 1998 Barnes and Baro set

5 For instance, in 2012 a study was published in Food and Chemical Toxicology linking genetically modified corn to rat tumors. Although, later, it was found that the study involved several methodological errors, and the journal withdrew it, at the time of its publication its inaccurate findings gained widespread currency in the news, which made them not easily retractable.

out to determine whether the conclusions of review articles on the health effects of passive smoking were associated with article quality, the affiliations of their authors, or other article characteristics. They found that the conclusions were strongly associated with whether or not the authors were known to be affiliated with the tobacco industry (Barnes and Baro 1998).

BOX 1: DEFINITIONS OF CONFLICT OF INTEREST

According to the Danish Code of Conduct for Research Integrity (Ministry of Higher Education and Science, 2014), a conflict of interest is 'a situation in which financial or other interests have the potential to compromise or bias professional judgement' (p.15).

The University of Copenhagen's code for good scientific practice in research collaboration with external partners highlights an important addition: the issue is not only whether the scientific judgement is actually being biased by the relevant interests, but also whether there is a reasonable suspicion of such bias.

Let us now consider more carefully why conflicts of interest are a problem at universities and other knowledge institutions. Scientists are very often epistemically privileged as regards their research interests. That is to say, they know more than non-scientists (and often, other scientists) about the topic of their research. The dermatologist knows more about the biology and treatment of skin diseases and the ophthalmologist knows more about the biology and treatment of eye diseases. Although science is always provisional and conclusions often turn out later to be mistaken, it follows well-tested methods and is, at least ideally, subjected to systematic critic. Therefore scientific specialisation implies epistemically privileged positions, or expert status, all else being equal. So, when non-experts want to *know* about an issue, consulting the scientific experts is very often the rational thing to do.

Suppose again you are an epidemiologist specialising in the impact of tobacco on various forms of cancer. You publish a paper arguing that common medical beliefs about smoking's impact on throat cancer are overstated. Non-experts on medical matters will have reason to believe that you know better than they do on such matters. You are in a better position than they are to describe and understand the causes of cancer. But obviously you might still be wrong. There may be errors in your reasoning. You might have interests that unconsciously bias your conclusions. You may even want to deceive your audience intentionally. Although non-experts should rationally grant that you are in a better position than they are to know about causes of cancer, it is a much more complicated question whether they should therefore believe your claim to be true. This is so because their reasons to believe that what you claim is true depend not just on their assessment of your expertise, but also on their judgements about whether, for instance, you are biased or intentionally trying to mislead them.

Now suppose they find out that you hold stocks in a tobacco company. This gives them reason to think that you have an interest in increased tobacco sales, and therefore some interest in encouraging people to think that smoking is less dangerous than it actually is. Because you own stocks in the tobacco company, other people's trust in your expert status is therefore jeopardised. Accordingly, others should lower their trust in your claim about the impact of smoking on throat cancer – not necessarily to the level of non-expert opinion, but to a level lower than that of a similar expert who does not hold stocks in the tobacco industry.

Thus, conflicts of interest can undermine trust in the scientist's expert status. The norm that scientists should be required to declare their conflicts of interest therefore has a clear purpose: if they are to be trusted as experts, they should be transparent about circumstances that have the potential to damage their expert status. When they conform to this norm they allow non-experts to evaluate their credibility on an informed basis.

It is worth noting that the importance of declaring conflicts of interest does not depend on whether the scientist's

'professional judgement' is *actually* compromised by 'financial or other interests'. You may hold stocks in a tobacco company and still be correct in arguing that the common medical belief on smoking's impact on throat cancer is overstated. The essential question is whether others, from their perspective, have reason to lower their trust in your professional/expert judgement *because of* financial or other interests that you have. You holding stocks in the tobacco company has the *potential* to compromise your professional judgement even if it does not *actually* compromise your professional judgement. Accordingly, there is an issue of trust even when you feel absolutely sure that your conclusion is right.

In the following sections we will discuss different kinds of conflict of interest; which conflicts of interest ought to be disclosed? By 'disclosure' we simply mean letting other people know about the relevant conflicts of interest. Disclosure ensures transparency and hopefully also trust. It helps to protect both individual scientists and their institutions from future criticism. But disclosing does not always sufficiently capture the scientists' responsibilities as regards conflicts of interest, and it is important that we do not use disclosure as an excuse to stop reflecting on how our conflicts of interest affects our scientific conduct.

2. Conflicts of interest and cognitive biases

A conflict of interest, as expressed in the Danish Code of Conduct, arises in situations 'in which financial or other interests may compromise or bias professional judgement. But what does 'other interests' mean here? The most serious cases of misconduct involve researchers failing to disclose financial interests (see Box 2). But which conflicting interests, other than financial, would amount to a conflict of interest in the relevant sense? Which conflicts of interest threaten epistemic trust? And which interests should we disclose?

BOX 2: RECENT CASES OF FINANCIAL CONFLICTS OF INTEREST

José Baselga is a Spanish medical oncologist, a specialist in breast cancer. Until September 2018 he served as chief physician at the Memorial Sloan Kettering Cancer Center (MSKCC) in New York. In September 2018, an article in *The New York Times* (2018) and *Pro Publica* revealed that Baselga had received at least $3.4 million in payments from drug, medical equipment and diagnostic companies between 2013-2017. Moreover, according to *The New York Times*, he had failed to disclose his ties to the industry in 60 per cent of the papers he had published since 2013, including papers published in prestigious journals such as *The New England Journal of Medicine* and *The Lancet*.

He resigned his position at MSKCC a few days after the article was published. In January 2019 AstraZeneca, one of the companies he received money from while employed at MSKCC, announced that they had hired him as head of oncological research and development.

Michel Aubier, a French lung specialist, was head of pneumonology and allergology at the Bichat-Claude Bernard Hospital in Paris until his retirement in September 2016. In April 2015 Aubier testified to a Senate commission about the financial and economic costs of air pollution, as a representative of the public authority that runs Paris's public hospitals. He told the Senate that the impact of pollution on lung cancer 'is extremely low and a subject of much debate' (*Nature* 2017). Though he testified under oath he failed to mention his ties to the oil industry, and, for example, that Total had paid him approximately €100,000 a year between 2012-2015. In July 2017 a French court fined Aubier €50,000 and sentenced him to a suspended 6-month term in prison for false testimony.

Aubier appealed the case, and in November 2018 the Paris Court of Appeal annulled his prison sentence and reduced his fine to €20,000. In his appeal, Aubier claimed that he had 'not really understood the question asked' (Teller Report 2018).

Many kinds of interest seem to have the potential to compromise professional judgement: these include honour, wealth, status, supporting students, political commitments and personal morality. In fact, just about any interest can be relevant as long as it has '…the potential to compromise or bias professional judgement'.

On the other hand, not all conflicts of interest necessarily need to be disclosed. Consider cognitive bias. Contemporary literature on cognition has highlighted the human tendency to be biased in quite a large range of situations (e.g. Kahneman 2011). For instance, we seem to suffer from a tendency to search for, interpret, and recall information in ways that confirm our prior beliefs and hypotheses (confirmation bias). Suppose a young scholar proposes a controversial hypothesis and builds a successful academic career on accruing evidence for this hypothesis. Suppose that towards the end of her career the professor (as she now is) is confronted by new evidence suggesting her hypothesis is incorrect. In a situation like this more than the 'truth of the matter' could easily be at stake. The psychological price of having our views 'proved wrong' can be very high, especially if we have invested a lot of time and energy in defending them. In such cases, our interest in our own public standing might outweigh our professional interest in advancing scientific knowledge. Confirmation bias towards one's own hypothesis might therefore be significant.

Now suppose that the professor publishes a further paper containing new findings that support her original hypothesis. Should she declare a conflict of interest? Does she have a duty to declare that she might be biased towards confirming her own original hypothesis? It would be unusual, perhaps even odd, to think she has a duty of disclosure here, but why do we think this? It is a good question: Why should we disclose our ownership of stocks in the tobacco company but not our bias towards confirming our own hypothesis? Cannot our interest in our own public standing be just as biasing as our interest in personal wealth?

A distinction may help to explain why the two cases are relevantly different. Whereas presumably only a small number of the medical researchers specialising in tobacco and cancer hold stocks in the tobacco industry, all of them – indeed all of us – tend to be biased towards the confirmation of our own hypotheses. But if we all have this bias, there seems to be little communicative value in declaring it every time we publish a paper. Of course, cognitive bias does not affect us all to the same degree, but the degrees to which we are cognitively biased seem hard to quantify. It might therefore be justifiable for us not to disclose our cognitive biases – in other words, it seems reasonable to say that conflicts of interest that we all have need not generally be disclosed. This does not mean that we should not take cognitive bias seriously. Indeed, cognitive biases are a challenge for scientific conduct generally; they should be reflected upon and discussed regularly within responsible scientific environments. Similarly, we can all be expected to be ambitious, to want an academic career. So if you are biased towards your own pet theories and hypotheses because this will increase your prospect of academic advancement, it would also seem odd to require you to disclose your ambition. Thus, whether or not an interest is universal might be a good initial litmus test of whether we should disclose it as a conflict of interest.

3. Conflicts of interest arising from payed public speaking

There seem, nonetheless, to be conflicts of interest that scholars do not always disclose, even though they are not universally shared: What if a scholar runs a significant business giving talks alongside her professorship? Suppose that, by virtue of being a professor, she has proposed the hypothesis that a certain vaccine programme has side-effects that the public health authority does not recognise. Her hypothesis is controversial and attracts a great deal of attention, so she starts a tour giving public talks about it. For each talk she accepts a non-negligible fee. Suppose now she is about to publish an academic paper expanding on her argument. Should she disclose the considerable income she has from giving talks as a conflict of interest? It seems likely that if she were to retract her hypothesis in light of better evidence, she might not be able to continue making money in this way. Does she not have a financial interest that potentially conflicts with

her professional scientific judgement? Should she therefore disclose it? The professor's situation seems relevantly similar to the case where a researcher owns stocks in the tobacco industry while publicly downplaying the dangers of smoking. Reading, for instance, the JAMA guidelines (applied by many medical journals) it seems that the professor does have a duty of disclosure here, as all authors should declare their financial interests, 'including … consultancies, honoraria or payment, speakers' bureaus, expert testimony, royalties…' Nonetheless, this does not seem entirely widespread practice, even though it is common for academics to charge fees for providing expert advice, giving talks, and the like, and even though such tasks are also supported or even expected by universities.

