



Vetenskapsrådet

GOOD RESEARCH PRACTICE



GOOD RESEARCH PRACTICE

SWEDISH RESEARCH COUNCIL
VETENSKAPSRÅDET

Box 1035

SE-101 38 Stockholm, SWEDEN

VR1710

ISBN 978-91-7307-354-7

Good Research Practice

FOREWORD

Ethics considerations and guidelines play a very important role in the quality and implementation of research, and in how research findings can be used in a responsible manner to develop our society. All who take part in the research process should discuss ethics issues actively. The Swedish Research Council considers initiating such discussions as one of its most important tasks, and has since 2001 had a group of experts in ethics who deal with research ethics issues, both those specific to the Research Council, and those of a more over-arching nature.

The expert group has taken the initiative for the book “Good Research Practice”. The aim of the book is to give readers the opportunity to orientate themselves among the issues and problems, to encourage thought and to contribute to a discussion on responsibilities and challenges. The book is aimed primarily at researchers, not least those at the beginning of their careers, to help them to make well-considered decisions on research and research ethics.

The current edition is a partially revised version of the most recent edition, published in 2011. The revision, which was carried out by the group of experts, covers areas such as changes in legislation.

Stockholm, 12 June 2017

Sven Stafström

Director-General, Swedish Research Council

CONTENTS

FOREWORD	2
INTRODUCTION	7
SAMMANFATTNING	8
SUMMARY	10
1 WHAT ETHICS DICTATES AND THE LAW DEMANDS	12
1.1 Ethics and morals	12
1.2 Research ethics and professional ethics	12
1.3 Merton's CUDOS norms	13
1.4 Ethics codes	13
1.5 The law and morals	14
1.6 The law and morals in the area of research	15
1.7 Various quality criteria	16
1.8 Review	17
1.9 Various regulatory systems	17
References	18
2 ABOUT RESEARCH – WHAT, WHY, HOW AND FOR WHOM?	19
2.1 Starting points for research	19
2.1.1 Some types of research	19
2.1.2 Why conduct research?	19
2.1.3 How is research conducted?	20
2.1.4 Who bears the responsibility?	21
2.1.5 Terminating research – when and why?	21
2.2 Making research results useful	22
2.2.1 The elusive and multidimensional benefit	22
2.2.2 Research funding and collaboration	23
2.2.3 Various forms of collaboration	24
2.2.4 Problems and pitfalls	24
2.2.5 Openness is your guiding light	25
2.3 Quality and reliability	25
2.3.1 General principles	25
2.3.2 Research question and method	26
2.3.3 Observational studies conducted through participating, observing and recording	26
2.3.4 Sources of error and reliability	28
2.4 Research ethics from a dynamic perspective	28
References	29
3 ETHICS REVIEW AND OTHER PERMIT REVIEW	30
3.1 Ethics review and other permit review of research involving humans	30
3.1.1 Approval according to the Act concerning the Ethical Review of Research Involving Humans, etc.	30
3.1.2 Other approval	32

3.2 Research on animals and laboratory animal ethics.....	32
3.2.1 The use of laboratory animals	32
3.2.2 Laboratory animal ethics	33
3.2.3 The ethics committees on animal experiments: organisation and task.....	33
3.2.4 Ethics review	34
3.2.5 Alternatives to using laboratory animals	34
3.2.6 Evaluating the ethics of animal experiments.....	35
3.3 Genetically modified organisms	36
3.4 Examples of problems that are still unsolved	36
References	37
4 HANDLING OF RESEARCH MATERIAL - THINK FIRST.....	39
4.1 Background and problems	39
4.2 Interest considerations and various types of research	39
4.3 Four concepts.....	40
4.4 What can researchers promise?	40
4.4.1 Secrecy	40
4.4.2 Professional secrecy	41
4.4.3 Anonymity	41
4.4.4 Confidentiality.....	41
4.4.5 Conclusions.....	41
4.5 Documentation	42
References	43
5 RESEARCH COLLABORATION	44
5.1 Introduction.....	44
5.2 Relations with fellow researchers	44
5.3 Interaction with funding and commissioning bodies	45
5.4 Commercial aspects.....	46
5.5 Responsibility for a collaborative project: general.....	47
5.6 Issues of responsibility in multinational research projects.....	47
5.6.1 Starting points	47
5.6.2 Conditions of responsibility	48
5.6.3 Moral and legal responsibility	49
5.6.4 The extent of responsibility	50
References	51
6 PUBLISHING RESEARCH RESULTS	52
6.1 Why publish?	52
6.2 Disclosure of financial and scientific dependence.....	52
6.3 Background, materials and conclusions.....	52
6.4 The third task and the media.....	53
6.5 Open access	54
6.6 Publication as a measure of worth	55
6.7 The author.....	55
6.8 Multiple authors – responsibility – publication rules	56
6.9 The responsible publisher and the editor	57

References	58
7 OTHER ROLES OF THE RESEARCHER.....	59
7.1 The supervisor and postgraduate supervision	59
7.1.1 The tasks of the supervisor	59
7.1.2 Whose ideas?	59
7.1.3 The thesis and its presentation	59
7.1.4 Responsibility for ethical and legal compliance.....	60
7.2 The teacher	60
7.3 Assessing applications and proposals	60
7.4 Reviewing manuscripts for publication	61
7.5 Committee work	61
References	62
8 RESEARCH MISCONDUCT	63
8.1 Introduction.....	63
8.2 Questions of definition and scope	63
8.3 Fabrication and falsification.....	64
8.4 Plagiarism.....	65
8.5 Unpublished material and self-plagiarism	66
8.6 Establishing plagiarism.....	66
8.7 Prevention	67
8.8 Sanctions for misconduct	68
8.9 Addressing issues of misconduct.....	68
8.10 A broader perspective	69
References	70
9. KEY LEGISLATION AND OTHER REGULATIONS WITH WHICH RESEARCHERS SHOULD BE FAMILIAR.....	71
9.1 Personal data handling.....	71
9.1.1 Legal support for personal data handling	71
9.1.2 International regulations	71
9.1.3 The UN's Universal Declaration of Human Rights, etc.	72
9.1.4 The European Convention on Human Rights	72
9.1.5 The Council of Europe's Data Protection Convention.....	72
9.1.6 OECD's Guidelines	72
9.1.7 The European Union's Charter of Fundamental Rights	73
9.1.8 The Data Protection Directive	73
9.2 Two important Swedish laws.....	73
9.2.1 The Patient Data Act	73
9.2.2 The Act concerning the Ethical Review of Research Involving Humans.....	74
9.3 Secrecy	74
9.3.1 Public principal	74
9.3.2 Private principal.....	75
9.4 Examples of other legislation	75
9.5 The CODEX website	75
9.6 The Declaration of Helsinki	75

9.7 Guidelines for Good Clinical Practice (GCP).....	76
9.8 The Council of Europe's Convention for the Protection of Human Rights and biomedicine	76
9.9 The CIOMS guidelines for research	76
9.10 Center for Open Science.....	76
9.11 Publication ethics and questions of misconduct.....	76
References	77
Reading tips	78
Laws, ordinances, directives	80
Declarations, guidelines, reports	80

INTRODUCTION

Research ethics is not static. New ethical problems arise when new scientific questions are asked, when new methods are used and when new materials are analysed. The early focus of research ethics was on protecting patients and research subjects against encroachments in the name of science. Through the development of epidemiologic research and register data research, other issues have to some extent become central. In recent years, stem cell research and nano technology research have attracted great interest, as has the commercialisation of research, and the effects of research on the environment and society in a more global perspective.

Ethical considerations in research are largely a matter of finding a reasonable balance between various interests that are all legitimate. The quest for knowledge is one such interest. New knowledge is valuable in several ways, and can contribute to the development of the individual and of society. Individual privacy interests as well as protection against various forms of harm or risk of harm are other legitimate interests. But sometimes, new knowledge can only be obtained if research subjects and participants are exposed to a certain amount of risk. This is clear not least in medical research. If the risk is to be non-existent, the opportunities for finding advances will be heavily restricted – which impacts on various groups of patients.

The harm and the risks this might involve varies considerably from one area of science to another. For this reason, research of different types also brings up distinct types of considerations. The risk/benefit analysis is done in varying ways, and the guidelines – which aim both to promote the search for knowledge and to safeguard the interests of participants – are not quite the same either. Ethical problems were acknowledged early on by medical researchers and psychologists, and others have since followed.

This book is a revision of the book *Good Research Practice*, published by the Swedish Research Council in January 2011. The previous book was produced during the period when Göran Hermerén chaired the expert group on ethics.

SAMMANFATTNING

Forskningen har en viktig position i dagens samhälle och stora förväntningar ställs på den. Men därmed riktas också fokus mot forskarna. De har ett särskilt ansvar gentemot de människor och djur som medverkar i forskningen, men också mot alla dem som indirekt kan påverkas av forskningen och gagnas av forskningsresultaten. Forskaren förväntas göra sitt bästa för att genomföra forskning av hög kvalitet. Forskaren ska också stå fri från yttre påverkan och manipulering och inte heller gå egna privata eller vissa intressenters ärenden. Ett välgrundat förtroende i samhället för forskarna och forskningen är en förutsättning för forskningens framtid.

De olika uppförandekrav som ställs på en forskare hör ihop med forskarrollen, så som den uppfattas idag. De ligger inbyggda i forskningsprocessen. Men kraven har ändå sin förankring i samhällets vanliga etiska normer och värderingar. Den som läser de rekommendationer som presenteras i denna skrift upptäcker att mycket av det som sägs kan sammanfattas i några allmänna regler som alla svarar mot mer generella levnadsregler:

- 1) Du ska tala sanning om din forskning.
- 2) Du ska medvetet granska och redovisa utgångspunkterna för dina studier.
- 3) Du ska öppet redovisa metoder och resultat.
- 4) Du ska öppet redovisa kommersiella intressen och andra bindningar.
- 5) Du ska inte stjäla forskningsresultat från andra.
- 6) Du ska hålla god ordning i din forskning, bland annat genom dokumentation och arkivering.
- 7) Du ska sträva efter att bedriva din forskning utan att skada människor, djur eller miljö.
- 8) Du ska vara rättvis i din bedömning av andras forskning.

Denna skrift ger en kortfattad och översiktlig framställning av det forskningsetiska området. Den bör därför kompletteras med annan läsning om man vill fördjupa sig i ämnet. Vissa dokument redovisas i texten men framför allt hänvisas till webbplatsen ”CODEX – regler och riktlinjer för forskning”, codex.vr.se. Här finns inte bara regler och riktlinjer samlade utan också korta forskningsetiska introduktioner till olika frågor, länkar till nationella och internationella dokument och dessutom en nyhetsbevakning.

Kännedom om både relevant lagstiftning och forskningsetiska kodexar krävs för att forskaren ska kunna reflektera över sitt projekt. Behovet av forskningsetik diskuteras inledningsvis under rubriken *Vad etiken föreskriver och lagen kräver* i kapitel 1.

I kapitel 2 *Om forskning – vad, varför, hur och för vem?* aktualiseras en rad frågor av forskningsetisk betydelse. De handlar om kunskapens värde, om tillvägagångssätt, om ansvar, om intressekonflikter, om metoder och om tillförlitlighet.

För att få genomföra viss forskning krävs tillstånd. Det gäller forskning som avser människor, forskning som innefattar djurförsök, men också vissa andra typer av forskning. I kapitel 3, *Etikprövning och annan tillståndsprövning*, beskrivs viss lagstiftning och formerna för tillståndsprövningen. Här diskuteras även etiska problem och överväganden i samband med försöksdjursverksamhet samt vid forskning i annat land.

Vid *Hantering av integritetskänsligt forskningsmaterial* är det viktigt att redan i ett tidigt skede fundera över olika intressen (forskarens, medverkande personers, andra forskares osv.), vad forskaren kan lova de medverkande, vem som äger ett forskningsmaterial etc. Vilka regler gäller? Dessa frågor har under de senaste åren ställts så ofta och av så många att vi valt att ägna kapitel 4 i denna bok åt dem.

I den pågående förändringen av forskningens organisering och villkor, nationellt och internationellt, ställs nya forskningsetiska frågor, medan andra ges en ny vinkling och prioritet. Ansvarsfrågor i multicenterstudier och stora internationella projekt är exempel som behandlas i kapitel 5 om *Forskningssamarbete*.

Publicering av forskningsresultat, diskuterad i kapitel 6, är en förutsättning för att forskningsresultat ska kunna komma till nytta, endera för omedelbar tillämpning eller för att ingå som en pusselbit i det fortsatta kunskapssökandet. Vem eller vilka som står som författare är inte bara av betydelse vid meritvärdering utan också för ansvarsfrågor. Rollen som granskare, ansvarig utgivare och redaktör reser särskilda etiska frågor. Det gäller också forskarens roll som handledare, som lärare och som sakkunnig. Dessa frågor berörs under rubriken *Forskaren och uppdraget* i kapitel 7.

Ett forskningsetiskt problem som ofta uppmärksammas, också i medierna, rör *Vetenskaplig oredlighet* och behandlas i kapitel 8. Det kan röra uppenbara övertramp som fabrikat, plagiat, fusk och frisering av data, men

också förtal, sabotage, missvisande framställning av egna meriter i samband med bidrags- eller tjänsteansökan etc. En rättssäker hantering vid misstankar om oredlighet är grundläggande, liksom ett tydligt och enhetligt sanktionssystem.

Det forskningsetiska fältet är stort. Det finns många olika lagar, direktiv, riktlinjer och forskningsetiska och yrkesetiska kodexar som forskaren bör känna till och beakta i sitt arbete för att detta ska kunna utföras på ett både lagligt och etiskt genomtänkt sätt. Vilken lagstiftning som är tillämplig varierar dock med vilken forskning som bedrivs och hur den bedrivs. Under rubriken *Några viktiga lagar och andra regler som forskaren bör känna till*, nämns i kapitel 9 ett urval som Vetenskapsrådets expertgrupp för etik anser vara särskilt viktiga att uppmärksamma.

I forskning ställs krav såväl på kvalitet i arbetet som på integritet hos forskaren. Ett reflekterat etiskt förhållningssätt och agerande i forskarens olika roller är därvid grundläggande. För att konkretisera har framställningen kompletterats med ett antal exempel från forskarlivet, många tillvaratagna från den tidigare boken *God forskningssed?*, andra nytillkomna. Exempelen är fiktiva men inte orealistiska. En av avsikterna med exemplen är att visa att god forskningssed i praktiken kan innebära svåra val mellan olika handlingsalternativ. Frågan är hur man bör handla i en komplicerad verklighet, där olika principer och intressen kan stå mot varandra.

SUMMARY

Research occupies a prominent position in today's society and much is expected of it. This places a focus on researchers, who have a specific responsibility not only towards the people and animals participating in their research, but also towards all those who may be affected indirectly, positively or negatively, by their results. Researchers are expected to strive to conduct research of high quality. Accordingly, their work must be free of external influence and manipulation, and they should not act in their own personal interests or in the interests of other stakeholders. Good research depends on robust, well-founded trust.

The various requirements of proper research conduct are in line with the role of the researcher as that role is perceived today. These requirements are built into the research process and based on society's general ethical norms and values. Those who read the recommendations presented in this text will discover that much of what is said can be summarised in a few general rules which are broadly in keeping with the familiar general rules of life:

- 1) You shall tell the truth about your research.
- 2) You shall consciously review and report the basic premises of your studies.
- 3) You shall openly account for your methods and results.
- 4) You shall openly account for your commercial interests and other associations.
- 5) You shall not make unauthorised use of the research results of others.
- 6) You shall keep your research organised, for example through documentation and filing.
- 7) You shall strive to conduct your research without doing harm to people, animals or the environment.
- 8) You shall be fair in your judgement of others' research.