Responsible conduct of research is not a static matter. What is considered 'good scientific practice' is constantly shifting (see Chapter 1). It is therefore reasonable to believe that there is a gap between the conflicts of interest that we ought to disclose (given the rationale we have offered for why we should disclose conflicts of interest at all) and the conflicts of interest that we actually disclose as things are now. The distinction between conflicting interests that we all have and special, less widespread conflicts of interest is a rule of thumb that can help to determine when a conflict of interest needs to be disclosed. We will come back to this matter, but first we need to consider whether the political, moral and religious views that scientists hold also have the potential to compromise their professional judgement in a way that demands disclosure.

4. Conflicts of interest arising from moral, political and religious views

In some cases, conflicts of interest can arise in connection with moral, political and religious views. Should these be disclosed too?

Helmuth Nyborg is a retired Danish professor of psychology from AArhus University. Postulating a general intelligence (or 'G') factor, he claims to have found that there is a significant difference in general intelligence between people from the north of the globe and people from south of the Sahara (JP 2016). However, he has also collaborated with *Den Danske Forening*, a right-wing political organisation opposing immigration to Denmark, and recently he ran for election for the right-wing political party *Stram Kurs* (Altinget 8. Maj 2019). It seems reasonable to wonder whether Nyborg's scientific work could have been biased by his political views. We do not know this has happened, of course, but it appears to be rational to lower our level of trust in his claims in light of his evident political beliefs. More generally, we might ask: Why not expand the norm of disclosure to include conflicts of interest involving moral, political, and religious views?

BOX 3: ON VALUE-FREE SCIENTIFIC CONDUCT

The ideal of value-free science holds that scientific conduct should be free of moral, political, religious and personal values. According to this position, scientific conduct should be insensitive to such values, so that two scientists holding very different moral, political and religious views can agree on scientific results – even if they do not agree on which scientific topics should be investigated and to which ends. It is worth noting that the ideal does not apply to epistemic values. Science is hardly possible without epistemic values such as the requirements of reproducibility, falsifiability, non-contradiction, coherence, simplicity, etc. (see e.g. Lacey 2005). It is also worth noting that this is an ideal – something that can be strived for, but not something we can always be guaranteed to achieve. And although it is widely accepted, there are scholars who argue against both the possibility and utility of striving for a science that is completely value-free (e.g. Miller 2014; Kincaid, Dupré, & Wiley 2007).

Obviously, we should look at our moral, political and religious views very carefully where they potentially compromise our scientific conduct. But this does not imply that we should also disclose them. Indeed, there seems to be other reasons against a norm of disclosure of political, moral and

religious views. First, there is a widespread tradition in liberal democracies that we are not obligated to disclose our political views, mainly to avoid intimidation and the trading of votes. Second, in much the same way that our scientific views are potentially biased by our political, moral, and religious views, our perception of scientific dissemination may also be biased by our perception of the political, moral and religious views of the disseminator (Mohsen and Ha-Joon, 2019). Consider a non-expert on obesity who believes that obese individuals themselves are responsible for being obese. He is now confronted with a scientific paper presenting evidence for an obesity gene which, to a large extent, predicts who will become obese and who will not. Now the credence he would ascribe to this paper might well depend on the political orientation of the authors. If he is informed that the authors hold the same political views as he does, he might be more inclined to accept the suggestion than he would be if, say, the authors were left of centre and known for their past declarations that obese people are not responsible for their own obesity. It can be seen, therefore, that the suggestion that scientists should disclose their political, moral and religious views may simply create a new epistemic problem – and one that is not minor than the problem it was intended to fix.

5. When should we disclose a conflict of interest?

We can now try to formulate general guidance on when a scientist should *disclose* a conflict of interest. Any such guidance should be read cautiously, not least because the demands of RCR are constantly shifting. Our suggestion builds on rationality considerations about what ought to motivate non-experts to lower their trust in expert scientific judgement. But rationally, non-experts also ought to lower their trust in an expert's scientific judgement in light of, for example, cognitive biases and (at least some) moral, political and religious views. We have suggested various reasons against a norm of declaring cognitive biases and moral, political and religious views, but the strength of those other reasons may change. Building the guidance on what ought, rationally, to motivate non-experts also has the weakness that non-experts, and indeed humans, are not always rational or even reasonable. You might find yourself in trouble simply because others (wrongly) believe you have done something wrong. Some precaution is therefore advisable.

When:

1) you communicate something publicly as a scientist, *and*
2) you communicate about ongoing or unsettled research that do not enjoy widespread and common scientific agreement.

You should disclose:

3) if the prospect is such that you, or your family or close friends, could gain financially, *or*
4) if your work is funded by, or you have ongoing collaboration with, companies, NGOs, or public or semi-public institutions other than your own university.

Let us consider the four conditions.

The first condition tells you when you should be concerned with conflict of interest disclosure at all. First, you need not remind your spouse over the dinner table how you earn your money, so the relevant scope is public scope. However, what is 'public' should be understood broadly, including not just journal publication, but also for instance teaching and presentations at workshops or conferences. Second, you may have other societal roles than your role as a scientist. For instance, you may be the chairman of the local football club, where you do not act or communicate as a scientist. As long as the interests of the different roles do not overlap, you need not be concerned with disclosing your conflicts of interest in such other roles.

The second condition reminds us that we should be concerned about conflicts of interest because they can damage other people's trust in our propositions. But others only have reason to lower their trust if what you propose does not enjoy widespread scientific agreement. Naturally, the contents of most publications do not enjoy widespread scientific consensus, but you need not, for instance, disclose your stocks in an airline company when, as a scientist, you remind the public of Newton's laws of motion. Similarly, it is not really

obvious that you should disclose holding stocks in the tobacco industry if you merely claim publicly that tobacco is extremely dangerous. First, this is the scientific consensus, and second, this consensus is not in your financial interest. It is not obvious that you should disclose your stocks in a wind turbine company if you claim publicly that the climate is changing. However, to stay out of trouble, precaution is advisable.

Regarding the third condition, we are motivated not only by *our own* assets, status and the like, but also by the assets and status enjoyed by our friends and families. The interest we ought to have in scientific truth may therefore conflict with a wider interest we have in benefits and advantages for our spouses, siblings and friends. According to a widely accepted ethical principle, and The Danish Public Administration Act (Justitsministeriet, 2004) public employees must be impartial when they contribute to decisions on, for example, who should receive funding or be employed, taking only professionally relevant considerations into account. Where an employee has a conflict of interest – e.g. if a close colleague is on the shortlist for a job or grant – they are deemed ineligible to act and must step back or 'recuse' themselves from taking part (see also The European Code of Conduct for Research Integrity ALLEA, 2017; p.7).

An identified conflict of interest need not necessarily amount to questionable research practice. It is hard to state when, precisely, it does do so, so we should make some room for

BOX 4: THE BEEF SCANDAL, AARHUS UNIVERSITY

In June 2019 a group of researchers from the Danish Centre for Food and Agriculture, Department of Agroecology, at AArhus University, together with one researcher from the Technical University of Denmark, published a report in which they attempted to estimate the climate impact of beef. The report compared the impact of beef to that of, among other things, coffee, sweets and alcohol. The report was financed by the Danish Cattle Levy Funder (itself financed by, and in service of, the Danish cattle industry) and done in collaboration with Danish Crown and Danish Agriculture and Food Council.

From 13 August 2019 and onwards, the Danish newspaper *Information* published several articles criticising the report for its data selection and methodology, and complaining that the researchers were not independent of their external partners. In a line of replies, the researchers of the report defended their data and methodology, and denied that their external partners had had any influence on their methodology and results. However, on 30 August *Information* published yet another article revealing that the external partners had written parts of the report. The same day the Minister of Higher Education and Science called upon the Rector of AArhus University to make a statement about the situation.

The rector criticised the report for violating both University guidelines and the arm's-length principle. On 2 September the University retracted the report, and on 10 September the rector sent his statement to the Minister. In this he criticised the project for lacking a contract to ensure the researcher's independence, for lacking external peer review, and for not being explicit about the different collaborators' text contributions.

Meanwhile, on 3 September the Head of the Department of Agroecology agreed to resign the headship. An internal investigation at the Danish Centre for Food and Agriculture was initiated to summarise the RCR of the last five years of external collaborations. The investigation found that in 19 out of 55 collaborations with external partners there were no contracts to ensure researchers' independence.

The faculty of Science and Technology at AArhus University launched a set of initiatives in light of the scandal designed to secure more transparency in external collaborations.

uncertainty. Suppose, for instance, that you publicly suggest a scientifically controversial view. Perhaps, if you give this view up you will have to cancel a talk for which you are promised two bottles of (ordinary) wine. Although your scientific decision about holding, or giving up, the view does affect the value of your future assets, the difference is hardly significant. A grey zone remains in which it is hard to decide whether an undeclared conflict of interest amounts to questionable research practice.

Even when we do not expect our family and friends to benefit financially from our results, or to benefit ourselves, we might still be biased by the interests of those we relate to. It is hardly psychologically abnormal to feel committed to our colleagues. Therefore, we suggest that the fourth condition applies even when the third is not satisfied. Suppose you have a hypothesis about some health-promoting effects of drinking beer in a certain quantity each week. You now get funding from a brewery to do research into the matter, and you find that your hypothesis is not only unsupported but contradicted. Although the research has no prospect of affecting the value of your own assets, or those of your family or friends, you may feel committed to the brewery's interests and somehow be biased in your interpretation of the data in the brewery's interests. This means we ought to disclose external funding and collaborations whenever the first two conditions are also satisfied.

6. How should we handle conflicts of interest?

The excerpt from the Danish Code of Conduct for Research Integrity (Ministry of Higher Education and Science, 2014, see Box 5) states that 'researchers are responsible for disclosing all conflicts of interest related to the research they are involved with.' And in this chapter we have mainly been concerned with the question of when to disclose a conflict of interest. However, our responsibilities as scientists and researchers go beyond disclosure. The Code emphasises that it is primarily the responsibility of the various relevant institutions (e.g. universities, research institutes, journals) to handle conflicts of interest, but also that 'all parties involved' have a 'joint responsibility'. We should think that conflicts of interest can be problems, even matters of questionable research practice, even when they are disclosed. Disclosing is necessary under the conditions we have outlined above, but does not always sufficiently capture the scientists' responsibilities as regards conflicts of interest, as will now be explained.[6]

First, one of the lessons learned from the beef scandal at AArhus University seems to have been that when scientists *collaborate* with external partners, companies, NGOs, interest groups, and public or semi-public institutions, the collaboration must be arranged so that, for instance, the scientists' right (and duty) to publish the results of their research is not compromised. It is advisable, and at some institutions it is required, that all external collaborations are built on clear, written contracts, or terms and conditions, that secure transparency and independence. See more at *The University of Copenhagen's code for good scientific practice in research collaboration with external partners*.