This summary provides a brief general overview of the field of research ethics. It should be followed up with further reading of other material if you would like to learn more about the subject. Some references are mentioned in the text, but you are referred primarily to the website: CODEX – Rules & Guidelines for Research (codex.vr.se/en/). In addition to collecting the rules and guidelines, the site offers short introductory texts on research ethics which cover a number of areas. It also provides links to national and international documents as well as links to relevant news articles.

Researchers need to understand relevant legislation and research ethical codes if they are to reflect properly on their own projects. The need for research ethics is discussed initially under the heading *What Ethics Dictates and the Law Demands* in Chapter 1.

Research – What, Why, How, and for Whom? in Chapter 2 addresses a range of issues with significance for research ethics. These include the value of knowledge, choices of approach, responsibility, conflicts of interest, methods, and reliability.

Some research requires ethical approval – for example, studies involving human beings, animal experiments, and some other types of research. Key legislation and forms of approval review are described in Chapter 3, *Ethics Review and Other Approval Review*, where there is also a discussion of ethical problems and considerations to be taken into account in animal research and studies in foreign countries.

Handling Research Material that is Sensitive with Respect to Confidentiality in Chapter 4 explains that it is important to consider various interests (e.g. the researcher's and participants') at an early stage, and to ask what the researcher is able to promise participants, who owns the research material, and similar questions. What rules apply here? These questions have been asked frequently, and by so many researchers in recent years that we have chosen to name Chapter 4 of this book after them.

As part of ongoing change in the organisation and terms of research, both domestically and internationally, new research ethics questions are being asked, while others are being given a new angle and new priority. Questions about responsibility in multi-centre studies and large international projects are dealt with in Chapter 5, *Research Collaboration*.

Publishing Research Results, which is discussed in Chapter 6, is a prerequisite if research results are to be of any use, either in an immediate application or as a piece of the puzzle in the continuing pursuit of knowledge. Who the author, or authors, of a piece of research are is of significance not only in the evaluation of the work's merits, but also in questions about responsibility. The roles of the reviewer, responsible publisher and editor

raise specific ethical questions, as does the researcher's role as supervisor, teacher and expert. These issues are covered under the heading *Other Roles of the Researcher* in Chapter 7.

An ethical problem that often receives attention, in the media as well within academia, concerns *Research Misconduct* (or scientific misconduct). This is covered in Chapter 8. Research misconduct may involve obvious breaches of trust and professional guidance such as fabrication, plagiarism, cheating and manipulation of data. It may also arise where there is slander, sabotage, or misleading presentation of one's own status or capabilities in applications for funding or positions. A common method of investigation to be applied where there are suspicions of misconduct is fundamental, as is a clear and unified sanction system.

The field of research ethics is broad. Many laws, directives, guidelines and codes define the regulatory framework governing research, and the researcher should also be familiar with, and take into consideration, the requirements of professional ethics: only in this way, will they ensure that their work is conducted in a manner that is both legally and ethically sound. However, other rules varies depending on the type of research and the way it is conducted. Chapter 9, *Key Documents Researchers Should be Familiar With*, presents a selection of the documents which the Swedish Research Council's Expert Group on Ethics considers to be of particular importance.

In research, there are demands on both the quality of the work and the integrity of the researcher. A properly considered ethical approach to the researcher's various roles is therefore fundamental. To flesh out what this means, the text provides a number of examples of research, many of which have been borrowed from the previous book *Good Research Practice – What Is It?* It adds some new examples as well. The examples are fictitious, but realistic. One of the aims is to show that good research conduct, in practice, may involve difficult choices between different courses of action. The question is how one should act in a complex reality in which different principles and interests sometimes come into conflict with one another.

1 WHAT ETHICS DICTATES AND THE LAW DEMANDS

1.1 Ethics and morals

In many contexts in which “ethics and morals” are discussed, no distinction is made between the two concepts. Everyday language is also unclear in this area, even though we can surely sense a difference in meaning between “Kant’s Ethics” and “Kant’s Morals”. There are established uses of the concepts that do make a distinction, however, and there is good reason to maintain such a distinction here.

It is reasonable to assume that everyone carries a set of morals, which manifest themselves in a person’s behaviour, especially towards other people. The person does not need to be aware of his or her moral positions and does not need to reflect on them. The specific values and positions these morals can be assumed to consist of need also not be particularly consistent with each other. They do not need to exhibit any systematics whatsoever, and the person does not need to be able to justify him or herself in any way. Every person, after all, has morals, be they more or less well-developed. Through choices and actions, a person shows what his or her morals are.

On the other hand, we cannot have ethics without being conscious of them, or without having reflected on them. When we use the term “ethics”, we mean a type of theory on the area of morals. We want precisely formulated norms, as general as possible, for which we can find good arguments. We want to justify our position. A set of ethics cannot be arbitrary. We also want our formulations to be able to work together and form a system. A set of ethics should also be able to be formulated in words.

Perhaps you could say that ethics contain moral precepts that are conscious, reflected on and motivated, which one formulates as clearly as possible and are presented in a systematic way. In a way, ethics provide a theory for morals, which are their practical expression. But you can sometimes have a practice without a theory; this is why one speaks of research ethics and, on a much smaller scale, research morals. It is a question of norms (principles) that the research community has reflected on and has tried to formulate clearly and motivate. These norms are assumed to work well together and offer guidance. A code is a collection of research ethics rules, i.e. more specified norms concerning a certain research area or certain stages of research projects.

Both ethics and morals contain normative assumptions that dictate what is good or bad and that recommend or forbid different behaviours. A distinction is usually made between statements about *values*, which attribute a value to something – “good”, “poor”, “bad”, “valuable”, “attractive”, “ugly”, etc. – and *norms*, which tell us what we ought to do, what our “duty” is or what is “right” or “wrong”; what we should do and what we should refrain from doing. As a rule, both ethics and morals contain degrees of assumption, and there is often a simple connection between them. For example, if we regard suffering as bad this also becomes a reason for us to maintain that we should not cause suffering and that actions that do cause it is wrong. By the same token, if knowledge is seen as valuable, we naturally embrace the norm that humans should seek knowledge.

1.2 Research ethics and professional ethics

The area of *research ethics* is not a well-defined area, even though it is obvious that it entails questions regarding the relationship between research and ethics as well as ethical standards for the researcher and the aim and implementation of the research. It is difficult to summarise this in a simply formulated definition. New types of questions also arise as research moves into new areas or as new techniques or research methods appear.

A crucial part of research ethics concerns questions of how people who participate in research as subjects or informants can be treated. It can seem self-evident that these people should be protected to the highest degree possible from harms or wrongs in connection with their participation in research. But how do you do this?

In many contexts, research ethics is limited to simply the consideration of ethical questions that apply to those participating in the research, while reasoning about ethical questions concerning the craft itself – the researcher’s responsibility towards research and the research community – is called *professional ethics*. Issues of the researcher’s behaviour in various roles, of responsibility in connection with publication, and of so-called research misconduct belong to this category. Many of the questions in this book are thus of the professional ethics type. It is also possible to distinguish between external and internal research ethics, with professional ethics corresponding to the latter.

1.3 Merton's CUDOS norms

In the 1940s, the American sociologist Robert Merton formulated four principles which he believed constituted a “moral consensus” in science, and these have had a significant impact on the discussion around professional ethics. Commonly referred to as the CUDOS (Communism/Communalism, Universalism, Disinterestedness and Organised Scepticism) norms, they have since been both modified and questioned but nonetheless merit attention as one starting point for a discussion about what constitutes good research practice.

The norm of *communism*, or *communalism* (C), means that the research community and society as a whole have the right to be informed of the results of research. New knowledge should not be kept secret and concealed. Scientific advances are regarded as a result of collaboration within and between generations of researchers; after all, the researcher does not work in a vacuum. Thus, according to Merton, there is no such thing as intellectual property, owned by the researcher.

Merton's norm of *universalism* (U) requires scientific work to be evaluated with reference to scientific criteria alone. When assessing the validity of the results, we are to take no account, for example, of the researcher's race, gender or position in society. The norm of *disinterestedness* (D) means that the researcher must have no other motive for his or her research than a desire to contribute new knowledge. The fourth norm, *organised scepticism* (OS), requires the researcher to constantly question and scrutinise, but also to refrain from expressing an assessment until he or she has sufficient evidence on which to base it.

Since these principles were put forward, the position of the researcher, or at least the general perception of it, has changed in many respects. Being a researcher can no doubt colour an individual's whole way of being and thinking, but these days it is quite a common professional role, and researchers are employed specifically as researchers. They, too, are expected to be loyal to organisations and superiors, and have to take financial factors and their own job security into account.

In many cases, therefore, Merton's norms will be difficult to live up to in reality. His requirement for disinterestedness, which says that the researcher's main reason for doing research should be to contribute new knowledge, is a case in point. Researchers must surely be allowed to have other motives as well, such as promoting their prospects of employment through the work they do. The important thing, rather, is that motives of this kind do not influence the researcher in such a way that he or she arrives at interpretations or conclusions for which there is no scientific basis, or withholds findings for which evidence does exist.

Merton's strict requirement of communism is also difficult to live up to in many types of research and in certain research environments, for example in an industrial setting, although the importance of publishing results and communicating them to society and to other researchers will nevertheless often be acknowledged in such environments as well. However, when it comes to publicly funded research, the requirement of openness is clear.

There are various problems with Merton's other norms, too. The ideals expressed in the CUDOS norms nevertheless provide one of the cornerstones for the present-day discussion about research misconduct (see Chapter 8). They are also reflected in the requirements of honesty and openness that were formulated in our introduction.

1.4 Ethics codes

While individuals participating in research should be protected from harms or wrongs (the *criterion of protection of the individual*), it is not reasonable for a trivial amount of harm to hinder important research. Research is important for both society and citizens due to the improvements in areas such as health, the environment and quality of life it can bring about. In addition to their benefits, research results are often valuable in their own right. You could say that there is an ethically motivated imperative to conduct research: the *research criterion*.

Many problems in research ethics can therefore be described as *achieving a balance* between these two criteria. We are to conduct qualitatively good research with an important purpose, and at the same time protect those individuals taking part in the research. How this is balanced and achieved depends on what type of research (questions, methods, participants etc.) is conducted.

The discussion on research ethics issues took off after World War II. Research ethics codes, collections of rules attempting to clarify how the researcher should act towards research subjects in an ethically sound way, were developed for various research areas. The codes stated what the researcher should do before conducting the research (information, consent), during the research (avoidance of risks, design issues) and after the

research (publication, retention and archiving of material). A number of ethical issues within research thus received attention, and the codes greatly contributed to creating a praxis and increasing awareness of possible ethical problems in research.

By far the most significant code is the medical *Declaration of Helsinki*, which has been adopted by the World Medical Association. The Declaration appeared its earliest version in 1964 and has undergone several revisions, most recently in 2013. Rules as well as concepts from the Declaration of Helsinki have proven to be useful in other research areas as well, which has contributed to the code's central position within research ethics in general.

A code is thus a collection of ethical rules. Through these rules, someone (a research group, a research funding body, an organisation of researchers or research institutions, etc.) attempts to interpret and formulate what morals in certain situations demand of the researcher in relation to the informant, and sometimes also in relation to other interested parties. However, a code is not a legal document.

With time, however, legislation has entered the area of research ethics. Clear examples of this are the Act concerning the Ethical Review of Research Involving Humans and the Animal Welfare Act. However, although the legislation in these cases has entered a specific area of ethics, this does not mean that ethics and the law have entirely converged.

1.5 The law and morals

Many differences between the law and morals can be noticed even at a glance. As a rule, that which is legally right, what a certain law prescribes, is very clearly and precisely formulated.

The law has also come to be through an established decision as a result of a special procedure. It is only when a decision has been reached in this way that a law is created. A law can also be abolished through a corresponding process; it is thus in effect between two points in time.

A law can be created for various reasons and can have different purposes. A law is also valid within a certain territory. Swedish law applies in Sweden while Danish law applies in Denmark; and even if the content of two laws, one Swedish and one Danish, is similar, it is still a case of two different laws – two separate decisions and decision-making processes. Breaking a law entails established sanctions. Each country has its own organisation for detecting when the law has been broken, and for trying the lawbreaker and applying sanctions.

What *morals* imply, on the other hand, is not always clear or precise. Instead, when facing a moral issue, we often must argue based on our own values to bring about a more precise moral criterion. The rules implied by, and the values connected with, morals are also not something we explicitly decide on or formally adopt. And, naturally, we cannot speak of any specific decision-making process either.

It is more reasonable to say that our values go along with our feelings and needs, both physical and psychological, and with the fact that we both want to and have to cooperate and share our life with others. For example, that suffering is bad and should therefore be avoided is nothing we decide to believe. It is also absurd to assume that a moral rule should apply from a certain point in time and be able to be abolished at another, as is the case with laws. A statement like “As from 1 July, it will be morally right to tell the truth” is absurd.

Morals can also not be assumed to have a limited geographical reach in the same way as a law does. Even when I am in Denmark, I have to hold that I should avoid harming my fellow humans just as I would in Sweden.

Another difference between morals and the law is that morals have no explicit system of sanctions. A breach of morals is of course followed by sanctions, but what these might be and how they are applied vary greatly.

That laws and morals are different is also directly observable in our everyday experiences. There are many situations in life when a law has nothing to say but our morals prescribe or forbid action. On the other hand, the law can in turn regulate conditions that from a moral perspective are completely neutral, for instance certain traffic legislation. There are also conditions that a certain law prescribes or allows, but cause us to ask ourselves: Is it morally right to do that? Certain behaviour is allowed in business law – thus no laws are broken – but should one really act in that way? This is another question, and one that is asked often. Answering the legal question is one thing, while answering the moral question is another.

What morals prescribe and forbid thus needs to be analysed and interpreted. But are there given answers, or are morals relative? It is reasonable to assume that certain fundamental values can be shared by all people, while others can vary from person to person and between cultures or traditions. Whatever the case is concerning this relativity, however, it is clear that a moral conviction or principle is different from a legal rule.

If we take the moral premises set forth in the Declaration of Helsinki, for example, these are premises that researchers around the world – not only those in the West – can relate to and apply in their research. Below, the mention of “common” ethical criteria for research refers to such premises, for example those formulated in the Declaration of Helsinki.

1.6 The law and morals in the area of research

It is important for the researcher to know what the various laws dictate concerning research, as well as what the various codes prescribe. The Swedish Research Council, like many other funding bodies, also places specific ethics requirements in conjunction with an application for funding. It is important to note the difference between these distinct types of requirements. Legislation in the area of research ethics, both historically and content-wise, has its starting point in ethical convictions, for instance as they are expressed in ethical codes. But legislation only addresses certain specific situations and certain specific conditions.

On 1 January 2004, the Act (SFS 2003:460) concerning the Ethical Review of Research Involving Humans came into force (riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-2003460-om-etikprovning-av-forskning-som_sfs-2003-460). The purpose of the Act is to protect the individual person and ensure respect for human dignity in research, and it is limited to certain aspects of research; professional ethics are not addressed.

This legislation has been complemented with the establishment of legal agencies – ethics review boards – which review research projects and decide whether they merit approval. The Act therefore also states (1) which projects must be board reviewed, (2) what parts of these projects are to be reviewed and what warrants approval, and (3) how the boards are to be composed.

In both (1) and (2) it is important to note the difference between the law and morals. According to (1), only projects with a certain content are to be reviewed in concordance with the Act. However, a great deal of research falls outside this description; this cannot mean that all such research is ethically problem-free. It only means that the lawmaker, the Riksdag, has made a choice regarding what the boards should review. Research that does not use personally sensitive data (3 §) and does not entail physical encroachment, aim to affect subjects physically or psychologically, or entail an obvious risk of harming subjects (4 §) is not to be reviewed, according to the Act. But this does not mean that this research can be conducted without considering ethical aspects. The researcher should not simply perform this type of research without providing information and obtaining consent, or choose subjects arbitrarily. The subjects’ identities must not be revealed in the published work either.

Research projects outside the scope described above *may* therefore be conducted without a legally based ethics review. However, the researcher must still observe the ethical criteria as cited in commonly used codes, as well as personally reflect on his or her project. The fact that the project does not fall under the law’s description does not provide an exemption from this.

The first version of the Act came into effect in 2004, and it was revised in 2008, the most notable change being an increase in its scope. In the first version, a great deal of research – even though it could entail significant research ethics problems – was left outside the Act’s scope and was therefore not included in what was to be reviewed. Since the revision in 2008, which includes more project types, more projects now come under review, and society’s insight into the process has thereby increased. There are also laws with specific relevance to research, such as the Personal Data Act and the Archives Act. The most recent review of the Ethics Review Act was done in 2016.

It is normal that a funding body, besides ensuring that a project is legal, is also interested in regular ethical rules being followed. For instance, applicants for grants from the Swedish Research Council have to present the ethical issues that might arise in their project (or other activity) and explain how they will be addressed in the research work. Furthermore, the Swedish Research Council requires that the research principal, i.e. the university or corresponding body, ensures that the research meets the requirements and conditions dictated by Swedish law. In addition, it is a requirement that the project leader is familiar with current legislation and understands ethical problems, and that he or she secures the necessary permits and approvals before the research work begins.

The fact that some projects do not need to be, and should not be, reviewed in concordance with the law can also lead to another problem. Particularly in the case of publication in international journals, it is often required that a project has been ethically reviewed. If a project that falls outside the law’s specifications cannot be

reviewed, reports on these projects can thus not be published internationally. To avoid this undesirable consequence, the option to request a so-called advisory statement from an ethics review board was introduced. In this case, the review board does not perform a review based on the law but instead evaluates the ethics of the project based on the description provided by the researcher and the common ethical criteria that are usually placed on research (for further information, see Chapter 3).

The differences between what the law demands and what ethical codes dictate also become clear when one considers what the law says should be reviewed, i.e. (2) above. The text in the Act explains in general terms that research should be conducted with respect to human dignity, that human rights should always be observed, that the risks should be weighed against the scientific benefit and that the researcher must be competent. In somewhat more concrete phrasing, it also states that informed consent should be obtained (for some projects), who can give consent and when research can be conducted without consent. The content of the points of review becomes clearer through the information the researcher is required to provide on the form describing the project in connection with an ethics review.

1.7 Various quality criteria

What is the relationship between good scientific quality and good research ethics? Might there be conflicts between demands for good research ethics and good scientific quality? For the sake of clarification, it is first necessary to distinguish between two cases: (1) certain ethical criteria make it harder – taking a longer time, costing more – to reach new and valuable knowledge, and (2) certain ethical criteria make it impossible to reach new and valuable knowledge. In some types of studies, it can be claimed that, for example, the requirement of informed consent resulted in such a high dropout rate that the results can be misleading. It is only the latter case, (2), that presents a principally interesting problem.

The problem must be clearly defined, however; the answer to the questions above also depends on how the key concepts are defined. For sake of simplicity, let us say that the criteria for good research ethics are reasonably met if the researcher has followed the principles described in this book. Good research ethics quality thus requires compliance with basic research ethics principles. The criteria for good scientific quality, on the other hand, can have both broad and narrow interpretations. In a narrow interpretation, these criteria are met by research that provides new knowledge, reveals conditions not previously known or sheds new light on previously known phenomena and relationships – it gives us more reliable knowledge maps to navigate by than we have had in the past.

With this narrow interpretation, the content of the criteria for good scientific quality is not completely unequivocal, as research can meet many of these criteria to higher and lower degrees. The criteria of stringency, representativity, generalisability, transferability, reproducibility, transparency, etc. can be interpreted and applied in somewhat diverse ways within various research areas, such as history, social sciences, medicine and technical and natural sciences.

Nevertheless, it is important to remember that the concept of scientific quality is used in a broader sense as well. In such cases this entails an overall judgement from which it is not possible to single out individual criteria. When the total quality of the research is evaluated, no single quality can be ignored. The quality is evaluated based on the collective qualities of originality, external and internal validity, precision and ethics. The requirement of good research ethics is thus included here; therefore, there can be no conflict between the demands for good research ethics and good scientific quality. A research report exhibits poor research ethics if it contains scientific shortcomings in the precision of its questions, uses incorrect methods (or uses established methods incorrectly), systematically excludes observations that do not support the author's hypothesis, handles the problem of dropout in a statistically unacceptable way, or uses a study design that does not allow for the research question to be answered. People's time has been used needlessly, and they may have been exposed to not only a certain amount of inconvenience or discomfort, but sometimes even suffering. In any case, resources that could have been used in a better way have been wasted. It is also quite easy to find examples of studies that, through superficial correlations between ethnicity, criminality, intelligence, education, etc., have led to the discrimination or stigmatisation of individuals and groups. Unfortunately, there are also examples of cheating in studies on methods for treating breast cancer or links between vaccination and autism. Here, poor scientific quality and poor ethics overlap, leading to the possibility that people can be harmed when the results of the research are applied in practice.

There can sometimes also be economic and time frames that tempt researchers to take shortcuts, which can cause the research to fail in meeting both scientific and ethical quality criteria. If the problem is due solely to these factors, there is no fundamental opposition between the two; with other time frames or better economic resources, the problem would not surface. We thereby find ourselves back in a situation of type (1), in which there is no fundamental opposition between the diverse types of quality criteria. Against this background it is reasonable to regard work to improve the ethical aspects of the research as a quality issue.

Stanley Milgram conducted experiments with volunteer subjects. The subjects were informed that they, as “teachers”, were to give an electric shock to “students” when they answered incorrectly, and that they were to increase the strength of the shock with each successive wrong answer. The students then simulated great pain. Everything was simulated, and everyone except the subjects knew this. Most of the subjects followed the instructions.

Milgram’s research provided important knowledge on subordination and the obedience of instructions from authorities – it revealed things about ourselves that we perhaps would rather not know, but that are important for the understanding of the success of Hitler and others like him – but Milgram’s research has also been criticised.

What ethical issues does this research bring to the fore? Is there a conflict here between scientific and ethical quality criteria? In what way? How do you feel this conflict should be handled?

1.8 Review

In summary, one must constantly distinguish between the law and morals and, when it comes to research, also between research ethics legislation and the rules found in research ethics codes. The ethical criteria can be more far-reaching than the legal requirements when their content is otherwise closely related. The ethical criteria can also address issues that do not appear in legislation at all. The collective ethical criteria on how good research should be conducted can be said to express what good research practice is.

Researchers should follow good research practice. It can therefore not be said, for example, that the Act concerning the Ethical Review of Research Involving Humans, replaces codes like the Declaration of Helsinki or eliminates or reduces the significance of one’s own moral judgement. The researcher’s own reflections on his or her project must instead be based on both knowledge of the content of laws and codes, and on his or her own moral judgement.

1.9 Various regulatory systems

Laws are made by Sweden’s Riksdag, its parliament, and are binding. *Ordinances*, issued by the Government, and *regulations* and *directives*, issued by public authorities (such as the National Board of Health and Welfare, or the Dental and Pharmaceutical Benefits Agency) with support from laws and ordinances, have the same legal character.

Within the EU there are *regulations*, which have the same authority as Swedish law, and *directives*, which normally must be implemented in Swedish law to be binding. Also in the international context are *conventions*, which are binding for the countries who have agreed to follow them, such as the Council of Europe’s Oviedo Convention.

Guidelines can be issued by authorities or different non-governmental organisations and assemblies. Though such documents are not legally binding, their content can be generally accepted. Supervisory authorities, such as the Central Ethical Review Board and the Swedish Data Protection Authority, produce guidelines, information brochures, etc. of importance to research.

Declarations, resolutions and *statements* are also generally issued by organisations and assemblies, and entail that these groups declare a certain stance within their field. These documents usually consist of calls for certain ethical approaches, and can sometimes reach a status similar to that of international conventions. An excellent example of a declaration with extremely high status is the Declaration of Helsinki, which provides the foundation of the work of research ethics committees and their like around the world.

Ethics codes usually have a pronounced voluntary character. They usually concern relations not regulated by law, and often concentrate on how those affected by the code conduct themselves in relation to their work, as well as the consequences the work can have for other people, the organisation, the environment, etc.

References

1. Forsman, Birgitta, *Forskningsetik: en introduktion*. Lund, Studentlitteratur, 1997. Forsman, Birgitta, Vetenskap och moral. Nora, Nya Doxa, 2002.
2. Hermerén, Göran, *Kunskapens pris: forskningsetiska problem och principer i humaniora och samhällsvetenskap*. Stockholm, Swedish Science Press & HSFR, 1986, 2nd edition, 1996.
3. Lag om etikprövning av forskning som avser människor (SFS 2003:460).
4. Merton, Robert "The Normative Structure of Science" (1942), in Merton, R., *The Sociology of Science*. University of Chicago Press, 1973.
5. Petersson, Bo, *Forskning och etiska koder*. Nora, Nya Doxa, 1994.
6. World Medical Association. Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, latest revision by the WMA General Assembly, Seoul 2013. Ferney-Voltaire, France, World Medical Association, 2013.

2 ABOUT RESEARCH – WHAT, WHY, HOW AND FOR WHOM?

2.1 Starting points for research

2.1.1 Some types of research

There are diverse types of research. Distinctions can be drawn between hypothesis-generating and hypothesis-testing research, and between research using qualitative and quantitative methods. One can also distinguish between research that tries to explain why something has happened by showing that it can be subsumed under a natural law and research that tries to increase and deepen our knowledge about events, processes or texts. From a research ethics perspective, another distinction is interesting. One usually distinguishes between three forms of research: basic, applied and commissioned (there are also other terminologies and distinctions).

Basic research entails the researcher seeking new knowledge without a particular application in mind, and can lead to unexpected and ground-breaking discoveries. *Applied* and *commissioned research* both have a particular aim. They are aimed at being of use to the party who initiated or ordered the research. Commissioned research is more directly and clearly driven by the commissioning party than applied research is.

As opposed to other knowledge-seeking activities, research entails a *systematic* search for knowledge. This knowledge must also be new, not simply a compilation of what is already known. However, attempting to replicate previously published (and thus not new) results with the aim of confirming them is also research. If the results can be replicated, this increases our belief in the soundness of the conclusions, and we learn something we did not know before. A systematic-critical review and compilation of previous results in a certain area can also raise knowledge levels, and can therefore also be regarded as research.

2.1.2 Why conduct research?

The reasons for research vary, partly depending on the type of research. Basic research is conducted to develop new knowledge, which can be valuable in its own right – but can sometimes also lead to valuable consequences, for instance new products. Applied research, on the other hand, primarily aims to develop knowledge that can lead to improved clinical diagnostics and treatment in medicine, or be applied in practice in the production or improvement of products, in planning and decision-making, for example in changes to organisations and communication strategies, etc. Besides providing knowledge about a specific area, all types of research provide methodological education and training in critical thinking. Thus, research can contribute in many ways to the development of both individuals and society.

Today, scientific research is a crucial element of society. The value of new knowledge is underlined in many different contexts. So, what is it that makes research valuable? Scientific knowledge has a value not only as an instrument, in other words as a means of achieving something else we value. Knowledge is also worth something *in its own right* – has its own value – regardless of how it might be used.

People need to make sense of the world, be able to explain and understand. This is true even when we do not directly seek a use or an application. Basic research is often justified in this way. The results of it might also later prove to be good instruments for promoting something we consider useful and beneficial to society; but the nature of research prevents us from knowing entirely in advance where its results will lead us. The desire to know and understand is very often sufficient justification for research.

When the *benefits* of research are discussed, this concept should be considered in a broad sense. It is not only a case of creating conditions to produce more and new products, or increasing society's industrial competitiveness, or even of creating more job opportunities. It also concerns promoting other values that have to do with *critical thinking*, better quality of life and a revitalised public discourse.

Meanwhile, history shows that the planned reasons for research sometimes do not coincide with its actual effects. Research that can facilitate developing new and stronger materials or more effective medicines can also have undesired and unexpected effects, or be used for negative purposes by countries, terrorists or others. The

challenge is therefore to optimise the opportunities of using the positive effects of research, and to minimise the negative ones. A vibrant ethics discourse is an essential element of these attempts.

The task of higher education institutions not only includes cooperating with the world around it and providing information about their activities, but now also includes “working towards research results obtained at the higher education institution being of benefit” (“verka för att forskningsresultat tillkomna vid högskolan kommer till nytta”, Chapter 1, Section 2 of the Higher Education Act, [SFS 2009:45]). There are undeniably many examples of research discoveries improving conditions for many people. Vaccines, the production of new materials and developments in telecommunications are examples of research results being further developed into products that have made life easier and improved the quality of life for many.

For the individual researcher, the purpose of research may be more *personal*, such as curiosity or a desire to solve a problem, contribute to the solution of some problem in society, build a career, or increase his or her income through inventions and patents. The attitude in the research community should be generous when it comes to the personal motivation of researchers.

The motivation for research can end up characterising the research environment, and the focus of the research. In an environment where the importance of commercialisation and patents is uniformly stressed, the space for more basic research-oriented researchers can be limited. On the other hand, an environment where the value of basic research is instead placed above, anything else risks being perceived as isolated and elitist. This type of goal conflict often integral to certain types of research, such as clinical research.

The risks involved with goal conflicts are reduced when the researcher is in an environment where the discourse is lively and where an open and generous view of the researchers’ motivations is maintained. The key factor is *that*, not *why*, someone wants to contribute to research, and that the significance different motivations have for the research environment and for the focus of the research is discussed openly within research groups, departments and faculties.

2.1.3 How is research conducted?

A central question in all scientific studies and in their evaluation concerns the relationship between question and method. Textbooks on theory of science discuss quantitative and qualitative methods, but the focus in this book is on research ethics.

A fundamental question in a research ethics review concerns the balance between risk and benefit. This always starts as a negative value, as every study demands time of its participants and exposes them to a certain amount of risk, even if it is sometimes minimal. A necessary condition for a balance to be reached is that the method used answers the question asked. The question should preferably also be important and its answer clearly and strictly formulated. If a study does not answer its question, it should not be conducted in its current design.

When you decide to begin a research project, you should choose a method with the fewest imaginable harmful consequences on the people and/or animals involved, if the methods are otherwise somewhat equal. Additionally, the benefit of the planned research and the scientific value of its expected results should always be weighed against its harmful consequences. This is discussed further in Chapter 3.

An example can illustrate how important is it to think about whether a certain study might provide an answer to the question you have decided to study. Assume that you want to determine who has power in a certain community. First, you have to specify what you mean by power. It is one thing to have the power to keep certain issues from being brought up on the agenda of meetings of political deciding making bodies, and quite another to have a reputation as powerful and influential. The latter phenomenon can be studied through interviews and questionnaires in which people are asked who they believe has power in certain issues, but it is doubtful that this method would help in answering the first question. Neither could the first question be studied by looking at who is the most successful in pushing their proposals through in political deciding bodies at various levels.

Another example: Determining whether there is a difference in the effect and safety of a flu vaccination between children who have not previously had the vaccination and those who have is a reasonable and interesting task. To study this, you should be able to conduct a controlled study of these two groups of children and examine whether there is any statistically significant difference. But if you want to answer the question by comparing to children previously vaccinated for something else, for instance hepatitis, it becomes unclear what function the control group has and what question is being answered.

2.1.4 Who bears the responsibility?

When it comes to how research should be conducted and who has the responsibility for its being conducted in a satisfactory way scientifically and ethically, it can help to distinguish between the respective responsibilities of the individual researcher, the project leader, the department head and the research principal, even if the borders between them are not always sharp. In certain types of research another aspect also arises: the responsibility of the commissioning party or funding body.

An issue for the individual researcher to consider is the choice of research question. This choice can be between, for example, a well-defined problem that can give relatively quick publishable results but does not seem to have any greater significance for society on the one hand and a more diffuse or less meritable project of substantial societal significance. This choice must be made by the individual researcher.