Second, as is also stated in the Code, a researcher should withdraw from assessment processes when there is reason to doubt her ability to act impartially (see Box 5). Thus, 'recusal' is a tool that can be usefully applied to conflicts of interest. If your financial or other interests are so strong and obvious that you are not in a position to offer an objective evaluation of the relevant matter, recusal may be the only responsible course of action. Precisely when recusal is the only thing to do is, of course, often hard to say. It is not something we can settle in this chapter.

We suggest that you discuss potential conflicts of interest with colleagues in all of the scientific projects in which you take part. If you identify a potential conflict of interest for you or your research group, try to find a way to bring it up with your colleagues, including your supervisor if possible. Ask them: Do they agree that a conflict of interest exists, and that it could be contrary to good scientific practice? Although we have argued that cognitive biases and moral, political and religious views should not generally be disclosed, they still

6 Note that although disclosure increases transparency, it does not necessarily promote public trust. See e.g. Stossel and Lee (2008).

BOX 5: THE DANISH CODE OF CONDUCT FOR RESEARCH INTEGRITY (MINISTRY OF HIGHER EDUCATION AND SCIENCE, 2014) – EXCERPT ON CONFLICTS OF INTEREST

6.1. Responsibilities

i. All parties involved with the research in question should disclose any conflicts of interest.

ii. Assessors of research and research proposals (e.g. editors, reviewers, research councils, etc.) who have a conflict of interest should withdraw from any involvement in the process.

iii. All parties involved with the research in question have a joint responsibility for handling issues relating to conflicts of interest.

6.2. Division of responsibilities

i. Researchers are responsible for disclosing all conflicts of interest related to the research they are involved with.

ii. Institutions are responsible for addressing conflicts of interest, and for ensuring that all conflicts of interest are handled adequately. In this context institutions should have a policy for handling conflicts of interest, which includes information on:

a. Situations that constitute a conflict of interest

b. Disclosure of conflicts of interest, including how to handle confidentiality issues

represent threats to the responsible conduct of research, so you need to discuss them and take them seriously.

Most often, when you submit a paper to a scientific journal you will be asked to declare your conflicts of interest. We suggest that you declare all potentially relevant financial interests relating to you, your partner and your close friends, and that you declare all ongoing external collaborations of relevance to the subject matter of your paper. Assume that when you submit a paper, the first two of the conditions we set out above in Section 5 are always satisfied: you communicate publicly in virtue of being a scientist, and what you propose in the paper does not enjoy widespread and common scientific agreement (at least, not yet). If it did, scientific journals would not be interested in publishing your paper.

There are other roles and tasks in academic life where it might be relevant to disclose any conflicts of interest – for instance, as regards public dissemination or engagement, where you are normally not asked to make a declaration, or indeed, in the foreword of your PhD thesis. You may therefore choose to list your conflicts of interest online. Employees of the University of Copenhagen can do this using the research information system CURIS (see University of Copenhagen, 2016), on CVs appearing on the University website, or in places where particular stakeholder groups will be able to access them. It is important, of course, to consider whether your disclosure is easy to find. Setting out a list of your conflicts of interest in a PDF that appears as a subpage of your personal webpage on a university website may make the information public, and available in principle, but no one is ever likely to see it. Finally, if you want to make a public disclosure, it is also important to check with your supervisor or legal office whether there any restrictions on whether and how you can do so.

BOX 6: PRACTICAL TIP: KEEP A LIST

Keep a record of the conflicts of interest you consider yourself to have, and of any financial interests outside of your primary employment, and update it regularly. A simple list saved on your computer will suffice. This is a useful and effective way to remain aware of the issues surrounding conflicts of interest, and how they may be affecting you, and it can be a useful reference in any discussions with your supervisor about, say, publication schedules. A regularly updated list can also make it quicker and easier to prepare full replies if you are asked about conflicts of interest (e.g. by a journal or a funding agency). See the Australian Code for the Responsible Conduct of Research, Section 7.2.1 (Australian Government, 2007).

7. Test yourself questions

- What is a conflict of interest?
- Why are conflicting interests a problem, and to whom?
- Do you think we should require each other to disclose our cognitive biases and our political, religious and moral views? If so, when and why? If not, why not?
- What conflicts of interest do you currently have, and what consequences could they potentially have for your scientific conduct if they are not managed correctly?
- Do you think scientists should strive to be value-free?

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8.
Public science communication

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Summary

This chapter examines the role of public science communication in responsible conduct of research. It addresses the what, why, who, and how of communication, within a complex media landscape where truth and expertise are increasingly at stake. Responsible science communication is not just a matter of explaining scientific results accurately, honestly and clearly. Communicating context, uncertainty, and disagreement are just as important if we want to build trust with public audiences and have productive societal conversations about research. The diverse media available today – from social media to video lectures and participatory public events – make it easier than ever before to engage people in research, and allow researchers at every stage of their careers to join in. However, researchers still need to reflect carefully on when and how to communicate their own results, and about how they present themselves, their institution, and their expertise. Being clear about *why* you are communicating – and being prepared for potential pitfalls – increases the likelihood of a good outcome. Practical tips and links to further guidance are included at the end of the chapter.

1. What is public science communication?

Before we start discussing public science communication as part of the responsible conduct of research (RCR), we will step back for a moment and ask what it *is*. One of the most prominent forms of science communication is reporting by journalists, including specialist science journalists such as Lone Frank in Denmark or Matt Ridley in the UK. Giving an interview to a journalist can be a highly effective way for

BOX 1: A DIVERSITY OF MEDIA FORMS FOR SCIENCE COMMUNICATION

- Newspapers, news websites and news programmes, often featuring prominent scientists. Scientists on the news sometimes talk about their own research, but often comment on news stories related to their broader expertise. For example, a political scientist commenting on elections or a plant geneticist commenting on protests about GM crops.
- Science magazines, e.g., *Scientific American, The Scientist, Wired, Discover, New Scientist.*
- Popular science books, e.g., those by Richard Dawkins, Ben Goldacre, Jon Turney, and Stephen Hawking.
- Documentary films on traditional broadcasters, streaming services, or YouTube.
- Online videos produced by scientists, both serious and for fun.
- Radio programmes and podcasts, e.g., *RadioLab*, *Science Friday*, *Inside Science* on BBC Radio 4, or *Hjernekassen* on DR.
- Live webcasts of public talks, e.g., *TED talks*.
- Blogs and crowd-sourced online magazines, e.g., *Science Blogs* and Field of Science blog networks, and the Science and Technology sections of *The Conversation* and *Medium.*
- Social media such as Twitter, Facebook, LinkedIn, and Q&A sites such as *Reddit Science*. For a humorous take on laboratory life, search the twitter hashtag #overlyhonestmethods.
- Museums and science centres, e.g., in Copenhagen *Experimentarium* and *Medical Museion.*
- Science fiction or novels with scientific or biomedical themes, e.g., *Frankenstein* by Mary Shelley, *Saturday* by Ian McEwan.
- Public lecture and discussion series, e.g., *Science & Cocktails* in Copenhagen.
- Science festivals and public engagement activities, e.g., in Copenhagen *Forskningens Døgn*, Bloom, and KU open days as part of the annual *Culture Night*. In the UK *Guerilla Science* develops innovative festival and pop up activities.
- Science comedy, choirs, and club nights.
- Theatre productions, e.g., *Videnskabsteatret* in Denmark and Complicité productions such as *A Disappearing Number*.
- *Consensus conferences* and citizen's juries, e.g. GM Nation in the UK.

a scientist to communicate their research or to enrich news coverage with expert commentary, but there are also many other possibilities – e.g. social media and public events can allow researchers to come into more direct dialogue with publics, and tell different stories about research[7]. Thus, different media present different opportunities, and also carry different risks. For example, the risk of misrepresentation might be higher if you give an interview to a journalist than presenting yourself, though the opportunity to reach a wide audience might also be higher. You can mitigate the risks of communication by being aware of the pitfalls of the particular media involved, and preparing for them. To come back to the example of giving an interview, you can check the past work of the journalist, prepare concise talking points, and prior to the interview negotiate to be allowed to check quotes before publication.

This chapter will take a broad perspective on forms of public science communication. Box 1 lists different communication media with examples, and Box 2 gives case studies of successful scientists who do public communication. Both demonstrate the diversity of media available, and Box 2 also demonstrates the diversity of roles scientists can play – from writing personal blogs about their daily work, to being interviewed for TV, speaking at public events, and appearing on radio shows.

For more examples, the University of Copenhagen's online newspaper *Universitetsavisen* published a list of KU's Top 20

7 In the science communication literature, rather than write about 'the public' scholars often write about 'publics' in the plural. This recognizes that there is not one homogenous public. Rather, there are groups with different attitudes, knowledge, and interests in scientific research. Many of these heterogeneous 'publics' (e.g. patient organizations) have significant if non-traditional forms of expertise.

BOX 2: CASE STUDIES OF SUCCESSFUL SCIENTISTS DOING PUBLIC SCIENCE COMMUNICATION

- Anja Cetti Andersen is a Professor of Astrophysics and Public Understanding of Science at the University of Copenhagen, and has won many awards for her public outreach, particularly interviews for television and radio and at public events (Andersen, 2011). By speaking in public, she can deliver her message in her own voice, rather than always being filtered through a journalist's lens.
- Ben Goldacre is a British doctor and epidemiologist who has authored four books including 2016's *Do Statins Work? The Battle for Perfect Evidence-Based Medicine*, following his popular newspaper column and blog *Bad Science* (Goldacre, 2017). You can also find Ben Goldacre on YouTube giving talks at public events such as TED and on Twitter @bengoldacre. Goldacre works to expose flaws in biomedical research and in media reports of research. In doing this, he communicates how epidemiological studies work methodologically, aiming to equip his readers better to evaluate other reports of clinical research in the future.
- Professor Oluf Borbye Pedersen at the University of Copenhagen engages in unusual forms of science communication, as well as giving interviews and talks. His popular book *Tarme I Topform* was a collaboration that combined microbiome science with dietary advice, and *Magtfulde Mikrober* brings together science communication with reflections on his own life, in collaboration with an illustrator and journalist. Prof Pedersen has also collaborated with KU's Medical Museion to bring metabolic science into exhibitions.
- Microbiologist Rosie Redfield ran a pioneering 'open science' blog called RRResearch reporting the daily work in her laboratory at the University of British Columbia until 2018; she is now active on twitter @RosieRedfield. After reading a 2011 paper in *Science* claiming that a bacterium had been discovered that could live on arsenic rather than oxygen, Redfield was sceptical and repeated the experiment, failing to replicate the results. She reported this on her blog, which was picked up by the scientific community and popular media, contributing to a retraction of the original study (Wolinsky, 2011).