Within all disciplines the researcher also chooses among the various subject areas, focuses and problems. For instance, within history a researcher can take an interest in the history of individuals, groups or countries from many perspectives, including mentality, political, legal, economic and/or others.

A task of the supervisor is to monitor the doctoral student's choices. Those responsible for the academic merit system should give the right signals so that a researcher can avoid the temptation of defining his or her research task based more on the merit possibilities instead of on the importance of the research question. Today, a great many studies are conducted that do not allow conclusions to be drawn – and “unnecessary” research is also conducted, in the sense that its questions have already been answered. This has been shown, for example, in systematic reviews by the Swedish Council on Health Technology Assessment (SBU) carried out in various medical fields.

Funding bodies naturally have an interest in their resources leading to research of high quality. The evaluation of a project proposal is often based on the weighing of a number of different criteria, listed, for example, in the Swedish Research Council's instructions to grant applicants and reviewers (see www.vr.se). Besides the scientific quality and the researcher's or research group's competence to conduct the project, originality, significance and in some cases also some form of benefit aspect may be considered.

The researcher is responsible for seeing to it that the research subjects¹ have satisfactory insurance coverage. Patient insurance covers injury in connection with research or treatment, as well as injury caused by treatment given due to an incorrect diagnosis. However, it does not cover injury or side effects caused by medication, or side effects of medication, which are instead covered by pharmaceutical insurance. Patient insurance applies within Swedish healthcare, public as well as private. Pharmaceutical insurance was established through an agreement between most of the pharmaceutical companies active in Sweden, and covers injury due to medication, regardless of whether it has been established what caused the injury, or whether the product used presented a safety risk. There only needs to be “considerable probability” for causality to be considered to exist.

2.1.5 Terminating research – when and why?

Research can be terminated if the researcher determines that it is leading nowhere or is not fruitful. For instance, new discoveries can show that the question addressed in a project are based on assumptions that are groundless or simply wrong. But there are also other reasons a researcher might ask him or herself whether a project should be terminated.

If a researcher realises that he or she is working with research that has or can have dangerous consequences, an important problem arises. While it is certainly very difficult to make such a judgement, the researcher in question is often just the person in society who has the best ability to do so. However, even researchers can sometimes be blinkered or short-sighted, looking after their own interests in conducting a certain research project.

The so-called Uppsala Code discusses this ethical issue. This ethical code, developed by researchers at Uppsala University during the 1980s, has received a great deal of attention. It appeals to researchers to avoid

¹In the Act concerning the Ethical Review of Research Involving Humans, a research subject refers to a “living person observed for the purposes of research”. Other typical expressions are subject, interview subject, etc. This covers, for example, persons who participate in experiments, are the subject of observations in studies, or provide information used in research.

research that can lead to ecological harm or the development of weapons, or that is in conflict with basic human rights.

The Uppsala Code is intended to be used by the researcher to evaluate his or her own research or that of colleagues. A researcher who determines that current or planned research will breach the Code is encouraged not to participate in it, and to make his or her opinion publicly known. The Code also states that colleagues and the research community should support such a researcher. A decision like this is difficult to make, not least for younger researchers just beginning their careers or still completing their studies. And, as a rule, it is easier and more reasonable to regulate the use of knowledge than to direct the quest for knowledge itself.

What would you do in the following situation?

You are the leader of a research group in the process of synthesising a virus that caused a lethal epidemic a long time ago. You realise that the results – if published – can easily be used by terrorists for biological warfare.

Do you publish the results? How do you respond to objections?

Meanwhile, it is also important that a researcher be loyal to his or her research task. With a decision to terminate, you should also consider the fact that other researchers may be depending on the work's completion. Loyalty to the research task, diligence and an ability to concentrate are therefore important qualities for a researcher as well as a research environment to have. Most research projects demand a great work effort and a high level of concentration. As a rule, the time it takes from the first ideas to results is both long and uncertain. Most research work certainly contains creative elements, but there are often long, laborious periods of routine and transition in between.

A researcher can have several reasons for leaving a project he or she has undertaken. Ethical reasons can include the research risking violating people's integrity or the published results being misused. Scientific reasons can include new discoveries making the purpose of the research no longer fruitful.

2.2 Making research results useful

2.2.1 The elusive and multidimensional benefit²

It is natural to connect the question of how research results will be made useful with the questions "Useful – in what sense?" and "For whom?". This is true for the simple reason that something that is of use to one person is not always of use to another. A product or method can also benefit many people in diverse ways: some may increase their income, others may get treatment that increases their life expectancy, and still others may experience an improved quality of life.

From a broader perspective, the concept can also include new knowledge that can lead to political decisions being made in a more insightful way or new unforeseen aspects arising and resulting in completely new considerations. For the researcher him or herself, or for other researchers, this new knowledge can lead to innovative ideas and hypotheses for future research.

Many important discoveries have been unexpected, and have sometimes occurred in the search for something else (Teflon). They have occurred purely coincidentally (dark energy) or by mistake (penicillin). But it is obviously necessary that the researcher realises the significance of the effects this coincidence or mistake can lead to.

The following examples show that research should not be driven all too strictly.

² In its upcoming report on future research strategies, the Swedish Research Council will address the question of a research project's benefit from a comparative international perspective.

Some facts on chance

Penicillin was discovered in 1928 by Alexander Fleming. After having accidentally left his staphylococci cultures in his laboratory for a longer time, he noticed that the mould growing on some of them had killed the surrounding bacteria.

Teflon was invented by chance by Roy Plunkett when he was trying to make the gas tetrafluoroethylene work as a refrigerator cooling agent. A bottle of the gas was left overnight and polymerised into polytetrafluoroethylene, a very slick plastic. Eventually it came to be used to coat fishing line and frying pans, and was also used on spacecraft because it does not react to UV light, ozone or oxygen and tolerates temperatures from -200 to over 200 °C.

Dark energy became a concept in 1998 when scientists were studying gravitation and cosmic acceleration. It suddenly became evident to them that we can only see around 30% of the universe – the other 70% is called dark energy.

A perhaps not completely comparable, but revolutionary, discovery from the humanities is *Linear B*, a script found on clay tablets at an archaeological dig at Knossos on Crete in 1900. The script was long indecipherable. Then a British architect, Michael Ventris, who first thought the scripts were Etruscan, made a guess that they might instead be Greek. With the help of Linear B findings from the Greek mainland, which did not contain certain words found in the texts from Crete, he guessed that these words might be Cretan place names. This allowed him, in 1951, to decipher Europe's first written language.

2.2.2 Research funding and collaboration

All research requires resources: time, place and equipment. Funding can be obtained through a position a researcher holds at a company, in which the research aspect is part of his or her duties. In such cases it can be the employer who formulates the research question. Research can also be conducted as an assignment the researcher has received, in competition with others or not. Finally, funding can also be obtained through grants from a funding body in the governmental or private sphere, or some other party.

You could say that there are two types of funders: those who do not have a direct interest in the results and those who do. The first group includes the government in the form of various foundations or research councils, as well as research foundations, based on collections and private donations with a specific focus, for instance the Swedish Cancer Society and the Heart-Lung Foundation. The second group includes commercial, non-profit and public actors who need research to develop their activities and, in some cases, to earn money.

External funding creates opportunities for research that otherwise might not have been conducted, but the ties and control it can entail are not without risk. This is illustrated in the many conflicts over publishing, access to data and the interpretation of results that are often debated in the media.

What would you do in the following situation?

You are researching the effectiveness of different toothpastes in a study commissioned by one of the larger manufacturers in this field. You design a comparative study in which the qualities and effects of different toothpastes from a number of aspects are compared.

However, the results are not what the funding body had hoped for and they want to stop publication or at least divide the report into multiple studies, which would make it difficult or even impossible to draw any conclusions. When you object to this they threaten to revoke their grants for a number of projects on which your doctoral students are dependent.

Do you go along with the funding body's demand in order to save your students' funding? Do you try to negotiate a compromise? Or...?

Funding bodies, no matter who they are, want to see results. Everyone wants to be sure that a research project is good enough to lead to new knowledge. Around the world public or open funders use reviewers to this end, in a process called peer review. Reviewers often work using templates containing clearly formulated criteria. The review always entails an evaluation of the scientific quality, often of the originality of the research question and sometimes also of how significant the question is from a specific, given perspective. This allows funding to be routed towards researchers who are judged to have the best design as well as the best ability to conduct their projects, but sometimes also to certain areas the funding body considers important.

For research results to be useful, it is normally necessary that they are developed further and that someone makes use of the new knowledge. Public institutions can have such an ambition, but it most often occurs through commercialisation. From society's perspective, it is important that new findings come into use as soon as possible if they can be expected to be of benefit and carry no risk. How this should occur is the constant subject of debate. The goals of a commercial actor or a public institution can compete with the ambition to further raise knowledge levels. Research results or a discovery can mean profit for the author or someone who develops it further, but can also have harmful effects on a large group or on society. In this case, as in all others, every researcher should think through the possible consequences of his or her research.

2.2.3 Various forms of collaboration

Collaboration between research and private or public funding bodies can occur in different forms. The researcher can be employed by a university only, and through his or her department collaborate with industry and other funding bodies, who reimburse the department for the researcher's contribution. Some institutions even have a special organisation for commercialisation, with separate bookkeeping and accounting.

Some researchers are employed within industry and are assigned with using scientific methods to develop new knowledge that is valuable to the employer's development projects. These researchers are also expected to participate in the scientific community and collaborate with researchers within academia, who receive their funding largely through external grants.

Some researchers choose to take an active part in development collaborations with industry, and some even prefer to participate in the development of companies in which they have proprietary interest. This type of engagement places great demands on the researcher, requiring that his or her actions in the scientific role are well thought out and appropriate, and that he or she does not allow the industrial engagement to undermine the scientific approach.

Researchers working within academia who are considering collaborating with a commercial company should try to find out what role and responsibility the industrial researcher has in his or her organisation. Research in this context can be of many types: everything from ground-breaking research to research activities more closely connected to the company's marketing. Researchers should be aware that this span exists to allow for positive and constructive collaboration with maintained integrity. The research community, for its part, should strive to take an open-minded position and evaluate each scientific contribution based on scientific quality and its own merits.

2.2.4 Problems and pitfalls

Quick publication and transferral to practical use are important goals, which we have just discussed. But there are many obstacles along the way: amateurishness in the ability to convert research results into practical use, attitude problems of the various actors towards each other and structures involving slow publication processes, sluggish handling of patent applications and a lack of risk capital.

Without the cooperation of the researcher, it is often difficult to convert academic research results into a benefit for society at large. Therefore, great demands must be placed on the individual researcher's awareness and on the environment in he or she works when it comes to handling situations and contacts involving profit motive.

In such cases, all researchers should carefully consider any agreements with other parties in order to maintain their personal integrity and scientific credibility. Two cornerstones in this stance are openness regarding ties and dependencies, as well as openness regarding all research results. This is important, regardless of whether the results meet or contradict a commissioning party's expectations. Conflicts have often arisen between funding bodies and researchers over the publication and interpretation of results, sometimes leading the researcher to suppress "undesirable" results. A researcher should also not let him or herself be convinced to over-interpret results in a certain direction. Angled reports can cause a great deal of harm, irrespective of whether they have a commercial angle or are affected by the ambitions of a public authority.

What would you do in the following situation?

You are working with technical research on new light, strong materials. You see an opportunity to apply for a patent and have started a company along with some entrepreneurs to commercialise the products. However, the commercialisation takes longer than expected and the company starts having economic problems.

A co-worker points out that fibres in the new material have qualities reminiscent of asbestos, and therefore suggests additional toxicological studies. But you want to speed up the development work.

Do you choose to interrupt the development work and examine the health risks? If no, how do you respond to the criticism from your co-worker?

2.2.5 Openness is your guiding light

Just like everyone else, a researcher has a legitimate need for appreciation. This can consist of economic compensation, honour and recognition or academic advancement, often in combination. But the way to attain recognition does not always follow the same path, and can be effective to different degrees at different points in time. Conflicts often arise. For instance, the individual researcher might be eager to quickly make his or her discovery publicly known, while the research group feels it is tactical or even necessary to withhold the information in anticipation of a patent application or further development.

A fundamental rule in all research is that all researchers should openly account for any conflicts of interest when presenting their results in a scientific context. For the credibility of the research community, it is also crucial that a researcher does not withhold new knowledge or postpone publication. Every researcher must also make it possible for other researchers to use – and check – his or her research results.

It is important that the surrounding world is informed if a researcher has a private profit interest in a certain project, or that commercial ties, such as details about ownership shares or research grants, are openly accounted for. Openness also contributes to forcing the researcher to clarify for him or herself what motives and research role he or she has.

The researcher's integrity is important "currency" that must not be allowed to devalue. If this should happen, it could cause the researcher to lose credibility for a long time to come. In projects of commercial importance, the integrity of the company will then also be called into question. It is thus in the interest of both the company and the researcher that commercial contacts are handled appropriately.

Companies often seek a dialog with leading researchers to keep themselves well informed on research. Like other researchers, those who work in researching companies participate in open scientific meetings. In these contexts, all participants are expected to account for existing ties, in accordance with the basic principle of openness. Such an account should be given in the introduction of a scientific presentation, to inform the listeners before the results are presented.

2.3 Quality and reliability

2.3.1 General principles

The requirement of quality in research can be clarified through a number of general principles that are also recognised within the research community. These principles have also been thoroughly discussed and argued for in theory of science and methodology books.

The various prerequisites and focuses in a study must be clarified and justified. The project should have a clear aim to answer or highlight certain interesting questions, which should also be formulated clearly. Methods that are used should be able to be explained, and it should also be possible to show that using these methods should allow the researcher to answer the questions being asked. The methods should be handled correctly and competently.

Projects based on empirical material should be characterised by systematic and critical analysis of carefully collected data. Possible sources of errors should be identified and discussed. The arguments should be formulated clearly and be relevant to the intended conclusion. The project as a whole, the documentation and the report should exhibit clarity, order and structure. But the quality aspect also entails things like scientific imagination and originality. If a project is creative and innovative in some respect, this greatly contributes to its quality. The quality aspect also covers well-designed studies that validate and/or reproduce research carried out earlier.

The criteria discussed above are by no means a complete list; nor can each individual requirement be regarded as a necessary condition for quality in a certain project. There must, for instance, be room for explorative studies without clear goals. The specification and application of these criteria are not the same in quantum mechanics and hermeneutics (interpretation theories), but if a project is lacking in many of the aspects discussed above, this is a clear warning signal.

2.3.2 Research question and method

In many fields, the research group's activities can be quite strongly method-oriented, based on a method developed within the group, which is the connecting link for various research efforts in which it is used. In such cases, the choice of research question can be driven by the method. This is in opposition to the schematic representation of the researcher as a problem-solver, first asking a question and then choosing a method to answer it. The research of method-based groups often becomes splintered, and many contributions can be rather superficial. On the other hand, a systematic study of the strengths of a newly developed method can be highly valuable.

In general, it should also be mentioned that advances in modern natural science, from astronomy to brain research, must be regarded as being greatly due to developments in technology that have allowed the use of new methods. The development of methods within areas like mathematics, statistics and information science should also not be underestimated. There is every reason for researchers and research groups to acknowledge their dependence on these contributions and give them the credit they deserve.

The choice of method for a research task is decisive for the value and character of the results. It is often difficult and requires a good deal of experience, often even boldness. Sometimes the method choice is based on existing knowledge and contributions, perhaps by previous generations in the same research group or at the department where the research is being conducted. It can happen that the research environment at a department is so focused on a certain method that alternatives are not discussed or even considered. In such a case, it can be beneficial to consciously seek out alternatives and – possibly in collaboration with researchers within other method traditions – conduct parallel studies using different methods.

In science, method issues are a hot topic and are linked to criteria for scientific quality. This is also the case in the humanities and social sciences. There is thus not only a practical difference between studies on people that are based on measurements, e.g. of reaction times or response frequency in schematic questionnaire surveys on the one hand, and on the other hand studies in which people's views are interpreted – as in letter collections or interviews. In discussions, the generalisability and more or less claimed objectivity of the results can end up being in opposition to the interest and “depth” of the scientific claims. This does not mean that research collaboration combining different methods cannot be fruitful, however.

Method choice also has an ethical aspect. In studies of the first type mentioned above, the researcher's relation to the people being studied is often more distant, while in the second type it is more involved. In both cases, the researcher's position can entail ethical complications or risks.

The choice of method can present many other important ethical considerations, for example whether animal subjects can be completely or partially replaced by tissue samples. Or there could be a question of how an interview study on children of abused mothers should be limited, to what degree violent tendencies or intelligence should be measured in studies on the socialisation of different ethnic groups, etc. At international level in particular, discussions are being held on the research ethics of so-called participant observation, a method used in the fields of social and behavioural science, among others.

2.3.3 Observational studies conducted through participating, observing and recording

For some research questions participant observation may be used, but this research method is associated with a large number of ethical problems.

The methods of participating, observing and/or recording can be used in several situations. A researcher may want to actually be in the research subjects'/informants' environment and observe what happens, hear what is said and follow the persons' interactions. In some situations, covert participant observation is used. This type of secret or disguised research is rare, however, and should be the exception rather than the rule.

The ideal situation is always that those to whom the research applies should be informed that they are the subject of research, and should normally also have given their written consent. If the research includes handling any personal data, the Personal Data Act applies. If the personal data is also so-called “sensitive personal data”

(see Chapter 3), then approval from an ethics review board must also be obtained. It is worth mentioning in this context that recording of sound from and/or images of persons constitutes handling of personal data (see Chapter 9).

Overt observation studies, in which participants know research is being conducted, are used, for example, to study the work within different organisations, or at an emergency room or a school. The observations should be performed systematically using observation schedules, notes, etc. The researcher should strive for objectivity and try not to influence research subjects or events.

Ethical considerations are very important in participant observation. The researcher is responsible for preventing any damage, and for ensuring the identities of those observed will not be revealed. Although this requirement may be difficult to fulfil, it is necessary.

One way to observe human beings is through video recording. Research using a video can intrude on the private lives and integrity of individuals, as it is possible to identify them. Video recording should therefore only be used when it is impossible to achieve the same results with the help of other data collection methods. For example, masked photographs can be used instead of video if it is not necessary to study the subjects' movements, facial expressions or interaction/communication.

It is important that the recording is done in a respectful and responsible way. Individual integrity must be respected. If underage subjects are to be video recorded, the same special rules apply as for other research involving children. This means that if the child is less than 15 years old, both guardians and the child must have consented to the participation. The information should be written in such a way that the child too can understand it (according to the Act concerning the Ethical Review of Research Involving Humans).

Just as for other research, the video recording shall be preceded by detailed information and consent be given afterwards. This information should describe the purpose of the research, and emphasise that participation is voluntary. Those asked to participate shall also be informed of exactly what the researchers intends to analyse in the video recording, and why other forms of registration have not been considered suitable or sufficient. As it is a question of personal data being handled, the personal data controller for the handling shall also be named.

The information (which should be both oral and written) to the informants shall also include more detailed information on the following:

- Whether any editing of the recording will be done, for example to disguise the face and/or voice
- Whether the video recording will be copied, and if so how many copies will be made
- Whether the recording will also be used for any other purpose than for research, for example educational purposes
- Whether any other analysis will be carried out in addition to those first stated – if so, both the regional ethics review board and the informant must be asked
- The informant is probably entitled to demand a copy of the recording as a registry excerpts under Section 26 of the Personal Data Act
- That any links between the recording and other personal data will be encoded
- How and where the recording will be stored, and for how long it will be saved

Once the informant has received detailed information as per above, consent must be requested, normally in writing. It is the practice in some fields of research, but not all, that consent is given in two stages. In these cases, the informant must first decide and possibly give his or her consent to the video recording itself. Thereafter, once the informant has had the opportunity to watch the video, he or she shall have the opportunity to give consent to the researcher to continue with the work of analysing it. Consent may also be given to show the video to persons named in advance, such as researchers, students, patient association, or similar.

The informant shall confirm that he or she has received information that the consent to the researcher analysing, using and showing the video may be recalled at any time. The research records and the information to the informant shall state whether the video material will be destroyed or not, in the event the informant recalls his or her consent. If it states that the material shall be destroyed in the event consent is recalled, this shall be done, or else the video recording given to the informant, provide he or she is the sole person shown in the recording. If several persons appear in the video recording, the identity of the person who has recalled the consent shall be edited out, if possible.

A video recording shall be stored in a secure manner, so that it is out of reach of unauthorised persons, and so that it is not destroyed through negligence. The researcher must ensure that only authorised persons can get

access to the video recording. If it is a case of sensitive personal data, more comprehensive and considered protective measures are needed.

2.3.4 Sources of error and reliability

When a scientific study starts to produce results, you are faced with the challenging task of evaluating their reliability. This is an integral part of the study, and an important aspect of the quality of the research. For example, a recent investigation of suspected research misconduct brought to the fore how important it is that the decision of how to represent decimals is well considered and clarified. A common, and tempting, mistake is to overestimate the significance of the results you have arrived at, and exaggerating their bearing power far beyond the area in which they have found to apply.

Within most research traditions a careful error analysis is required, or at least a discussion of possible error sources and other conditions that might affect the soundness of the results. The challenge is to make realistic evaluations. It is ethically problematic, and damaging to research as such, if a researcher knowingly suppresses indications of significant sources of error. It could be a case of withholding certain data to be able to get an article published, or taking a chance that the results will hold in order to be the first to report a new discovery. At the same time, one also should not refrain from publishing results due to exaggerated caution. The most important thing is to be clear, critical and honest in evaluating sources of error.

The evaluation of error sources is often limited by the research tradition and method a researcher is working within. Some sources of error do not “show” if one performs the analysis based on a certain theoretical standpoint or model. It is thus important in the error analysis not to limit yourself to the possible “internal errors” within the frame of your chosen viewpoint, but rather to allow the analysis to broaden the perspective to show other, alternative viewpoints. This can be very difficult, however. One is often forced to lower the level of ambition, but in such cases, it is all the more important to be accurate in explaining the basis for the analysis and its limitations.

2.4 Research ethics from a dynamic perspective

The landscape of research ethics is changing. When researchers ask new questions, use new methods and work with new materials, new research ethics issues arise. Early on, the purpose of research ethics was to keep researchers from harming or violating patients and research subjects in numerous ways in the name of science. This was the overarching purpose of the Declaration of Helsinki, against a background of events including the research that had been conducted on prisoners in concentration camps and jails. Therefore, the Declaration stressed standards for informed consent and risk-benefit analysis, as well as that the interests of science and society not being allowed to carry more weight than the protection of the individual’s well-being and safety.

With the development of epidemiological research and register data research of diverse types, some other issues have now come to the fore. The persons who are subject to such research, where data about them is collected and analysed, participate in a different way than those who take part directly in clinical trials of new medicines, for instance. Those who contribute to a register study do not need to be aware that they are part of the study and thereby a subject of research. Meanwhile, this type of research can be sensitive from an integrity perspective, and the knowledge that information, which the people in question may not even know has been recorded, can be gathered and analysed can be cause for concern. The study design and the presentation of results are essential elements in alleviating unfounded (or well-founded) worry over discrimination and stigmatisation. The likely value of new knowledge must thus be weighed against the risk that subjects’ integrity will be compromised and the need to protect individuals’ right to privacy.

New methods, and/or those coming into more frequent use, in humanities and social science research, such as video-recording and participant observation, have raised new issues in research ethics. With questionnaires and interviews, the requirement that the participants’ identities are protected is met through the use of code keys and by masking and de-personalising answers. However, this is not possible with videos, for instance, in which the interplay between body language and verbal communication is studied. In participant observation, the researcher is sometimes not able to obtain informed consent in advance without making it impossible to conduct the research. This presents new challenges to researchers and ethics review boards.

In recent years, stem cell research and nano technology research have attracted great interest, as has the commercialisation of research, and the effects of research on the environment and society in a more global perspective. Besides traditional research ethics issues regarding informed consent and risk-benefit analysis,

some types of stem cell research bring up specific issues regarding both the research object and the methods being used. These concern the moral status of fertilised eggs, and, for instance, whether methods such as nucleus transfer from one cell to another are ethically acceptable. The existence of gaps in knowledge and uncertainty, such as about what happens when nano particles enter the body, is highlighted when results from nano research are applied within new areas, such as the automobile industry, medicine, cosmetics, etc. Limited toxicological studies have been conducted, but the gaps in knowledge make it difficult to perform a meaningful risk-benefit analysis and points to the need for method development in this area.

Issues concerning the commercialisation of research and the effects of research on the environment and society from a more global perspective have recently attracted growing interest; these issues are discussed earlier in this chapter as well as in Chapter 5. The background is not only globalisation and the increased international collaboration between research groups in different countries, but also the fact that large-scale research demands significant resources and public funding is not sufficient. Research groups are therefore becoming increasingly dependent on collaboration with and financial contributions from non-public funding bodies. This enables research that might otherwise not have been possible to be conducted, but also brings to the fore issues of control, dependency and the supervision of research.

Human rights are universal. To the extent research ethics principles are based on and protect these rights, they can be accepted in various cultures. At the same time, they then have to be formulated with a certain amount of vagueness. For example, the requirement of informed consent can be interpreted and applied as a requirement of individual informed consent in liberal, western societies. But in cultures where the family, group, clan or village elder gives consent, this requirement must be interpreted slightly differently. Research ethics are thereby placed in a cultural and social context. Some values reflect technical and economic development, while others are slower to change and are based on more basic human needs.

References

1. Chalmers, Alan F., *Vad är vetenskap egentligen?* Nora, Nya Doxa, 2003.
2. Föllesdal, Dagfinn & Wallöe, Lars & Elster, Jon, *Argumentationsanalys, språk och vetenskapsfilosofi*. Stockholm, Thales, 2001.
3. Gilje, Nils & Grimen, Harald, *Samhällsvetenskapernas förutsättningar*. Göteborg, Daidalos, 1993, tredje upplagan 2007.
4. Hermerén, Göran, *Kunskapens pris: forskningsetiska problem och principer i humaniora och samhällsvetenskap*. Stockholm, Swedish Science Press & HSFR, 1986, andra upplagan, 1996.
5. Hermerén, Göran, "Challenges in the Evaluation of Nanoscale Research: Ethical Aspects". *NanoEthics*, 2007, 1:223–237.
6. Hermerén, Göran & Hug, Kristina (red). *Translational Stem Cell Research: Issues Beyond the Debate on the Moral Status of the Human Embryo*. New York, Springer, 2010.
7. Högskolelag (SFS 1992:1434).
8. Rydén, Lars (red), *Etik för forskare*. En antologi med utgångspunkt i arbetet med Uppsala- kodexen. Stockholm, UHÄ, 1990.

3 ETHICS REVIEW AND OTHER PERMIT REVIEW

To be allowed to conduct certain types of research, it is necessary to obtain a permit. This applies especially to research that involves humans or entails experiments on animals, but also to some other types of research.

3.1 Ethics review and other permit review of research involving humans

3.1.1 Approval according to the Act concerning the Ethical Review of Research Involving Humans, etc.

As mentioned above, the Act (SFS 2003:460) concerning the Ethical Review of Research Involving Humans came into effect as from 1 January 2004.

The Act states what types of research projects must be reviewed. It also lists factors and conditions that should be addressed in order for a research project to be approved, as well as how the review bodies – the ethics review boards – should be composed.

It is the researcher (or the supervisor of a doctoral student project) who, together with the research principal³ applies for an ethics review, when the research falls within the scope of the law. Simply starting or completing a research project that falls within the scope of the law without approval from an ethics review board is a breach of law and is punishable.

Ethics review carries a fee, which varies depending on the type of project (one or multiple principals) and the type of application (new project or supplementary application). For concrete information on how to apply and who should apply, etc., please see the Central Ethics Review Board's website on epn.se or the CODEX website at codex.vr.se.

A research project falls within the scope of the Act concerning the Ethical Review of Research Involving Humans because of its *content*. What is to be reviewed therefore has nothing to do with how the project is funded. Also, research that is not funded by external bodies, but is carried out within a position at an institution, shall therefore be reviewed if the content so requires.

A research project shall be reviewed by an ethics review board if any of the following conditions exist. Namely, if the project (A)

- entails physical encroachment on the research subject
- will be conducted using a method aiming to affect the research subject physically or psychologically, or that carries an obvious risk of physical or psychological harm to the research subject
- entails studies on biological material taken from a living human being and can be traced to this person
- entails physical encroachment on a deceased human being
- entails studies on biological material taken for medical purposes from a deceased human being and can be traced to this person. Act (SFS 2008:192).

A research project shall also be reviewed if it (B)

- entails the handling of sensitive personal data according to Section 13 of the Personal Data Act (SFS 1998:204), including information on race, ethnic origin, political views or religious conviction, or personal

³The research principal is the government authority or the physical or legal entity within whose organisation the research is conducted. A researcher employed at a university or a county council has the same as his or her research principal. The research principal, through its internal work or delegation order or through power of attorney, determines who is authorised to represent the research principal. The research principal always has ultimate responsibility for the research.

data according to Section 21 of the Personal Data Act, including information on judgements in criminal cases.

Condition (B) thus means that *all* research dealing with sensitive personal data shall be ethically reviewed, regardless of how the data has been collected and whether or not the researcher has obtained the participants' consent.

When an ethics review board evaluates a project, it has a number of aspects to note and consider. Generally, the research in question can be approved only if it can be conducted with respect for human dignity. In the review, the board should also evaluate how the human rights and basic freedoms of those involved are treated in relation to the value of the research. The welfare of human beings should be placed before the needs of society and science, and the knowledge value of the research must be assessed as outweighing the risks. The research cannot be approved if the expected results can be reached in another way that presents fewer risks, for instance using other categories of research subjects, or an alternative study design.

For the board to be able to approve certain types of research, *informed consent* must have been obtained from the participants (research subjects, stakeholders). The law also briefly describes how this consent should be constituted, and from whom and how it may be obtained.

The law requires informed consent in the first three types of projects in (A) above; that is, research entailing physical encroachment on the research subject, using a method aiming to affect the research subject physically or psychologically, or carrying an obvious risk of harm to the research subject. This research thus cannot be approved if those involved in the project have not been given sufficient information and been allowed to properly give their consent.

For research projects falling under (B) above, which only involve the handling of sensitive personal data, the stipulations in the Personal Data Act on information and consent apply: normally, informed consent is required. An exception is allowed, however: it is not necessary to inform research subjects if it is impossible, or if it would mean an unreasonably great work effort. The possibility to conduct research without obtaining informed consent is thus not excluded. Each individual case is reviewed and decided on by an ethics review board.

Research projects that fall outside the scope of the Act concerning the Ethical Review of Research Involving Humans can thus not be approved by an ethics review board. In many cases, however, some form of ethics review is desired for these types of projects. This can be in connection with applying for support from national or international research funding bodies, or with attempting to publish the research results in certain scientific journals. In such cases, an ethics review board can issue an advisory statement (Ordinance SFS 2007:1069 with Instructions for Regional Ethics Review Boards, Sections 2–3). This allows the board to state that it can see no ethical obstacles to conducting the project. This corresponds to an approval based on review under the law. An advisory statement can also contain pure advice or conditions that must be met for a positive statement to be issued.

There are six regional ethics review boards (REPNs) assigned with reviewing research projects. There is also a central ethics review board (CEPN). The boards are individual authorities and are independent of each other.