Media Darlings in 2018; listing the university researchers with the most media mentions (Friis & Balslev, 2018).

Many of the challenges of public science communication overlap with those of internal scientific communication. A peer-reviewed journal article can seem worlds apart from an article in a tabloid newspaper. However, both involve selecting what to include and in how much detail, and deciding how to contextualize the findings and their implications. Even when producing a peer-reviewed article, scientists inevitably omit a lot of what actually happened in the lab – such as failed experiments, changes in methodology, or alternative explanations of the findings. And unless publishing in a highly specialized journal, authors are often communicating to scientists from different fields and so have to simplify or explain technical terms. Whilst a lot *more* detail is omitted for a non-scientific audience, the job of translating from one 'language' to another is fundamentally the same. At heart, both scientific and public communication present a storyline or narrative – if in very different genres.

Gregory and Miller (1998, p.245) write:

> *"Scientists take for granted that the scientific paper is not literally true: it is not a blow-by-blow account ... But the scientific paper is truthful even though it is written according to a formula which deliberately distorts the literal truth in order to make the research accessible to other scientists. So popular accounts of science should not be viewed as somehow 'untrue', merely because they, too, have to leave out a lot and simplify what they include to match the expectations and abilities of their audiences".*

Bucchi (2004) argues that we should therefore think of science communication as a continuum with highly technical scientific publications at one end and popular media at the other – in-between lie media such as science magazines, textbooks and detailed documentaries. Thinking in terms of a continuum also highlights the fact that the boundary between popular and scientific communication is far from clear-cut, and reminds us that scientists consume popular media too. For example, social media like Twitter are now a hotspot of networking, debate, and sharing amongst scientists as well as with various publics and stakeholders (Van Noorden, 2014).

2. Public science communication as part of the responsible conduct of research

In recent years, governments, universities, and funders have placed more pressure on scientists to do public science communication – or, in other words, to engage more closely with the society that supports and will be affected by their work. Indeed, societal impact is now generally seen as the third arm of the modern university, alongside research and teaching (see Doubleday, 2009; Pickersgill, 2011; Meyer & Sandøe, 2012).

In Denmark, the University Law states that "The University must as a central knowledge and culture bearing institution exchange ideas and competences with the surrounding society and encourage employees to participate in the public debate." (Uddannelses- og Forskningsministeriet, 2015, Chapter 1, Paragraph 2, Section 3. Translated by Jeppe Berggreen Høj). The Danish Code of Conduct for Research Integrity reinforces this message, stating that "researchers have a right and an obligation to publish and communicate their results to the research community, to professional practitioners, and to society at large" (Ministry of Higher Education and Science, 2014).

However, courses and textbooks on RCR or research ethics rarely cover science communication. This leaves researchers with little guidance on why they might want to communicate, when they have a responsibility to do so, and how to communicate responsibly (Meyer and Sandøe, 2012). The present chapter addresses this gap, focusing on early stage researchers.

One of the key norms of scientific research is that the knowledge it produces should be shared openly within the scientific community. This helps knowledge to advance by avoiding unnecessary repetition of experiments and opening research up to peer scrutiny. It also allows potential applications of basic research to be explored as early and efficiently as possible. In his 1942 sociological study of the

principles under which scientific institutions operate, Robert Merton describes openness or 'communalism' as one of four central norms; the idea that scientists should feel a sense of common ownership of the products of science (Merton, 1973 [1942]). Contemporary formulations based on Merton's work (e.g. Ziman, 2000) still include communalism, and whilst scientists often keep new results or novel techniques under wraps until they are published, the importance of publication in scientists' lives indicates how central a principle communalism still is. Indeed, the contemporary push toward open access journals is part of a long history of scientists attempting to make results freely available to the research community (see Wikipedia, 2020 for a timeline), and more recent moves towards 'open data' also encourage researchers to make materials, data, and code available (see Chapter 5).

Meyer and Sandøe (2012) argue that this principle of openness should extend further, encompassing not just scientific publications read by other scientists but also communication via popular media. Or in other words, common ownership of research results and communication of scientific uncertainty should include those outside scientific institutions. If we fail to share and discuss research in public, we leave people unequipped to deal with scientific controversies when they arise and exclude them from discussions about possibly conflicting research findings.

Openness between scientists and publics can also help to facilitate the progress of research. For example, the translation of research into real world applications can be improved when the people who will use those applications are involved from an early stage. It is also worth noting that as science increasingly emphasizes interdisciplinarity and international collaboration, popular media are an important route for scientists themselves to learn about each other's work and thus focus their efforts most efficiently (Research Councils UK, n.d.).

3. Benefits of public science communication

So why do universities and government institutions emphasize public science communication as a part of responsible research practice? This section breaks down the motivations for public communication, on societal, institutional and personal levels in order to give a fuller picture of the roles science communication can play, and to encourage readers to reflect on which potential benefits might motivate their own communication. As discussed further in Section 5.1, being clear about your reasons for communicating is key to doing it both responsibly and well.[8] Considering motivations for public communication also reveals the fundamental importance of communication in the operation of science itself. From the shaping of research priorities and recruitment of scientists, to the functioning of interdisciplinary collaborations, basic knowledge sharing, and the weaving of translation into 'real world' contexts, communication to non-expert audiences is unavoidable.

3.1 Benefits to society

Research does not occur in a vacuum, it is woven into the society that supports and informs – but can also challenge and hinder - its progress. Public communication is a crucial stage on which relations between science, citizens, and societal institutions are formed: a place where knowledge is transmitted, trust won or lost, and cultural attitudes developed. When journalists misunderstand controversial techniques or politicians use social media to criticize experts, the public sphere can feel like an irritation, but it also keeps us honest. Being prepared to explain why we do what we do can sharpen scientific thinking as well as strengthen our professional ethos. The benefits of responsible communication on a societal level thus span ethical, political, pragmatic, and cultural domains.

- *Democratic imperative*: Publicly funded research institutions rely on taxes, and should communicate with taxpayers about how their money is spent. Even privately funded institutions rely indirectly on the infrastructure of a tax-funded democratic society. Setting aside economic

8 Note that this section focuses on the motives of scientists and their institutions. Media producers – ranging from professional journalists to bloggers, artists, and museum curators – might have other motives for communicating, not least fascination, aesthetics, and entertainment.

arguments, research institutions produce knowledge and aim to affect society for the better. As such, they should arguably involve those who will be affected – though to what degree is a matter of ongoing debate (see e.g. Irwin, 2009; Bultitude, 2011; Davies & Horst, 2016).

- *Scientific citizenship*: If citizens are expected to engage with research and join in debates, they arguably need to know something about science and how it works. *What* exactly they should know is a matter of controversy – is it more useful for citizens to know scientific facts, understand methodologies, appreciate the social and economic contexts of research, or ponder the philosophical implications? (Gregory & Miller, 1998; Bell, 2010). Scientists can span these domains of knowledge, offering not just clear explanations of research findings, but also offering an inside view on the processes, uncertainties, and implications of research.

- *National prestige and economics*: The televised moon landing of 1969 was in part a celebration of the scientific and technological advances that allowed it to happen. As TV viewers around the world watched Neil Armstrong's 'giant leap for mankind' they were also taking in a message about US power and prestige (Gregory & Miller, 1998; p.13). International EXPOs and science and technology fairs are also examples of how communicating research on the international stage enhances a country's reputation, which can then attract future talent and investment in research (Gregory & Miller, 1998, ch.8).

- *Improved research translation*: Research institutions are increasingly asked to translate their research into practical (and profitable) applications. User research is an important part of this process and involves communicating about science with non-experts. In a wider sense, the more that research is part of public culture, and the more that scientists listen to public responses, the stronger basis there will be for designing applications in a way that will be both effective and socially acceptable (Stilgoe, Irwin, & Jones, 2006; Wilsdon & Willis, 2004).

- *Shared culture*: It can be argued that science is part of a shared heritage and as such should be widely accessible, independently of educational goals (Bultitude, 2011). Similar arguments are sometimes made for other supposedly elite cultural domains such as classical music. Davies & Horst (2016) suggest that science is not something outside our daily lives that we just need better access to, but that it is already "part of how we understand ourselves, an integral aspect of the cultural fabric in which we exist … science communication is an activity that allows us to make sense of science and thereby the societies in which we live." (p.2)

- *Public attitudes*: For scientists working in controversial areas, public attitudes can affect their ability to do their work and to obtain future funding. For governments, applications of research in areas such as agriculture, food safety, and social policy can also be hindered by public protest. Contributing to accurate media portrayals of controversial research, providing expert commentary, and participating in public debate can help combat hype (Cossins, 2014), nurture trust (Bultitude, 2011), and possibly prevent protest (Taylor, 2007). To take a more cynical perspective, communication can be used to control public reactions – e.g. by emphasizing the safety or potential benefits of new techniques and downplaying the risks (see Irwin, 2009). But increasing public discussion of controversial research is not guaranteed to have positive results – it can also draw more attention to controversial areas and increase public anxiety. It is also unclear how exactly public responses should be used. For example, how should we handle religious perspectives, what happens if different public groups disagree, and to what degree is it appropriate to allow non-experts shape future research directions?

3.2 Benefits to universities

As mentioned in Section 2, universities are increasingly under pressure to engage with the society around them. A manifesto by the UK's National Coordinating Centre for Public Engagement (2010) highlights that the benefits can be mutual; "higher education institutions can play a … vital

role in the UK's community, intellectual and cultural life through their engagement with the public. It is a role that enables institutions not only to rediscover their roots as active contributors to positive social change but also to gain practical benefits of lasting value." Some of these benefits are listed below (see also Bultitude, 2011).

- *Branding*: Communicating about research in popular media can increase awareness of a university, its staff, and funders. In other words, it is an important part of 'branding' the institution and thus increasing its competitiveness in attracting funding and investment.

- *Reputation and Trust*: Scientists participating in open communication, comment and debate can increase public trust and improve the university's reputation in the wider community. Whilst openness can of course backfire if scandals and controversies come to light, being found to have hidden something is arguably more dangerous.

- *Social Accountability and Responsibility*: Demonstrating social accountability is particularly important in a climate where universities are increasingly under scrutiny for their benefit to society. Social responsibility can be improved both by involving publics in research and its translation and by making researchers more aware of social issues and public perspectives – both are activities that involve communicating about science in public contexts.

- *Recruitment and Training*: Communication with the wider society can help to inspire and recruit future students and staff.

3.3 Benefits to individual scientists

The benefits to society (3.1) and research institutions (3.2) discussed above might seem irrelevant to individual scientists – or at least less pressing than their research. And scientists might also argue that the collective responsibility of the university to communicate does not apply to them individually (Section 4). But there are also a range of individual benefits to taking part in public science communication (Research Councils UK, n.d.):

- *Enhance your scientific CV*: As universities are under pressure to engage more with society, experience in this area can be a bonus point on top of a good research and teaching record.

- *Build a career outside science*: For those young researchers who decide that a career in research is not for them, communication experience signifies valuable transferable skills. It can also lead to specific research dissemination or public engagement roles in, for example, universities, funding bodies and charities, and government research or education departments.

- *Improve your grant success*: Whilst it is a minor part of an application in highly competitive funding rounds when every point counts, a stand-out section on dissemination or public outreach can give you an edge. Previous experience is helpful, but so is being able to come up with original and thoughtful ways of communicating with public groups. Doing media work can also draw funders' attention to your research field and your personal research profile, again improving the chances of success in grant applications.

- *Improve your scientific communication skills*: Intra-scientific communication such as writing journal papers or preparing conference presentations has more in common with public communication than you might think – both involve storytelling, being clear about your main messages, and translation for an audience that is less informed than you (see Section 1). So practicing how to explain research in public will benefit your scientific writing too – and your skill in building interdisciplinary collaborations.

- *Make connections with other scientists*: Scientists are also part of the 'public', and as the use of social and online media increases, the boundaries between science communication for the general public and for interested experts are blurring (e.g. Wolinksy, 2011; Andersen & Söderqvist,

2012). Communicating 'in public' can thus enhance your reputation and recognizability amongst other scientists too. It can also be a way of making direct connections with potential colleagues, collaborators and future employers (Research Councils UK, n.d.), especially through social media (Andersen & Söderqvist, 2012, p.10), and it can, for example, lead to invitations to present your work in person.

- *Keep up with your field and its impact*: Many scientists read the front section of journals such as *Nature* and *Science* to keep up with developments in their field and with wider issues in science funding, governance, and careers. Keeping an eye on how your field is covered on social and popular media can be an extension of this process – many scientists are active on e.g., Twitter and LinkedIn, in part as a way of finding out about research developments (Van Noorden 2014). Following your field in the media can also simply be part of a passion for research and how it shapes and responds to society. Noting what you do and do not like about other media coverage of your field can also help you plan your own public communication work.

- *Have fun!* Lots of scientists who do public communication work do it because it is enjoyable. It can give you a break from research and make you feel more connected to the world outside the lab.

4. Whose responsibility is it to communicate?

4.1 Individual vs. collective responsibility

The Danish Code of Conduct for Research Integrity (Ministry of Higher Education and Science, 2014) states that university researchers have "a right and an obligation" to communicate. This does not imply that all individual scientists have an obligation to communicate all of their research – indeed, there wouldn't be readers enough to process all of the resulting communication! Rather, the duty is a collective one, and therefore lies primarily with the institution. If researchers do want to get involved, particularly at an early stage of their career, their institutions should support them through a culture that values science communication and advises researchers on how to communicate responsibly (see Ministry of Higher Education and Science, 2014; Section 3.2 v. & vi.).

In Section 3.3 we listed positive benefits of doing public science communication for individual researchers. There are equally many reasons scientists give *not* to communicate. One of the main reasons scientists give for avoiding public communication is that they do not have enough time (Royal Society, 2006, p.10). Researchers must of course balance a shared duty to communicate against other duties in relation to research, teaching, administration etc., and be aware of potential conflicts of commitment. Scientists also often refer to it being the wrong time to communicate – e.g. to avoid being scooped or due to restrictive publication agreements with funders or industrial sponsors. And if scientists participate in public conversation about controversial topics, they may be drawn into a polemic or being misinterpreted.

Some years ago a PhD student in applied economics suddenly found herself at the heart of a media storm. She spoke at a scientific meeting about the idea of economic incentives to encourage people to lose weight. A press release ascribed the idea of a 'BMI tax' to her, and a journalist from a Danish tabloid then covered the story (Poul Bøgh, 2003) and significantly distorted her message. Of course, the storm eventually blew over, but this case reminds us to be prepared for misinterpretation, and for the speed with which news coverage moves. It also emphasizes the power of a snappy title – without the phrase 'BMI tax' the story might not have been presented in the same way.

In 2009, KU professor of religion Margit Warburg led a government-commissioned report on the prevalence of the burqa and niqab in Denmark, and reported that it was very low. This led to a great deal of politically-motivated criticism in the media, and the researchers and university had to work hard to defend their research methods and correct misreporting. In other cases, researchers themselves make political comments in the press, which can result in backlash. For example, in 2011 Professor of Political Science

Marlene Wind made comments about a political agreement on increased Danish border control and was accused of using her position as expert to air her personal opinions, resulting in her taking a break from media work (Wikipedia, 2016). But by 2018, Prof Wind was back at Number 3 of KU's 'Media Darlings' (Friis & Balslev, 2018).

Another reason researchers often give for *not* doing public communication is that it is the journalists' responsibility, not theirs. But when researchers are an expert in a field that is currently in the news, they may feel a duty to share their expertise and improve media coverage by, for example, giving interviews to journalists. Even as an early stage researcher, you are likely to be able to offer valuable insight into your research area. It is also worth thinking about the benefits of communicating more directly with public audiences. This can offer the researcher more control over the conversation, and without the strict length constraints of news articles, it can also allow researchers to give greater insight into the 'behind the scenes' of how science works. In the past, only the most high-profile or dedicated scientists would have spoken in their own voices – e.g. through televised lectures or writing popular science books. Today, public events and online and social media have massively expanded scientists' opportunities to communicate directly, even at an early stage in their career.

Even if you decide not to communicate about your own research, talking about research in general achieves many of the same goals. For example, you can inspire future scientists by talking about biology in a school or organizing an activity in your lab as part of a science festival, without mentioning sensitive details of your own studies. This also applies to researchers in highly abstract or technical areas, although it is worth remembering too that the Internet has opened up access to audiences even for geeky or esoteric subjects.

4.2 What role should the public play in science communication?
For many scientists, the main goal of communication is to increase public understanding of science (Royal society, 2006, p.9). From this perspective, the task of the communicator is to translate technical details as accurately as possible into simple language to disseminate information. But thinking of communication as dissemination can also imply that it only goes in one direction: that the listener has nothing to say in return. This has been referred to as the 'deficit model'; assuming that the public is deficient in knowledge, and that good science communication will solve the problem. The deficit model also tends to assume that the public's *attitudes* are deficient, and that knowing more science will make them feel more positive towards research and researchers – that 'to know it is to love it'. Another naïve assumption of the deficit model is that if people understand what science has to say, they will change their behavior accordingly, particularly in public health contexts (Bernhardt, 2004).

In the late twentieth century there was a widespread perception that public trust in science had been damaged (e.g. by the atom bombs of World War Two), and governments and scientific organizations instigated explicit science communication programmes in response. These programmes tended to be grounded in the deficit model and focused on improving public knowledge. Towards the end of the century ongoing public protest around issues such as GM crops, BSE and vaccines suggested that this was not having the desired effect, and sociological studies of scientific controversies emphasized the shortcomings of the deficit model as well as its failure to acknowledge the democratic arguments outlined in Section 3.1. The conclusion taken up by government and scientific institutions was that scientists should 'engage' with publics in a more two-way dialogue, rather than lecture them. In other words, think of non-experts as scientific citizens who might inform and shape as well as consume and appreciate science (for fuller accounts see e.g., Taylor, 2007; Davies & Horst, 2016; Broks, 2004).

Two-way public engagement formats range from informal discussions, creative activities and crowd-sourced research (Davies et al., 2009) to formal consultation exercises set up to gather public perspectives on controversial issues. There is a strong tradition in Denmark of this kind of work (e.g. see Horst, 2008). Social media are another key medium of two-way engagement, as they are fundamentally structured

to invite reciprocal communication and break down barriers of expertise – although this also presents new problems with deciding who to trust and what to pay attention to (Wolinksy, 2011; Mandavilli, 2011; Andersen & Söderqvist, 2012). In practice, it can be hard to draw a clear line between one-way and two-way communication. Many forms of communication lie somewhere in-between, or involve elements of both. Indeed, either one-way dissemination or two-way engagement can be appropriate, depending on your goals (see Section 5.2), though it is surprisingly difficult to produce genuinely reciprocal dialogue (Irwin, 2009; Broks, 2004; Einseidel 2008).

In recent years, there has also been significant critique of public engagement activities that claim to be listening to their participants, but are actually 'deficit model in disguise', prioritizing scientist voices and failing to act on public inputs (Einseidel 2008). A new focus has emerged on the material, affective, and cultural dimensions of public science communication, implying that if we want to understand when and how communication 'works' we need to pay attention to how people feel as well as to what they know (e.g., Davies & Horst, 2016). At the same time, the changing media and political landscape has led to a profound sense of anxiety about how we know what to believe: an era of anxiety about 'fake news' and 'post-truth' where it might be tempting to stick to 'the facts' and avoid communicating about the processes and uncertainties of science. But now more than ever, transparency is key to generating trust; rather than hide the complexity of how research produces knowledge, we need to find new ways to communicate, celebrate, and strengthen it.

5. How to communicate responsibly

If you have decided to communicate, how can it be done responsibly? The Danish Code of Conduct for Research Integrity states that "Research results should be published in an honest, transparent, and accurate manner" (Ministry of Higher Education and Science, 2014), and the European Code of Conduct for Research Integrity ALLEA, 2017) states that "Authors (...) are honest in their communication to the general public and in traditional and social media" (p. 7).

Whilst researchers should always aim for honesty in public (and should certainly avoid *dis*-honesty), it is often impossible to be accurate in the same way for a popular audience as you are for expert colleagues. This, as Gregory and Miller (1998) argued in the quotation in Section 1, does not make popular communication untrue – and it does not mean we should give up and indulge in hype. Rather, it should encourage researchers to work as well as possible within the constraints of public communication.