A research principal who has received a rejection from an REPN can appeal this decision and have the project reviewed by the CEPN. A regional board also has the option of referring a case to the central board, if the case brings up new and difficult issues of a principal nature. CEPN also supervises compliance with the Act concerning the Ethical Review of Research Involving Humans and the regulations issued based on the Act.

Some facts

A regional ethics review board is divided into two or more departments. As a rule, there are one or more departments for medical research and one for what is called “other research”. Each department is headed by a chairperson who is or has been a regular judge, and also has ten members with scientific competence, of whom one serves as scientific secretary and five represent the public interest.

The central ethics review board is also headed by a chair who is or has been a regular judge. It has six further members, of whom four have scientific competence and two represent the public interest. At the central board, one of the scientific members serves as scientific secretary too.

In addition to the task of addressing decision appeals and cases referred from regional boards, the central board also supervises compliance with the Act concerning the Ethical Review of Research Involving Humans and the regulations issued with support of the Act.

3.1.2 Other approval

Besides approval from an ethics review board, other approval can also be required for research involving humans.

In clinical trials, except so-called non-intervention studies, it is a requirement that approval is obtained from the Swedish Medical Products Agency (see Chapter 7 Section 9 of the Medicinal Products Act SFS 2015:315). This also applies to trials of a drug for an approved indication, at an approved dosage and with an approved method of administration with the aim of further showing effect and/or safety. The Agency has issued detailed rules for how clinical trials of drugs for humans shall be conducted. Applications to the Swedish Medical Products Agency shall be made by the sponsor, i.e. the individual, company, institution or organisation that assumes responsibility for starting, organising and/or funding the clinical trial. More information on regulations and the steps of the application process can be found on the Agency's website (www.lakemedelsverket.se).

Applications for clinical trials within the EU are registered in the database Eudra CT (European Clinical Trials Database). Currently, this database is only accessible to national medical products agencies, for instance the Swedish Medical Products Agency, the European Medicines Agency (EMA), and the Commission. As a step towards increasing the transparency within the EU, access to certain parts of the database's content will soon be given to the general public via the website www.clinicaltrialsregister.eu. On this website, information on issues such as ethics committee decisions regarding clinical trials on children will be publicly accessible. In the US, the corresponding database is ClinicalTrials.gov.

To conduct a research project involving the irradiation of research subjects with ionising radiation, the project must be approved by a local radiation protection committee. (See 22 § of the Swedish Radiation Safety Authority's rules regarding general obligations in medical and odontological activities involving ionising radiation, SSMFS 2008:35). For multicentre studies, an application must be sent to all local radiation protection committees within the study's scope.

3.2 Research on animals and laboratory animal ethics

3.2.1 The use of laboratory animals

Laboratory animal ethics deals with the ethical issues that arise when animals are used in scientific experiments. In society, it is a common perception that animal experiments are needed for development and research within both human and veterinary medicine. Research using animals is thus conducted partly because it provides new knowledge, partly because it benefits humans, and not infrequently also for the sake of animals themselves.

The production of new medicines is highly dependent on animal experiments. A long line of medical advances that have saved many human lives were possible thanks to the use of animals. The law does not allow the testing of medicinal preparations on humans, and even less their being used in treatment, before they have been tested on animals or through another appropriate method to arrive at dependable research results.

The EU's definition of laboratory animals includes only those animals that are actually subjected to invasive procedures, at minimum a needle-prick. Based on this definition, the Swedish Board of Agriculture received reports that 258,403 laboratory animals had been used in Sweden in 2015. Sweden's definition is considerably broader, however, and includes all animals used for scientific purposes. Based on the Swedish definition, the Board of Agriculture received reports that 16,373,330 laboratory animals were used in Sweden. The large difference is because Sweden includes the fish collected to evaluate or tag the fish population, which in 2015 amounted to 16,042,533 fish (the Swedish Board of Agriculture, *Användningen av försöksdjur i Sverige under 2015*, report Dnr: 5.2.17-5428/17).

In recent years, a number of issues concerning laboratory animals have been raised in public debate, for instance the use of genetically modified animals as disease models. Also worth mention is the discussion of whether primates should be used in research on Hepatitis C and HIV, which only afflict humans and chimpanzees. Another debated issue is the EU's REACH Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (ordinance EU 1907/2006). This has entailed increased requirements concerning the testing of chemicals on animals, with the aim of protecting human health and the environment.

Regulations on animal experiments can also be found in the Animal Welfare Act (SFS 1988:534), which has undergone a number of changes since it was passed.⁴

An EU directive on the welfare of laboratory animals and the ethics review of research on animals was recently passed (2010/63EU)⁵, aimed at harmonising existing laboratory animal welfare protection and establishing common minimum and maximum levels within the EU. The establishment of a maximum level means that member countries cannot legislate stricter rules themselves in the future; however, a country is allowed to have stricter rules if they were already in place before the directive went into effect. Further information can be found on the Board of Agriculture's website (jordbruksverket.se).

3.2.2 Laboratory animal ethics

Work using laboratory animals raises a number of difficult ethical issues. Positions on these issues have a great deal to do with fundamental ideas concerning views on humankind, that is to say the essence, function and task of human beings, and not least their position in relation to other living beings. In addition, ethical notions regarding animal experiments are influenced by our general moral convictions.

Anyone considering conducting research using animals in order to better understand how the human body works, or to contribute to improvements to human medicine, faces difficult ethical challenges. Similar challenges arise in other fields of research as well. This is clearly demonstrated in the so-called paradox of animal experimentation, which summarises the dilemma that animal experimentation entails: *we use (nonhuman) animals in experiments, because they are sufficiently like us (to achieve relevant results) – and since they are sufficiently different from us (to allow us to justify the suffering we cause).*

This paradox is not new; it has existed as long as animal experiments have been conducted, or at least since ancient times. Humans have always had a relationship with all other animals, but differing notions of how humans should relate to animals have been dominant at various times, and have reflected the norms and values of those times and cultures. It cannot be assumed that one unified view exists of what this human-animal relationship should be like within one single era and culture.

Even today, there are a number of differing views of how the responsibility of humans to animals should manifest itself. The discussion itself on how this responsibility should be exercised, and its limits, can enrich our self-understanding, and contribute to changes in how animals are treated in research. Within the subject of animal ethics, this relationship is highlighted through an analysis of views of the moral status and intrinsic value of animals, as well as of the responsibility of humans. Animal ethics also involves the study of theories on the rights of and obligations towards humans and animals, for both present and future generations.

3.2.3 The ethics committees on animal experiments: organisation and task

Experiments using animals can only be conducted at a facility approved by the Swedish Board of Agriculture, where there is an approved supervisor, an approved veterinarian and personnel with sufficient competence. Review by an ethics committee on animal experiments is obligatory.

In Sweden, the legal requirement of the advisory ethics review of animal experiments was introduced in 1979. Since 1988, the ethics committees on animal experiments have had the task of approving or rejecting applications, and since 1998 their ruling has been legally binding. In total, around 1,700 applications are reviewed each year.

The responsibility for the ethics committees on animal experiments and the review function rests on the Board of Agriculture since 2007.

There are six ethics committees on animal experiments in Sweden, and each committee has fourteen members.

⁴A summary of its development is given in the Swedish Board of Agriculture's regulations on change in the Central Laboratory Animals Board's regulations from 1988; see the Board of Agriculture's Code of Statutes 2008:70 as well as Borgström 2009.

⁵http://ec.europa.eu/environment/chemicals/lab_animals/index_en.htm

Some facts

The chair and vice chair of the ethics committees on animal experiments are lawyers with experience of court work. Of the other twelve members, one half are scientists or staff who work with laboratory animals and other half are laymen, of whom at least one represents an animal welfare organisation. It is a stated political goal that the laymen should represent the general public to the greatest degree possible. The composition of the research group should be such that the committee as a whole has broad competence.

3.2.4 Ethics review

The main task of an ethics committee on animal experiments is to weigh the purpose of the experiment against the suffering that may be inflicted on the animals, and determine whether the purpose is sufficiently important to justify the animals' expected suffering. This is a challenging task. It is important that the application be clear and informative, so that the committee can form an opinion on how important the experiment is, and how the animals may be affected.

Central questions that must be answered by the applicant to enable the committee to make an adequate assessment are: the purpose of the research, whether this can be achieved using another method than animal experimentation or with another type of animal, whether the animals will be subjected to greater suffering than is absolutely necessary, whether anaesthesia or painkillers will be required, and whether the experiment is an unnecessary repetition of an earlier one.

A report on the ethics review of animal experiments (*Etisk prövning av djurförsök*, SOU 2002:86) contains a well/structured suggestion for discussion subjects that highlight which ethical aspects need to be stressed in connection with each application.

A researcher who wishes to make a sound decision in the question of whether or not an animal experiment is justified must, just like the ethics committees on animal experiments, consider the purpose of the research by *weighing the expected benefit of the experiment against the expected suffering of the animals*. The fundamental principle in all research, weighing benefit against possible harm, was touched on earlier. Here, a number of factors determine the outcome.

As regards benefit, the researcher should consider the importance of the knowledge gain or possible application, for society in general as well as for the research itself. He or she must think about whether, for example, it applies to a considerable number of people – each suffering relatively little – or if it is a matter of only a small number of people, who each suffer a great deal or have a disability that affects their everyday lives.

The task of the committee is then to make its legally binding decision on the application and to ensure that only experiments that are relevant to the research and well-designed are conducted. Committee members representing the research community review the scientific stringency and methodical relevance of the application. The lay members' task is to confirm the societal importance of the animal experimentation and to represent the general public's observation and evaluation.

The applicant must submit a complete application and describe the project in such a way that all committee members can understand and discuss it, based on the information it contains. As necessary, the committee may call the applicant to the meeting to provide clarification, or request an expert opinion. The committee may decide that a partial or pilot study should be conducted if a method must first be evaluated; the committee can also do this to reduce the number of animals used, before it has been determined to the best possible degree how the animals will feel or if their suffering is directly regarded as severe.

To simplify the evaluation of the animals' suffering and in the interest of achieving uniformity among the committees, a four-part categorisation has been introduced. Based on this, the applicant him or herself assesses whether the experiment in its entirety entails *terminal*, *mild*, *moderate* or *severe* suffering for the animal – this is the experiment's so-called classification of severity. Here, both the researcher and committee may refer to the list of experiments according to degree of severity in the Board of Agriculture's instructions. The committee must determine whether the applicant has made a reasonable evaluation and, when necessary, correct the information.

3.2.5 Alternatives to using laboratory animals

Many researchers try to find animal-free methods that allow them to reach results that are equally dependable. There are several reasons for this. Reasons can include the researcher not wanting to inflict suffering on

animals, or the fact that it is relatively costly to keep animals. A third reason, which is being discussed increasingly, is the uncertainty of how transferable results from medical experiments are; that is, how relevant results from experiments using animals are in the medical treatment of humans.

For example, comparisons between treatment effects on animals and clinical trials using humans might show poor correspondence. This indicates both that animal experiments and clinical trials may need to be better coordinated, and also that animal experiments do not always provide meaningful information for the treatment of humans. An example of the latter instance is studies aimed at developing methods for treating rheumatoid arthritis by studying patients' tissue samples. Here we can see two of the reasons for not using animals: arthritis is a painful disease even for the animals serving as disease models, and only humans and primates have the central receptors the treatment involves. This means that experiments on mice and rats would have lower relevance.

Computer programs are also sometimes used instead of animal experiments, for example to evaluate and calculate side effects of various treatment methods. Cell models can also be used to test, at cell level, the impact of certain chemicals or to study the effects of medication.

In Sweden, there is governmental support for research grants for alternative methods to animal experimentation according to the 3R principle, i.e. methods that refine, reduce and replace animal experiments, which can be applied for through the Swedish Research Council. Alternative methods refer to methods that refine, limit and/or replace experiments on animals. It is also possible to apply for research grants from the Swedish Fund for Research Without Animal Experiments (forskautandjurforsok.se). The EU has a centre for the coordination, development and evaluation of alternatives to animal experimentation, ECVAM (the European Centre for the Validation of Alternative Methods), located near Milan, Italy. Since April 2010, there is also an industry-funded centre for alternative methods, CAAT-EU (the Center for Alternatives to Animal Testing Europe) at the University of Konstanz in Germany. Its parent organisation in the US was established in the 1980s.

Together with a number of universities, the Swedish Research Council is responsible for providing information to researchers and the general public via the website www.djurforsok.info.

3.2.6 Evaluating the ethics of animal experiments

A researcher who uses laboratory animals, as well as the majority of the members of the ethics committees on animal experiments who have the task of determining what is ethically acceptable, have all reached the fundamental conclusion that there are animal experiments that are ethically defensible. Every experiment, however, must be preceded by an ethical evaluation. The following concepts (in italics) may help in highlighting important questions to ask when evaluating what is ethically defensible.

A fundamental element to consider is who or what has moral relevance, that is who or what should be considered in the ethical deliberation. A distinction must be made between whether something or someone has *moral relevance* in itself – *intrinsic value* – or is relevant for the sake of someone or something else – *instrumental value*. Intrinsic value is often not measured in degrees, but is instead regarded as either existing in an individual (or a material entity), or not. On the other hand, the instrumental value of an individual or a material entity is possible to measure. Its value can differ, depending on the user or beholder.

It is not unusual either for an individual to be considered as having both intrinsic and instrumental value. For example, a genetically modified mouse of a certain lineage can be a highly valuable instrument within a certain research project and at the same time be regarded as having intrinsic value, for instance because it is an experiencing individual, able to feel pain. A sibling mouse that does not express the desired genetic modification has a low instrumental value, but the same intrinsic value.

Animal ethicists who argue that animals have *rights* usually base this on the idea that animals have intrinsic value. Individuals who have intrinsic value also have certain fundamental rights, such as those to food, water, a place for rest, protection from the elements and access to social contact.

This reasoning does not necessarily lead to the conclusion that animals and people have the same rights, however. Perceptions of what rights animals are considered to have, and how far-reaching they are, differ among animal ethicists, but are often tied to the capacities of the species in question. A shrimp's rights are less extensive than those of a mouse, which in its turn has a shorter list of rights than a primate. The point of rights is thus not to argue that "pigs should have the right to vote", but rather that animals' physical and social needs should be met, to the degree they exist.

A highly central issue in animal ethics concerns the fact that humans are traditionally regarded as something special – as having a *special dignity* and *integrity* – and therefore enjoy an elevated level of protection. It is unrealistic to believe that we can arrive at one single reason that is valid for everybody why humans hold this exceptional position. Perhaps the philosophers are right when they say it is impossible to justify it in any other way than to say that someone born by a human thereby has the right to a certain moral protection that is not extended to other living beings. If this is indeed the case, then we have just as great a responsibility to contemplate what we should do with this special position.

Our rationality and knowledge allow us to exercise power over other animals. But with power comes responsibility – power over the animals' situation and power over what issues we choose to research, for both the sake of the people who put their hopes in science and the sake of the animals whose lives are used to this end.

What would you do in the following situation?

Millions of people today have HIV and risk contracting AIDS if they do not receive effective inhibitor medications. A great deal of research is being conducted to find a cure for HIV/AIDS using chimpanzees which, besides humans, are the only animals that can get HIV/AIDS.

You are a member of an ethics committee on animal experiments that is to ethically evaluate a research project aiming to test the effectiveness of a potential vaccine. The researchers inform the committee that the vaccine's effect needs to be tested on advanced AIDS, which means that the chimpanzees will be in very poor health when the actual experimenting begins.

What ethically significant aspects to you feel should be considered to ethically evaluate whether this experiment should be approved? Consider the issue from both a researcher's and a layman's evaluation perspective.

3.3 Genetically modified organisms

Basic research and applied research with genetically modified organisms, i.e. organisms whose genetic material has been changed in a way that does not occur naturally through mating or the natural recombination of genes, is covered by a detailed system of regulations. Supervisory responsibilities are divided between several authorities, including the Swedish Work Environment Authority, the Swedish Board of Agriculture, the Swedish Board of Fisheries and the Swedish Medical Products Agency. The different authorities' areas of responsibility, as well as the applicable regulations, can be found at the web portal of the Swedish Gene Technology Advisory Board, (genteknik.se).

For research involving the enclosed use of genetically modified organisms, for example the growing of cultures in tightly shut containers or cultivation in a greenhouse, to be conducted it is necessary either for the responsible authority to have given its approval, or for the research to have been reported to this authority. The research should always be preceded by an investigation that serves as a basis for a risk assessment, and the results of this assessment then determine what protective measures will be necessary.

Research that involves the intentional exposure of genetically modified organisms, for instance field experiments using genetically modified plants or microorganisms, should always be preceded by an investigation so that the risk of harm can be assessed. Additionally, approval must be received from the proper supervisory authority; and approval can only be given if the research is ethically acceptable. A researcher who ignores the obligation to notify the proper authority or obtain approval can be found guilty of conducting unauthorised environmental work.

3.4 Examples of problems that are still unsolved

The Swedish legislation and regulations concerning research are not comprehensive – and never can be (see Chapter 1 on the law and morals). However, there are currently a number of shortcomings that deserve attention, so that workable solutions can be discussed and, if possible, be implemented.

First, there is the problem that Swedish legislation is only applicable in Swedish territory. This affects the ethics review of projects that will be conducted wholly or partly in another country, even if researchers from

Sweden participate and Swedish funding bodies contribute money. Ethical standards that appear self-evident in Sweden can then be difficult to find support for in international research environments.

It is especially worrying if researchers perform their work in countries with lower ethical standards, just to take advantage of this. It can, for example, be easier to find research subjects, easier to get permission to use primates in research, cheaper to conduct studies, or involve less extensive application procedures. If these advantages come at the cost of the integrity of the research, it will in many cases involve a breach of the standards in the Declaration of Helsinki:

Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

It is unacceptable for studies to violate this principle. The Norwegian National Committee for Research Ethics in Science and Technology states precise and necessary requirements, namely that

a researcher is not to conduct parts of his or her research in another country simply because it has lower ethical or safety standards than at home;

and that researchers shall inform funding bodies of divergent ethical or safety standards in the country or countries where their research is being conducted.

Another problem is that the most fundamental protection for research subjects – that the research project must be ethically reviewed before it can begin – is not always self-evident in other countries. The Declaration of Helsinki requires this review for all medical research performed on humans, and this requirement is held by many funding bodies and journals.

Here, the Swedish legal requirement of ethics review is less comprehensive. However, as mentioned earlier, in Sweden there is the option to request an advisory statement from an ethics review board regarding a project that does not formally need to be reviewed. It is good research practice to request a statement in the event research collaborations in other countries are expected to present ethical difficulties for the researchers.

The ethics review boards have no obligation to issue these advisory statements however, just the right to do so. If the regional ethics review board refuses to issue such a statement, however, this may cause profound consequences for the researchers' chances of obtaining further funding and being published.

There are issues concerning the withdrawal of consent that are problematic for research ethics. In biobank research, the research subject has the option of withdrawing consent. If this happens, it is the responsible party at the biobank who determines whether the biological material should be destroyed – which is likely to be the research subject's wish – or only de-identified. In the latter case, the research subject can feel tricked. In research projects using video or audio recording, the research subject is often told he or she can withdraw consent after the recording and that the tape will be destroyed. However, this is in conflict with the regulations governing archiving and storage of research material, as well as with the rules regarding withdrawal of consent in the Act concerning the Ethical Review of Research Involving Humans.

References

1. Alexius Borgström, Katarina, *Djuren, läkarna och lagen: en rättslig studie om djurförsöksetik*. Uppsala, Iustus förlag, 2009. Arkivlag (SFS 1990:782).
2. Brambell, Rogers, F.W. (Chairman), *Report of the Technical Committee to enquire into the Welfare of Animals kept under Intensive Livestock Husbandry Systems*, London, HMSO, 1965. This states five freedoms for farm animals: freedom from hunger and thirst, from discomfort in housing, from pain and injury, from fear and worry and the opportunity to exhibit natural behaviour.
3. Cavalieri, Paola & Singer, Peter (red.), *The Great Ape Project: Equality Beyond Humanity*. New York, St. Martin's Press, 1994. A proclamation from 34 researchers and authors for three rights for certain primates: the right to life, the right to freedom and a prohibition against torture.

4. Centrala försöksdjursnämnden, *Författningar, allmänna råd och anvisningar om användningen av djur för vetenskapliga ändamål*. Stockholm, CFN:s skriftserie: 45, 2002.
5. Den nasjonale forskningsetiske komité for naturvitenskap og teknologi (NENT), *Forsknings- etiske retningslinjer for naturvitenskap og teknologi*. Oslo, 2007.
6. Djurförsöksetiska utredningen. *Etisk prövning av djurförsök: delbetänkande* (SOU 2002:86). Stockholm, Fritzes offentliga publikationer, 2002. Djurskyddslag (SFS 1988:534).
7. Egonsson, Dan, *Filosofiska essäer om människovärde*. Nora, Nya Doxa, 1999.
8. Förordning om etikprövning av forskning som avser människor (SFS 2003:615).
9. Förordning med instruktion för regionala etikprövningsnämnder (SFS 2007:1068)
10. Förordning med instruktion för Centrala etikprövningsnämnden (SFS 2007:1069).
11. Förordning om utsättning av genetiskt modifierade organismer i miljön (SFS 2002:1086).
12. Förordning om innesluten användning av genetiskt modifierade organismer (SFS 2000:271).
13. Jordbruksverket, *Användningen av försöksdjur i Sverige under 2015*. Rapport, Dnr: 5.2.17-5428/17.
14. Hug, K. and M. Johansson, *The ethics of withdrawal: the case of follow-up from first-in-human clinical trials*. Regen Med, 2017. 12(1): p. 25-36.
15. Hug, K., G. Hermeren, and M. Johansson, *Withdrawal from biobank research: considerations and the way forward*. Stem Cell Rev, 2012. 8(4): p. 1056-65.
16. Karlsson, Fredrik, *Weighing Animal Lives – a Critical Assessment of Justification and Prioritization in Animal-Rights Theories*. Uppsala, Acta Universitatis Upsaliensis, 2009.
17. Klareskog, Lars & Rönnelid, Johan & Lundberg, Karin & Padyukov, Leonid & Alfredsson, Lars "Immunity to citrullinated proteins in rheumatoid arthritis." *Annual Review of Immunology*, 2008, 26:651–675.
18. Lag om etikprövning av forskning som avser människor (SFS 2003:460).
19. Lag om biobanker i hälso- och sjukvården med mera (SFS 2002:297).
20. Läkemedelslag (SFS 2015:315).
21. Läkemedelsverkets föreskrifter om kliniska läkemedelsprövningar på människor (LVFS 2011:19).
22. Perel, Pablo, & Roberts, Ian & Sena, Emily & Wheble, Philipa & Briscoe, Catherine & Sandercock, Peter & Macleod, Malcolm & Mignini, Luciano E. & Jayaram, Pradeep & Khan Khalid S., "Comparison of Treatment Effects between Animal Experiments and Clinical Trials: Systemic Review". *British Medical Journal*, 2007, 334 (7586):197.
23. Personuppgiftslag (SFS 1998:204).
24. Personuppgiftsförordning (SFS 1998:1191).
25. Rodman, John, "The Dolphin Papers", *The North American Review*, spring 1974, 259:13-26 (page 18).
26. Statens Jordbruksverks författningssamling (SJVFS 2008:70).
27. Strålsäkerhetsmyndighetens föreskrifter om allmänna skyldigheter vid medicinsk och odontologisk verksamhet med joniserande strålning (SSMFS 2008:35).
28. World Medical Association. Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, latest revision by the WMA General Assembly, Seoul 2013. Ferney-Voltaire, France, World Medical Association, 2013.

4 HANDLING OF RESEARCH MATERIAL

- THINK FIRST

This chapter, with the exception of Section 4.5, is the translation of a text that is virtually identical to that of Göran Hermerén's article, "Hantering av integritetskänsligt material".

4.1 Background and problems

The fundamental openness in all public organisations is required by law and established constitutionally. Universities and individual researchers can therefore not take it upon themselves to weigh the interest of public access against other interests.

The Declaration of Helsinki, adopted by the World Medical Association, is an important document for medical research ethics. The ethical principles stated in the Declaration are in part also applicable to other research, not least certain social medicine and social science research. This document has been updated a number of times, most recently in October 2013.

However, the Declaration of Helsinki is not legally binding. This was reiterated by the Swedish Court of Appeal for Western Sweden in a case a number of years ago that received a great deal of attention; A view that was upheld by the European Court of Justice in 2010. The issue concerned a request that a researcher in Göteborg make public the research material from a controversial study on children with neuropsychiatric disabilities.

Swedish law carries more weight than this international declaration in cases when they come into conflict. These issues have received attention in medical research, for instance in the debate and trials that have followed in the wake of the Göteborg case. But the issues have a more general and fundamental side as well, as they also arise in many other scientific areas, such as the humanities (integrity-sensitive information on famous politicians and authors) and social sciences (integrity-sensitive information on individuals and groups that may be revealed in studies).

In these cases, the requirements for public access, openness and transparency sometimes come into conflict with the requirement to protect the integrity of research subjects and informants. These issues also carry a danger that current regulation systems increase the risk that studies will be performed outside the healthcare arena, where there is less transparency. It is thus important to have a general discussion on ethical issues in the handling of integrity-sensitive material. Awareness of both the rules and the problems needs to increase within the research community.

4.2 Interest considerations and various types of research

In research, this means finding a reasonable way of weighing up many types of interests which are all legitimate, but which in some situations can conflict with each other: the researcher's interest in obtaining new knowledge, the interest of participants and those affected by the research to have their integrity and private lives protected, and patients' interest in information they have given their doctor remaining only between them.

Funding bodies for basic research, such as the Swedish Research Council, have an interest in openness and transparency. Other funding bodies may have an interest, from a societal perspective, in material being reused or used by many groups – an important task in this case is to specify the conditions under which this can be done.

How this weighing of interests is done depends on aspects such as the type of research is being conducted. A significant difference in this context is the distinction between research which is not being conducted in connection with healthcare, and that which is. This distinction is important, as different regulations apply in the two cases.

If research is combined with healthcare, for example, the Patient Data Act and the provisions applicable to healthcare operations in the Public Access to Information and Secrecy Act apply. It is therefore important to keep several types of journals – both on the patient/treatment being provided, and on the research itself. The patient/treatment journals should only contain information that is necessary for the patient to receive good and

safe treatment. Information required for the research project should be reserved for the research journals. The same applies in retrospective studies, especially if they deal with integrity-sensitive questions.

But in any type of research, the material collected is not the private property of the researcher or research group, something they own and can do with as they wish. It must be stored and archived according to the general regulations issued by each authority in question.

4.3 Four concepts

Four important concepts in the debate that are sometimes confused with each other or used synonymously are secrecy, professional secrecy, anonymity and confidentiality.

Information can be covered by *secrecy* only if it is stated in law, normally the Public Access to Information and Secrecy Act.

Standards for *professional secrecy* apply to some professions by law, as well as by ethics rules. All personnel in health and medical care, dental care and social services, for instance, must observe professional secrecy. This means that they are not allowed to discuss patients' and clients' health or personal situation with unauthorised individuals, or in any other way communicate this information. Similar standards for professional secrecy also apply to psychologists and clergy, for example. If a certain task is covered by secrecy, it means the person carrying out the task has a duty of professional secrecy.

Anonymising or *de-identifying* involves eliminating the connection between samples or questionnaire answers and a certain individual, so that neither unauthorised persons nor the research group can re-establish it; no one should therefore be able to combine a certain piece of information with a specific person's identity, for example. The code list is destroyed. Anonymity can also be achieved by collecting material without noting the identity of specific individuals.

What is described above differs from a situation where the research group can use code keys to link information or samples to specific individuals (pseudo-anonymising) – which is usually necessary in longitudinal studies, for instance, or to enable auditing of the research. The question of who is and is not authorised, however, is not something for the researcher to determine ultimately. Disputes over this issue can be settled in court. Usually, it is a case of other researchers wishing to use the information in their research. In some cases, it can be stipulated that their research is ethically reviewed. Various reservations can be set in this context, for example that the researcher may have access to the information but is not allowed to contact the subjects studied.

Confidentiality is a more general obligation not to communicate information given in confidence, and entails protection against unauthorised persons partaking of the information.

4.4 What can researchers promise?

There are some things researchers cannot promise and yet do promise anyway – due to being poorly informed of applicable rules or because they confuse the four concepts discussed above.

4.4.1 Secrecy

The basic principle is that public documents shall be publicly accessible and that information can be covered by secrecy only if falls under a specific provision of the Public Access to Information and Secrecy Act. The Act contains a chapter that specifically addresses secrecy to protect the individual in research (Chapter 24). But in addition, the Act contains many other provisions that the researcher may have to address, for instance regarding secrecy to protect the individual within health and medical care in Chapter 25.

The principle of public access covers public activities, and those activities listed in the appendix to the Act. When a request for information from public documents is received, the authority where it is being stored (for example a university or a county council) is required to evaluate whether the information may be handed out, that is to say whether or not the information is covered by secrecy.

4.4.2 Professional secrecy

Professional secrecy follows from secrecy to the extent that if certain information is covered by secrecy, then this also entails a requirement of professional secrecy about it. However, the opposite is not true.

If professional secrecy applies for a certain activity, this does not necessarily mean that what is said during the activity is automatically covered by secrecy or that it falls under the Public Access to Information and Secrecy Act. Furthermore, it can happen that a researcher, through his or her work on a project, becomes aware of some circumstance that must be reported by law (such as child abuse or paedophilia). In such cases, the obligation to report outweighs the secrecy requirement.

4.4.3 Anonymity

In some cases, the anonymising of information is a condition set by an ethics review board for its approval of a study. This can be done, for example, by removing personal information on completed questionnaires or samples, so that it is difficult or in practice impossible to link a certain answer or sample to a specific individual. In some types of studies, the identity of the individuals is not relevant, for instance studies on variations in attitudes towards a certain issue in a specific group over time. In such situations, researchers can promise anonymity.

It should be noted, however, that this strategy has other drawbacks. Not only is it difficult or impossible to verify the researcher's information, but it can also happen that an entire group is stigmatised or discriminated against due to the publication of certain research results, even if no individual person in the group can be identified.

4.4.4 Confidentiality

The Declaration of Helsinki stresses the importance of confidentiality and of the researcher taking measures to protect the integrity of research subjects and their right to protection of their private lives. This is stated in the latest version of the Declaration from 2013, where it is stressed that:

Every precaution must be taken to protect the privacy of the research subjects and the confidentiality of their personal information and to minimise the impact of the study on their physical, mental and social integrity.

4.4.5 Conclusions

As just discussed, a researcher cannot promise that no one outside the research group will ever have access to the material or information collected in the course of the study. There are many situations in which access to research material is justified and necessary. For example, it could be a case of other researchers wanting to test the strength of scientific results, an opponent at a disputation requesting access to the basic data, or a report of suspected research misconduct, clinical trials (e.g. inspection), a court ruling or an ongoing court case.

It also cannot be ruled out that research material may be handed over to other researchers in cases besides those referred to above. Research costs money, so it is also in society's interest that material collected is used as much as possible in research. Two general conditions for this to be possible are that the new research project is ethically reviewed (if the law so requires), and that the new researchers adopt the previous researchers' promise of confidentiality and safe storage of the material.

Naturally, the researcher can and should describe to the research subjects the measures taken to prevent, or reduce, the risk that sensitive personal information will be disseminated. The researcher should also explain the conditions under which these protective measures can be enforced. These measures can include the use of code keys, the encryption of certain information, etc.