In 2019, the association of Danish universities proposed seven principles for good research communication, attempting to flesh out concepts such as 'accuracy', 'relevance' and 'uncertainty' (Universities Denmark, 2019). But they also acknowledge that what exactly these concepts mean in practice depends on the context and the discipline: "the seven principles should be understood and applied in accordance with the distinguishing features, methods and history of the various research traditions, and they must be adapted to the many different formats that research communication may have" (Universities Denmark, 2019).

In the remainder of this section, we go through some key questions to consider when planning public communication, to help researchers make the most of the benefits it offers whilst also satisfying the demands of research integrity (5.1-5.5; summarized as a checklist in Box 3). These questions are not highly technical – they just require some reflection and common sense – and writing out answers to each one is good preparation for media work. If you are preparing for public communication activities your department or faculty communication office or media section can also help and advise you. There are also many practical guidelines, courses and workshops to help scientists learn more and improve their communication skills (see Section 7).

5.1 Reflecting on your goals

Being clear about your goals is essential for planning communication effectively and can help to avoid frustration and disappointment. Reflecting on the possible outcomes from a societal, institutional, personal and audience

BOX 3: CHECKLIST OF QUESTIONS FOR RESPONSIBLE RESEARCH COMMUNICATION

1) Reflect on your goals – why do you want to communicate, and what kind of relationship do you want to have with your audience? (Section 5.1)
2) If you have a choice, which media will best match your goals? If you cannot choose which media to use, do you need to adjust your goals? (Section 5.2)
3) Which aspect(s) of research do you want to communicate about? (Section 5.3)
4) Within the constraints of your medium, what is your key message? How can you honestly and accurately describe the novelty, importance, certainty, statistics, practical applications and ethical or societal implications of your research? (Section 5.4)
5) Are there any requirements or restrictions (a) on what you communicate and (b) how you present your affiliation and expertise? (Section 5.5)

perspective (see Section 3) can also draw your attention to potential unanticipated effects. For example, your primary goal may be to raise the profile of your department, but emphasizing your cutting-edge techniques may also draw attention to uncertainty surrounding their safety or ethical status. Being clear about the goal of communication can also help you to explain and defend your activities to others, and is crucial to a meaningful evaluation of whether the communication was successful (Research Councils UK, 2011). Enjoyment and connection are also legitimate goals, recognizing that communication can be an emotional or identity-building activity, as well as a cognitive process of improving knowledge and understanding – and this is equally true for both scientists and publics (Davies & Horst, 2016).

One key dimension to consider when thinking about goals is what role you want the audience to play – do you want them to learn or to contribute? In other words, will you focus on one-way dissemination of information from a scientific expert to a public audience, or do you want to engage in two-way dialogue or public engagement? Section 4.2 gives a brief history of this key distinction, which also relates to the democratic arguments for involving publics in discussions about research outlined in Section 3.1. Of course, many communication activities will contain elements of both one-way dissemination and two-way engagement, and both are appropriate in different settings. What matters is being clear about your expectations and communicating them clearly to your audience or participants. This helps to avoid the frustration that can arise when, for example, scientific institutions say they will take public opinion into account and then fail to do so.

When thinking about your goals, it is important to recognize that communication professionals such as journalists or university media officers have different goals, duties and constraints. For example, journalists may consider it their duty to report how basic biomedical research is relevant to patients, whilst scientists may consider it their duty to downplay how close we are to practical applications. Understanding and respecting each other's professional goals can help the diverse players in the science communication landscape to make the most out of working together. To continue the example above, if you respect a journalist's need to report on the future clinical application of research you can prepare an answer that clearly emphasizes the uncertainties and timescale of translation. There is of course always a risk that a journalist will misquote, misrepresent or misunderstand you, but this is often a risk worth taking. You can reduce the likelihood of being misrepresented by preparing well for interviews – write out clear take home messages, both about what your findings mean and about what they *don't* mean. And always ask to check the reporting for accuracy before publication – this is standard practice within Denmark, though varies internationally.

5.2 Matching the media to your goals

Once you are clear about your goals, consider which media would best help you fulfil them. For example, if you want to

encourage young people to take part in democratic debates about the use of cloning technology, a discussion activity may be more effective than a lecture. If you want to get as much attention as possible for a high-profile result from your lab, working with the university press office to get the national newspapers and digital media interested may be better than writing a detailed blog post about methodology (although the impact of a blog post going viral should not be underestimated).

Of course, sometimes the medium is decided for us – if a newspaper calls for a quote about your recently published *Nature* paper, you are unlikely to turn it down in favour of using Facebook. If the media is decided for you, you may need to adjust your goals. For example, you are likely to be frustrated if you aim to communicate a nuanced picture of the uncertainty surrounding the future trajectory of research by giving a quote over the phone. It's also important to note that if the publication or journalist who approaches you has a history of misrepresenting research, you may want to turn down the interview. If you decide to go ahead but are uncomfortable with how an interview is going, you can decide to politely end the conversation and request not to be featured.

Communication is not just about information; it is also about emotions, identity, and culture (Davies & Horst, 2016; Broks, 2004). And just like different media are suited to different kinds of information-transfer; different media tend to pull towards different emotional tones. This is also worth bearing in mind when choosing or adapting to your medium: a public talk tends to work well if the presenter is relaxed and friendly, whereas 'experts' are more likely to be believed on television if they act with seriousness and professionalism. The emotional connections an audience brings to the topic are also important to bear in mind; for example if talking to a group of parents about vaccination.

5.3 Communicating different aspects of science

At several points in this chapter it has been suggested that if we want public audiences to engage in meaningful discussions about research, we need to communicate how science *works*, not just the results that come out at the end. There are several reasons for this. First, science is always 'in the making' (Shapin, 1992) – a scientist should never express 100% certainty that a particular finding will hold forever. More likely, they will admit to some uncertainty over how future experiments will refine or revise current knowledge. Communicating about this uncertainty is a difficult task, but it is often worth the effort. For example, someone who has read about changing advice on drinking during pregnancy might think either that scientists are lying or that the research is unreliable. But if they understood that certainty about the effects of alcohol evolves over time, and were given information about the levels of certainty attached to current recommendations, they would then have a firmer basis for deciding how to utilize those recommendations in their own lives.

Another reason for communicating about the processes and methodologies of science is that this kind of knowledge can be generalizable. If people understand how clinical trials work, for example, they can apply this knowledge to future media reports about other trials. And finally, if we are serious about doing two-way public engagement that invites audiences to participate in the discussion of research, some knowledge of methodology is essential. 'How science works' most obviously refers to methodology or theory of science. But it can also refer to social, ethical, and even personal aspects of science – for example, to the way funding and safety legislation works or to ethical debates surrounding particular techniques. Communicating about these wider aspects of research also contributes to a culture where people are equipped to take part in debate, to act as scientific citizens, and see scientists as fully-fledged human beings.

This section has focused on what *scientists* would like to communicate, and how to get our message across. If we take arguments for two-way engagement seriously, we should also be asking what aspects of science are important and interesting from the perspective of the public groups we are trying to engage (Turney, 2003; Broks, 2004; Bell, 2010). Turney (2003) argues that rather than deciding in advance what people need to know about science, we should focus

on situations where science is relevant to their lives or where they are genuinely being invited to participate, and then communicate the information that *they* want in those contexts. On the other hand, audiences may not know they are interested in something until it is offered: whilst the news media often claim to cover stories that are of public interest, they also shape those interests over time.

5.4 Novelty, importance, certainty, statistics, and practical applications

In attempting to communicate *"in an honest, transparent, and accurate manner*" (Ministry of Higher Education and Science, 2014) there are several common pitfalls relating to the temptation to 'oversell' the importance of research findings. This temptation can be strong when your goals include increasing the public profile of your work or institution, and it is exacerbated by the drive of many media outlets to produce 'big splash' stories. A recent case that illustrates this problem is that of former PhD student at Aarhus University Ole Henrik Hansen, whose studies of interactions between teachers and children in Danish nurseries were widely reported. His findings were troubling, but were overstated in the media, which then led to a backlash – Hansen later wrote that he had been "an elephant in a china shop". A crucial detail of this case is that early newspaper reports stated that Hansen's results were based on 40.000 survey responses, whilst in fact the number was 1.412 (Buch-Andersen, 2012). This case reminds us that being as cautious about the details and the implications of our findings is as important in public media as in scientific publication.

Making a list of phrases that accurately describe the novelty, importance, certainty, and practical and societal relevance of your research is good preparation for any communication activity (see *Guidelines for Scientists on Communicating with the Media* (Social Issues Research Centre, 2006) for more details and other practical tips):

- How *novel* are your findings? How do they relate to other work in the field? Do they contradict an accepted view or introduce a new hypothesis?
- How *important* are your findings? For example, do they close a gap in our knowledge, provide a missing technique, or promise to lead to an important practical application?
- How *certain* are you about the results? What are the sources of uncertainty, and are there experiments in progress that will help to confirm, refute or revise your findings? How widely accepted are your findings by other scientists in your field?
- Do your results include a *probability*, or do you need to communicate a level of *risk*, particularly in relation to health? If so, be very careful how you present these statistics and consider how to make them meaningful to a public audience.
- What are the potential *practical applications*, how close are they, and what factors stand in the way of progress? Relatedly, are there any *ethical* or *societal issues* associated with your research which you may be asked about or want to communicate?

5.5 Restrictions, requirements and affiliations

University of Copenhagen legislation supports scientists in their freedom to communicate about research (Uddannelses- og Forskningsministeriet, 2015; Ministry for Higher Education and Science, 2014). However, there may be specific restrictions on when you communicate, as well as on what exactly you say. These might come from your supervisor or from colleagues, in which case they can often be negotiated. Restrictions may also come from funders, sponsors or professional bodies, or from a journal embargo that prevents you discussing a paper before it is published. As a researcher you may also wish to adjust the timing of communication to avoid being scooped; in some fields it is considered important that scientists don't communicate before their research has been published, though in some fields data is shared in 'preprint' archives. If you have any concerns, check with your supervisor, or funder, or with other parties whose interests may conflict with your own (see Chapter 7 for a discussion of how to define and handle conflicts of interest).

There may be requirements as well as restrictions when you do public communication. For example, a funder may require

that you mention them, or your university may require you to include a link to a media enquiries page whenever you write online about your research. There may also be rules about when you present yourself as a representative of your institution. Again, check with your supervisor or media department if you are unsure.

Finally, it can be unclear how to present your expertise. Scientists sometimes worry about not being experts outside their own specific research niche, but even when you are talking more broadly about research, your expertise is probably greater than the interviewer's. On the flip side, scientists sometimes offer opinions on the implications of their research – e.g. on societal or ethical issues – that step well outside of their field of expertise. To tread this fine line responsibly you are not necessarily required to avoid discussing topics outside your specific research niche. It is important, however, to be clear about the limits of your expertise and to be certain whether what you are saying is backed up by evidence. Acknowledging the different kinds of expertise that your audience bring with them can also smooth the way for dialogue about the meanings and values of research.

6. Practical advice

Section 5 summarized some key points to consider and prepare before doing public communication work. The guidelines below give more details. They are split into general advice and practical tips for science communication and public engagement (6.1) and for using social media (6.2), plus some suggestions for courses and workshops if you are interested in learning more (6.3).

6.1 General advice on communication and public engagement

- Universities Denmark (2019). Seven Principles for Good Research Communication.
- National Institutes of Health, US. (2016). *A Checklist for Communicating Science and Health Research to the Public*.
- Social Issues Research Centre (SIRC) (2006). Guidelines for Scientists on Communicating with the Media.
- Science Media Centre UK. Publications. These short leaflets offer practical tips for a range of communication scenarios.
- National Co-ordinating Centre for Public Engagement, UK (2010). *The Engaged University: A Manifesto for Public Engagement*. See also case studies and practical guidance on the same website.

6.2 Advice for social media communication

- Nature has an online collection of articles on *Social Media for Scientists*.
- Mollett A, Brumley C, Gilson C, & Williams S (2017). *Communicating your Research with Social Media: A Practical Guide to Using Blogs, Podcasts, Data Visualisations and Video.* Sage Publications.
- Bik HM & Goldstein MC (2013). An introduction to social media for scientists. *PLoS Biology* 11(4): e1001535.
- Lewis NA, Van Bavel, JJ, Somerville, LH, & Gruber J (2018). A social media survival guide for scientists. *Science* [Weblog].

6.3 Courses and workshops

- In Denmark, search phdcourses.dk for 'communication'.
- Danish newspaper *Information* runs a longer medieskole course for PhD students which happens in the spring as part of their PhD cup programme.
- In the UK, there are residential science communication courses at the University of the West of England and the Royal Society.
- Online certificate/masters course from Edinburgh University in Science communication and public engagement.
- Online science journalism course from the World Federation of Science Journalists, in close cooperation with the Science and Development Network SciDev.Net.

7. Test yourself questions

- Give three reasons for doing public communication from a societal perspective, three from a university perspective, and three from the perspective of an individual scientist. Which do you find the most convincing and why?

- Describe two motivations for communicating science to the public from an individual researcher's perspective, and for each discuss whether there are conflicts of interest involved.
- Why is public communication included in a textbook and course on RCR? Do you agree that it should be?
- Describe the difference between top-down dissemination of scientific knowledge, and two-way public engagement. Discuss some of the reasons for engaging the public in dialogue, and some of the things that can go wrong.
- Discuss whose responsibility it is to communicate about scientific research in public, and how you think the responsibilities of the individual scientist and the university differ.
- What does it mean to do public communication responsibly?
- As a researcher, what challenges might you face in talking to journalists? Give four examples of questions you should prepare to answer before giving an interview.
- Discuss the role of public communication in establishing public trust in science – and whether you think anxiety about 'fake news' and a 'post truth' era should change how we communicate.

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9.
Appendix 1:
Key guidelines, policies, and legislation

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Appendix 2:
A short introduction to GDPR

Lene Stevner and Peter Sandøe

What is GDPR?

GDPR, or General Data Protection Regulation, regulates the processing of personal data relating to individuals when data are processed in an EU Member State.

The purpose of GDPR is to impose a uniform level of privacy protection within all Member States when data are processed in the Member State or transferred to other Member States within the EU/EEA.

This puts companies, researchers and other actors on a level playing field when it comes to personal data protection. Due to the EU's global importance in trade and international science, GDPR will have an impact on personal data protection requirements globally.

The privacy and data protection requirements of GDPR include:

- Consent of subjects to data processing
- The need to anonymise collected data as soon as possible to protect privacy
- Provision of personal data breach notifications to authorities
- Requirements for safe handling and transfer of personal data across borders
- The need for larger companies and institutions to appoint a data protection officer (DPO) to oversee GDPR compliance (University of Copenhagen (UCPH) has appointed Lisa Ibenfeldt Schultz as DPO).

Which data count as personal?

Any information which can directly or indirectly be linked to an identifiable person counts as personal. This definition means that a wide range of data are personal, including names, identification numbers, location data, biological material, or online identifiers.

LINKS

- DPO: dpo@adm.ku.dk
- Legislative acts
- KU-guide in Management of Personal Data – Research Portal

Personal data in research?

The processing of personal data in research projects must comply with the GDPR.

Why?
Apart from the need to comply with the legislation, additional requirements are imposed by funders, journals and the institutions to which international collaborators belong.

Potentially there are grave economic consequences: The University of Copenhagen (UCPH) can be fined up to four per cent of annual global turnover for breaching GDPR, or 20 million euro.

What must a researcher do to comply with GDPR?

Before the project
All projects involving the collection, handling and/or processing of personal data must be registered at the University by completing the registration form (see link below).

If personal data are entrusted to external processors who are to perform a task or handle the data for the University, a data processing agreement must be concluded and signed by the Head of Department. A copy must be sent to the Faculty Secretariat. The Tech Trans Office negotiates the data processing agreement if the main contract is negotiated by them.

For data processors outside the EU, the Standard Contractual Clauses Template must be used as the agreement with data processors and signed by the Head of Department. A copy must be sent to the Faculty Secretariat. The Tech Trans Office negotiates the agreement if the main contract is negotiated by them.

Project managers who grant students access to research data must enter into a data processing agreement with the individual student.

Create a project-ID list. The ID list must be the only document/key connecting the subject's personal data/ biological samples with his or her name or other identifiers. It must restrict access to the identity of the subject via a unique project-ID. Store the project-ID list separately from all other documents or biological samples.

All study documents and samples must be identified only by project-ID (pseudonymised).

The ID list in hard copy must be stored under lock and key in a "room" with a limited number of keys and restricted access.

The electronic ID list must be stored in a folder on the personal drive or the S-drive if it is to be shared with other staff. The ID-list must never be shared with external processors.

Never use DropBox, OneDrive, etc. for personal data.

"One Drive Business" can be used for sharing with external collaborators, but all personal data must be encrypted.

E-mails containing personal data must maximum be stored in outlook for 30 days. If an mail contains important information and needs to be saved as documentation, it must be transferred to the personal drive or the S-drives.

Implement a "Good Data Management Procedure" for handling personal data.

Train project staff in the procedures.

The project manager is responsible for carrying out an impact assessment if personal data are to be processed in research projects and the processing of personal data will result in a high risk to project participants. Questions about the risks associated with the data processing is implemented in the registration form (see below).

NOTE that there may be requirements going beyond those relating to the processing of personal data:

If the trial includes biological material and/or a medicinal product or a medical device, additional approvals from a committee on health research ethics and/or the Danish Medicine Agency is mandatory.

For other research it may be advisable to apply for permission at the Research Ethics Committee for SUND and SCIENCE.

During the project
Data subjects must give informed consent to the processing of their personal data for one or more specific purpose or protocol.

The researcher must be able to demonstrate that the data subject has consented to the processing of his or her

LINKS

- Registration form
- Risk and impact assessment
- Processing of sensitive data in health and social sector
- Privacy impact assessment
- Agreement with data processors
- Standard contractual clauses
- Student Contract
- Create a folder on S-drive
- Guidelines about notification etc. of a biomedical research project to the committee system on biomedical research ethics (in Danish)
- Research Ethics Committee for SCIENCE and SUND
- Guideline for applications for authorisation of clinical trials of medicinal products in humans
- Application for clinical investigations for medical devices

personal data: Archive the Informed Consent Forms or other documentation under lock and key or on the S-drive as a scanned copy.

New data processing agreements must be completed in an ongoing way when new processors become involved and always before data are transferred to the processor.

ID lists are to be updated in an ongoing way as long as subjects are included in the project and their data are recorded.

The project should be considered as ongoing for as long as the data are being processed.

Where personal data are no longer required for the project, they must be anonymised – the sooner the better.

Data are anonymous when it is no longer possible for anyone (including the researcher) to re-establish the identity of the subject with reference to remaining information/data. Hence proper anonymisation requires the ID list to be destroyed. Qualitative data may need to be checked and redacted to remove information that could serve to identify a specific person.

Likewise, with biological material it may be necessary to delete or remove certain meta-data.

After the project
A project can only be viewed as ended when anonymization has been successfully completed, is transferred to the Danish National Archives (Rigsarkivet), or, if the participants have consented to this, transferred to a secure database.

Good Clinical Practice (GCP) Guidelines require the archiving of source data for 15 years. (A new EU regulation expected to apply from 2020 will extend that period to 25 years.)

The Danish government's "patient insurance" requires material to be archived for 10 years.

The Ethics Committee Act requires that sources are stored for as long as clinical analyses are being performed and clinical findings can be made. It also requires the subject to be informed.

Non-anonymised data without consent can only be archived at the Danish National Archives (Rigsarkivet).

If things go wrong
If there is a breach in security, such as an accidental unauthorised breach of data protection, contact the department's Information Security Representative who will assist with further procedures:

- ensure that the information is no longer available
- inform affected persons of the incident
- inform the UCPH Information Security Unit by filling in the form in the employee guide. The Information Security Unit will inform the Data Protection Agency about the incident within 72 hours of its being discovered if required.

OTHER USEFUL LINKS

- GDPR for Researchers
- GDPR and research projects
- Danish Data Protection Agency (in Danish)
- Guide in Data management of Personal data in Research/ NEXS (English version in process)
- Employee guide: Handling of security incidents

For at more thorough introduction to data management, see chapter 5.

ABBREVIATIONS AND GLOSSARY

DDPA	Danish Data Protection Agency
DMA	Danish Medicines Agency
DPO	Data Protection Officer
EC	Committee on Health Research Ethics
EU	European Union
EØS (EEA)	The 28 EU countries plus Iceland, Liechtenstein and Norway
GDPR	EU General Data Protection Regulation
GCP	Good Clinical Practice
KU/UCPH	Københavns Universitet/University of Copenhagen
Pseudonymisation	"Pseudonymisation" means replacing any identifying characteristics of data with a pseudonym, or value, which does not allow the data subject to be directly identified. Pseudonymisation should be distinguished from anonymisation. It provides only limited protection of the identity of data subjects, as in many cases it still allows identification via indirect means. Where a pseudonym is used, it is often possible to identify the data subject by analysing underlying or related data.
Pseudonymised data	Pseudonymised data remains personal data.
Anonymisation	"Anonymisation" of data means processing it with the aim of irreversibly preventing the identification of the individual to whom it relates. More specifically, data are anonymised when they do not allow individuals to whom they relate to be identified, nor is it possible for individuals to be identified from the data by any further processing of that data or by processing it together with other information which is available or likely to be available.
Anonymised data	Irreversibly and effectively anonymised data are not "personal data", so the data protection principles do not have to be complied with in respect of such data.
Data controllers	Data controllers can be either human persons or "legal persons" such as companies, governmental departments and voluntary organisations. All data controllers must comply with important rules governing their collection and use of personal information. They must also re-register annually in order to make their data handling practices transparent.
Data processor	The data processor is someone distinct from (working at a different university) the data controller for whom she/he is processing the personal data.

Appendix 3: What to remember and consider when you submit your PhD thesis and papers to scientific journals

Martin Marchman Andersen and Peter Sandøe

When submitting a paper or a PhD thesis one is typically confronted with a great deal of *responsible conduct of research*-issues, RCR-issues. These are issues on open access requirements, data management, authorship issues, documentation of ethical and legal permissions, declaring one's conflicts of interest, and etc. It is not always easy to navigate these issues. Below you find a checklist of things to remember and consider when you submit papers to scientific journals, and when you submit your PhD thesis. The list covers the most general RCR aspects of submission, but there might be RCR-issues not covered in the list. We hope you will find it helpful.

1. The right journal

Specific to submissions to journals

When looking for the right journal consider the following:

- What is the scientific scope of the journal? And how does your work fit into the scientific scope of the journal?
- If it does not fit, find another journal.
- If in doubt, you may try to write and ask the editor.

Is the journal trustworthy?

- If you are in doubt, ask yourself some of the following questions: Does the journal publish research that you would read yourself? Which organization publishes the journal? Are prices transparent? Do you know/have you heard of any of the editorial board members? If still in doubt, see more at: thinkchecksubmit.org

2. Issues of plagiarism and self-plagiarism

Plagiarism, if grossly negligent or done deliberately, is *research misconduct* and self-plagiarism is *questionable research practice*. It is advisable to stay clear of both. Consider the following:

General considerations

- If you copy text from others, be sure to quote the originals! Copied text should always appear in quotation marks.
- If you paraphrase, be sure to make clear references to the originals!
- Plagiarism does not only concern text, but also e.g. images, figures and tables. If you use an image/figure/table that is not of your own creation, be sure to write explicitly that you have copied from (…) with a clear reference to the original!
- If you re-cycle text from your other papers, or your PhD/master thesis, be sure to quote and make references to your own work.
- If you paraphrase yourself, be sure to make clear references to yourself.
- If you re-use an image/figure/table that you have published elsewhere be sure to write explicitly that you have copied from (…) with a clear reference to the original!

See more in the Danish Code of Conduct for Research Integrity.

NOTE *These are tips as for how to stay clear of plagiarism and self-plagiarism. But staying clear of plagiarism and self-plagiarism is not sufficient for scientific quality. In PhD theses based on articles, it is necessary that the PhD student writes the synopsis of the thesis in his/her own words. This is particularly important in parts of the synopsis that are rich on text such as the abstract, introduction/background, discussion and conclusion/perspective. It is not possible for the assessment committee to specifically evaluate the PhD student's independent contribution to co-authored articles, so if long text paragraphs in the synopsis have been copied/paraphrased from co-authored articles, the assessment committee is less able to evaluate his/her skills and competences.*

In concise parts of the thesis where precision is pertinent, such as methods & materials descriptions and data intensive results sections it is generally acceptable to duplicate text, as long as there are clear and explicit references to the originals.

Considerations specific to journal submission

Papers are often desk-rejected by the editors because of formalities. Be sure to follow the 'instructions to authors' of the journal in regards to:

- Manuscript formatting
- Citation and referencing style
- Format and details about figures, tables and statistics

Considerations specific to submission of your PhD thesis

- Make sure that quotes are easily seen as quotes, and that you quote in a consistent manner throughout your thesis.
- Pick a referencing style that is common for your scientific field and apply it consistently throughout your thesis.

3. Open Access Issues

Does your funding source require the use of Open Access? Fully or partially publicly funded research (and research funded by some private funds, e.g. the Carlsberg Foundation), must be made freely available to everybody via Open Access insofar the journal allows it. Open Access is often in your own interest too. It makes it easier for others to access your work.

See Denmark's National Strategy for Open Access.

Considerations specific to journal submission

What is the journals policy on pre-print and post-print? And does it impose an embargo?

- *Pre-print* usually means a version of your paper prior to peer review. But there may be differences from journal to journal, so check your journal for the right definition.
- *Post-print* usually means a version of your paper after peer reviewed, but not the publisher's version. But there may be differences from journal to journal, so check your journal for the right definition.
- *Embargo* is usually the time from publication until the journal allows you to share publicly a post-print version of your paper.
- You can check most journals policies on pre-print, post-print, and embargo on sherpa.ac.uk.

What are the journal's policies for reusing single diagrams or pictures, for future scholarly purposes?

Considerations specific to submission of your PhD thesis

- If parts of your thesis have been published, or is under peer review, are there potential conflicts between the policy of the journal and the requirement of your PhD thesis being publicly available?

4. Authorship Issues

According to the Vancouver Recommendations everyone contributing substantially to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work should be given the opportunity to fulfill further three conditions and thereby be honored with authorship.
See chapter 4.

General considerations

- Have you added ALL authors, and ONLY all authors, to the byline of your paper/thesis? Can you describe the contribution of each author and why it qualifies to authorship?
- Do you acknowledge scholars who have contributed to your paper/thesis, but who do not qualify as authors? If so, did you ask for their permission?

Considerations specific to submission of your PhD thesis

If you plan papers to be part of your PhD thesis, consider the following:

- If you have co-authors, have you collected your co-authors' signatures on a co-authors statement?
  Find the declaration here.
- Are there PhD students other than yourself among your co-authors who will include the paper in their PhD thesis? If so, you should synchronize your estimations of the size of each authors' contribution!

5. Conflicts of interest

Often journals require you to declare your conflicts of interest, and according to the Danish Code of Conduct for Research Integrity you should disclose any conflict of interest. If you have financial conflicts of interest it is wise and in accordance with the Code to disclose it.
See chapter 7.

General considerations

- Is any of your work funded by companies, institutions, or organizations that could be thought to have a financial interest in the results of your study being in one way rather than another? If so, declare it!

- Do you, your close family or friends, hold assets, the value of which may be affected by the result of your study? If so, declare it!
- Are you affiliated with, or do you hold a partnership with, companies, institutions, or organizations that could be thought to have a financial interest in the results of your study being in one way rather than another? If so, declare it!
- If still in doubt, see the specific guidance of the journal, or write and ask the editor of the journal.

6. (Ethical) Permissions

Journals may require you to document the relevant legal and ethical permissions of your study. You might also be expected to, or it may be required of you to, document relevant legal and ethical permissions in your PhD thesis. You should therefore be aware of the legal and ethical requirements to your study, and you should know how to document the granted permissions.

General considerations

Does your study involve clinical research?

- Journals often require a filenumber referring to the registration of the Regional/National Committee on Health Research Ethics' permission of your research.
- It is increasingly required that clinical trials are registered in international databases like clinicaltrials.gov

Does your clinical research project include test of drug(s) and/or medical equipment?

- Approval from Danish Medicines Agency (Lægemiddelstyrelsen) is required and journals often requires a filenumber referring to the registration of the permission.

Is your research based on information from hospital records?

- Approval from the Danish Patient Safety Authority may be required and journals may have requirements of documentation.

Does your research involve gene- technology or therapy?

- If so, it should be approved by the The Danish Working Environment Authority. Journals may have requirements of documentation.

Does your research involve radiopharmaceuticals?

- If so, it should be approved by the Danish Medicines Agency (Lægemiddelstyrelsen). Journals may have requirements of documentation.

Does your study involve animal testing?

- Journals may require documentation of The Animal Experiments Inspectorate's permission of your study.

Does your study involve personal data?

- If so, it should be approved by the Faculty Secretariat. Journals may have requirements of documentation.

Sometimes journals require (or encourage to) permissions form the institutional review board. This is often, but not only, in regards to research including surveys and interviews. Journals may require permissions from the Research Ethics Committee of Science and Health, Copenhagen University.
See chapter 5.

7. Data Management

Submitting a paper, and even more your PhD thesis, gives you the opportunity to check your data management. Journals may ask questions pertaining to data management.
See chapter 5.

General considerations

- What is your primary material? Where is it stored now? Where and how do you aim to store it in the future?
- What are your data? Where are your data stored now? Where and how do you aim to store them in the future?

Do you work with personal data? Have they been anonymized?

- If yes, where did you store the informed consents?
- If no, where and how are they stored? See more at KUnet.

Do you intend to, and are you required to, share your data at the end of your project? If so, where will you share them? See more at KUnet.

If you have questions about data management you may ask them at: datamanagement@ku.dk

8. Other issues

Considerations specific to journal submission

- If your research involve animal research, your paper should be aligned with the ARRIVE guidelines!

Considerations specific to submission of your PhD thesis

- Have you discussed with your supervisor who to nominate as members of your assessment committee for your PhD thesis? See more at your PhD School.
- Did you consider and have you talked to your supervisor and other partners about your work responsibilities in regards to publication of articles after your PhD project? For example, if you receive an 'accepted with minor revision' feedback from a journal you submitted a paper to while you were still a PhD student. Who shall revise and re-submit the paper?

General considerations

- Make sure your English is correct (linguistically fluent etc.) in your papers and your thesis.
- If you intend to apply for a patent on an invention you have made, do not publish or present your work publicly before you have filed an application! See more at dkpto.dk
- Do you consider your work to be a piece of responsibly conducted research? If not, do not submit it!

Since 2011 it has been mandatory for all new PhD students at the University of Copenhagen to take a course in RCR (Responsible Conduct of Research). This book will serve as a textbook for the courses held at the Faculty of Science and at the Faculty of Health and Medical Sciences.

The book aims to give an accessible presentation of what PhD-students are supposed to learn about RCR; to present a clear and consistent terminology; and to focus on the way RCR is dealt with in Denmark and at the University of Copenhagen. The intended readers are from two faculties where the large majority of research falls under the umbrella of the natural sciences, broadly construed.

The book can also be of use to other scientific staff at the University.

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