There is of course a risk that some persons will not want to participate in a study if the researchers truthfully explain what they are able to promise, based on the rules that apply. But as a rule, people are willing to participate in medical research if they are asked, informed according to the principles in the Declaration of Helsinki and are told why and to whom the research is important. Of course, it is easier and cheaper to do things right from the beginning. In research that is not conducted in connection with healthcare one can, for example, use a code key and record coded information directly in the research journals, even though there is a certain extra cost involved. This makes it possible to give other researchers access to the information on

condition that they assume or take over the professional secrecy promised by the previous researchers. The new researchers then become the personal data controllers.

It is not only names that can be replaced with code numbers. Other information in the material that could identify individual subjects can also be disguised in this way (see Chapter 9). The ethics review boards should be able to determine the level of encryption required.

Costs can be significantly higher if material that will be shown to other researchers is not collected using codes and code keys, especially if a project is conducted over a prolonged period of time. But it is neither ethical nor legally acceptable for an individual researcher or research group to breach the rules applicable with reference to such costs.

What would you do in the following situation?

A researcher, Adam, collects data from a specific group of adult informants. He promises that no one outside his research group will have access to the data. Later, his findings are questioned by two other researchers, Brian and Cecilia, who request access to his source data. Adam refuses to hand them over, referring to his promise to his informants. The case reaches an unexpected conclusion when colleagues of Adam's say they have destroyed the source data on their own initiative.

Is the action taken by Adam's colleagues ethically defensible? Is it compatible with existing legislation? Has Adam promised more than he can deliver?

4.5 Documentation

Data collected for a research project is called source data. Sometimes, researchers consider source data to be their own individual property. This might possibly be the case if the research is privately funded and conducted by individuals not associated with normal research environments, and the data does not include personal data.

But when the research is conducted at a university or other research institution, or when it is funded with public funds through grants from a research council or foundation, it is the organisation where the research is conducted that owns the material. The researcher or research group can thus not do whatever they want with it, for instance take it with them upon changing jobs, without agreements and special arrangements. Source data and material that documents the research process and the project's various steps should instead be regarded as documents (submitted, upheld) belonging to the organisation and fall under the Public Access to Information and Secrecy Act and the Archives Act.

The material from a completed research project should therefore be stored and archived, with subsequent preservation and occasional sorting. If it is integrity-sensitive, there are also specific requirements for how it should be stored. Information on this is provided by the Data Inspection Board, among others. There are many reasons to keep material. For instance, it must be possible to verify research results⁶, or the material might be requested in the investigation of an accusation of research misconduct. It can also happen that the researcher who obtained the results, or other researchers, wish to reuse the material in another project. As a rule, this type of reuse requires a new ethics review. The material may also be of great value in itself, for example if it documents current societal conditions, in which future generations may have an interest.

Whether, when and how an organisation may sort material is addressed in the Archives Act. If material is considered valuable, for instance for the way in which current society will be regarded in the future, it should be saved by the institution. The National Archives should be consulted as to how to proceed.

It is important that research institutions and similar establish procedures for documentation, archiving and sorting, and that these procedures are known and observed by their researchers.

Making data material collected available to other researchers contributes to facilitating both the scrutiny and the development and application of research. Digitally stored data can today be uploaded onto platforms where it becomes available to other researchers. The conditions under which this may be done are shown in the Open Science Framework (www.osf.io).

⁶ The importance of other researchers being able to verify the results naturally also applies to publication, including the increasingly common requirement of open access; this is discussed in Chapter 6.

References

1. Arkivförordning (SFS 1991:441). Arkivlag (SFS 1990:782).
2. Bohlin, Alf, *Offentlighet & sekretess i myndighets forskningsverksamhet*. Riksarkivet, 1997:2. Those interested can read more about public access and secrecy issues in the Uppsala University handbook “Hantering av allmänna handlingar vid universitetet” (3 uppl. 2009), which can be downloaded from Uppsala University’s website (regler.uu.se, search for handling of public documents at universities).
3. Hermerén, Göran, *Hanteringen av integritetskänsligt forskningsmaterial*. Vetenskapsrådet, 2007.
4. Justitiedepartementet, *Offentlighet och sekretess hos det allmänna*. 2009.
5. Offentlighets- och sekretesslag (SFS 2009:400).
6. Riksarkivet, *Om gallring – från utredning till beslut*. Rapport, 1999:1.
7. Riksarkivet. Riksarkivets föreskrifter och allmänna råd om gallring av handlingar i statliga myndigheters forskningsverksamhet. Riksarkivets författningssamling, RA-FS, 1999:1.
8. Sveriges universitets- och högskoleförbund (SUHF), *Övergripande principer för offentlighet och sekretess i integritetskänslig forskning*. SUHF, 2006.
9. Tryckfrihetsförordning (SFS 1949:105).
10. Uppsala universitet, *Hantering av allmänna handlingar vid universitetet*. Tredje upplagan, 2009.

5 RESEARCH COLLABORATION

5.1 Introduction

Research is an activity that involves the creation and accumulation of significant amounts of knowledge, and its results can be of lasting value for many people. This means that research can be very rewarding activity for an individual to be involved in, but it also means that it can never be a purely private matter, least of all when paid for out of public funds. Research projects are often collaborative endeavours, with a large number of stakeholders.

In fields of research where large-scale projects need to be undertaken – perhaps involving heavy investments in instrumentation, large computer programs, detailed interview surveys, questionnaires sent to thousands of informants or clinical studies – extensive collaboration is a practical necessity. Today, much research is conducted by large teams that sometimes include hundreds of researchers scattered across the globe. Such collaborative projects do not come about by themselves.

Administration and project management are important in making the research functional. If they are to be concluded, moreover, purposeful efforts are needed and more or less clearly stated rules have to be followed. The organisation of projects of this kind, and the collaboration that occurs within them, raise particular problems.

5.2 Relations with fellow researchers

A common reason for establishing scientific collaboration is to broaden the competency within the planned project, for example by involving a colleague who is a specialist in a method of analysis with which you yourself are not familiar. Another reason might be that a colleague has access to resources, such as an instrument, that is not available to you. Yet another could be that the project requires more working hours than you yourself are able to devote to it, or that you wish to complete the project in a shorter time by involving more people in it. It is also common, no doubt, simply to want to have other people to work with, to be part of a team. Collaborations can also arise naturally when researchers supervise students within the framework of their own projects.

Whatever the motives for collaboration, it is crucial to form a clear idea at an early stage, and to make it clear to your fellow researchers, what you expect of each other, and not least what you yourself are able to contribute. It is important to establish a time plan for the various parts of the project, even if it has to be updated from time to time. Like all joint ventures, scientific collaboration requires a certain degree of reliability in keeping to agreed timetables.

It is still possible to see examples of scientific collaboration in which the participants take such responsibilities quite lightly. Collaborators contribute to the common undertaking “when the spirit moves them”. If the project involves postgraduate students or researchers in the early stages of their careers, this is totally unacceptable. They are so dependent on being able to produce a track record of publications and other results in order to be able to continue at all, that collaborative projects in which they participate must involve a realistic sharing of the workload and a viable and quite strictly regulated time plan.

In many collaborations, a modified division of labour gradually crystallises out, with some researchers not contributing in accordance to the original plan, while others fill the gap by doing more. Such adjustments are natural, but they should be openly discussed when they become apparent, and should be reflected in the authorship of the final publications. It causes a great deal of trouble and frustration if researchers who do not have time to participate as intended nevertheless continue to promise to contribute to the joint project, with no realistic chance, or perhaps even intention, of actually doing so.

The distinct roles that various participants assume in a collaborative research project are not always what everyone would wish. Just as in other joint efforts – whether it be a matter of domestic chores or team sports – you can end up with certain people taking on responsibility for broader plans, or tricky details, while others look after routine tasks or maintain order. Preferably, of course, everyone should have the chance not only to use the abilities they already possess, but also to learn new skills. This is particularly true of research students and other young researchers; senior members of a group have a special responsibility to ensure that their younger colleagues’ interests in this respect are provided for.

It is a good idea to broach the subject of publications and their authorship early on, at the planning stage. These issues should be discussed again if the division of labour changes, or the project develops along new lines. It may be tempting to put off crossing that bridge until you come to it, but experience tells us that, by then, it may be too late. Plain speaking about what rewards different individuals expect and lay claim to in terms of publication credit greatly reduces the risk of conflicts later.

When the project and its results are presented in more informal settings too, for example in papers at international conferences, care should be taken to give a correct picture of the contributions of the various participants. In such contexts, the results presented are commonly perceived chiefly as the speaker's own, and precisely for that reason emphasis should be placed on the contributions of one's colleagues.

A large research group often generates a sizeable and valuable common database of experimental data, computer software, etc. Who owns such material? This question is sometimes raised, not least when doctoral students or postdocs from the group move to other centres to continue their careers. Will they then have free access to the database? This cannot be taken for granted, especially if the researchers in the group have not yet completed and published their analysis of the data. It is important to discuss such questions when the database is created, or at any rate before doctoral students and other collaborators leave the group.

5.3 Interaction with funding and commissioning bodies

Major collaborative projects may involve or affect dozens of research groups in as many countries. They may be supported by a large number of funding bodies, often national research councils. An honest and open attitude to these funding agencies is important and, in the long run, beneficial to the research undertaken.

In an international project, there may be a temptation to describe your own national involvement as more advanced or extensive than it really is. This can occur both in your direct dealings with the funding body, for example when you apply for grants; and more indirectly, in your dealings with the media: differently targeted press releases may perhaps be written for the media of the various participating countries, lending exaggerated prominence to each individual country's own researchers.

In the case of large-scale projects in particular, funding agencies quite justifiably wish to monitor progress. It is therefore important for project managers and participating researchers to develop appropriate ways of keeping them regularly informed. It is particularly important to give ample warning of forthcoming decisions within the project which will have far-reaching financial consequences. The agencies' experts, who will usually have introduced the original proposal to the relevant review panel, are often colleagues of the researchers who make up the project management. They, too, should be kept posted on how the work is progressing. In principle, researchers should show the same openness to non-public commissioning and funding bodies as to public ones.

Of particular interest in this context, of course, are private companies. It is not uncommon for the researchers involved in a project to have partly different motives from the companies that have commissioned and supported it. This is not something that should be denied or hushed up – on the contrary, once again openness is to be recommended. But these differences in motives may very well resurface in new ways, not least when a strategy is to be adopted for the way ahead in the light of results necessitating a reappraisal of the project design. In such circumstances, researchers should make it clear where they stand, and not try to negotiate with hidden agendas.

What would you do in the following situation?

In the course of a research project, you discover that a classic problem of applied psychology, which you and others have long been working on, has in fact been wrongly formulated. With your deeper insight, you now realise that a number of earlier contributions in this field are irrelevant. Certain chemotherapeutic methods which seemed promising will probably not work. On the other hand, completely new possibilities have now opened up, though hardly of a kind that can be turned into commercial therapeutic products in the foreseeable future.

You have an annually renewable contract with a company to develop the originally envisaged chemotherapeutic methods into commercial products. That grant provides funding for a PhD student who needs another three years to complete her doctorate.

How do you act? Does the situation influence your eagerness to publish the new results without delay, results which you are almost certainly the only group in the world to have arrived at?

The biggest collaborative scientific projects are funded by international research organisations. Sweden is often represented on the governing bodies of such organisations by researchers or officials, appointed by central government agencies. It is important that researchers selected for such positions do not simply regard their appointment as a personal distinction, but also see themselves as representatives of the country's research agencies and its research community. This entails, among other things, ensuring that the positions which they adopt on important issues enjoy broad support from the relevant agencies and community, and regularly reporting back to their constituencies on what is happening in the organisations concerned.

5.4 Commercial aspects

A growing proportion of Swedish research is paid for by external funding organisations, some of which provide their support in pursuit of commercial goals. Such research is often directly commissioned by the companies concerned, and to a certain extent they may temporarily reserve an exclusive right to make use of the results by deferring publication. A reason for this is that patent rights must be secured before a decision can be made regarding larger investments in costly, risk-filled development projects. However, this gives rise to problems regarding the openness otherwise practised in international research today.

In terms of the principles involved, these problems are accentuated by the fact that, when all is said and done, central government generally pays part of the bill for such research projects. According to the Swedish Research Council's current rules, an agreement with a commercial actor or other stakeholder may not limit the opportunity to publish the results of research carried out with a grant from the Swedish Research Council. Nor may such an agreement delay publication by more than two months. However, the delay may amount to at most four months if the purpose is to enable a patent application based, wholly or partly, on the research results referred to above. Many public funding bodies have similar rules.

The largest international database for the registration of clinical trials is currently the US-based ClinicalTrials.gov, developed by the National Institutes of Health (NIH) in collaboration with the Food and Drug Administration (FDA). There are rules stating the conditions under which ongoing studies are to be reported to and registered in the database, one reason being to reduce the risk of the unnecessary duplication of work. Many prominent medical journals currently require that a study be registered in a database of ongoing clinical studies for it to be considered for publication.

Matters become especially complicated in projects co-funded by commercial organisations when, as often happens, they involve doctoral students, or assume the form of major international collaborations. A doctoral thesis is fundamentally a public document – the whole point of it is that it should be open to public scrutiny by critics. But if the doctoral student's work has been funded by an industrial company that wishes to use the results in product development and therefore wants to defer publication, problems can arise.

What would you do in the following situation?

A company is funding a series of drug studies. Your research group has been given a large grant for such a study, in which you are comparing the company's products with similar products from other manufacturers, under varying conditions and on different target groups. The company has views on the publication, and tries to influence it so that the studies with the results most positive to the company are published first, the less positive ones much later, and the negative ones not at all. You protest at this.

What action do you take?

When commercial aspects arise in an international project, the diverging regulatory frameworks of different countries can cause particular problems. In Sweden, the "teacher exemption" allows research results arrived at during working hours, for example at a university department, nevertheless to be patented by the individual researcher concerned, resulting in private financial gain. In other countries, such as the United States, patent rights shall instead be assigned (either wholly or partially) to the university where the work was done. The question of ownership of the results of an international collaborative study can be extremely complex, and can easily poison the atmosphere in such a project.

Issues of this kind, including purely practical aspects of how any commercially exploitable results are to be handled, must be discussed in detail by the research groups concerned – preferably before they become a

pressing concern. All participants in the project, and not least any doctoral students involved, should be informed about what rules apply.

5.5 Responsibility for a collaborative project: general

In certain contexts, it is necessary to identify the individual or individuals formally responsible for a joint project. If, for example, use is to be made of a major international research facility, such as CERN or ESO, a *principal investigator* (PI) must be designated. Preferably, this should be the initiator of the project or its administrative leader and coordinator.

A PI also has to be identified in an application for ethics review.

It is important not to fall for the temptation to choose a “high profile” name, if the person concerned cannot take on full responsibility for leading the project. In general, it is also advisable to refrain from naming celebrated researchers as co-applicants, members of reference groups etc., merely to give the project greater credibility. Such individuals can express their favourable opinion of the work in other ways, for instance by writing a letter of support.

As part of a professional evaluation of project proposals, funding bodies will seek to clarify the real management structure of projects and the capabilities of those actively involved in them. It increases credibility if such matters are dealt with openly. When a project involves a large number of researchers at different stages in their careers, large quantities of unique equipment or very substantial funding, competent management and effective administrative arrangements are essential. Many research projects are wanting in precisely these respects, making the research inefficient and completion times unnecessarily unpredictable.

For postgraduate or early-career researchers especially, such a situation creates difficulties. From the point of view of society at large, too, it is obviously unsatisfactory if resources made available are not put to efficient use. The bohemian charm often associated with creative environments does not excuse laid-back or incompetent leadership or careless management of funding. Public agencies and other funding bodies have a right to expect all researchers entrusted with public funds to make sure they are used in the best possible manner. Clearly this applies not least to major projects, where there are resources that can be devoted to this purpose. Resources must also be set aside for documentation.

The special issues of responsibility that can arise in large multinational research projects are discussed in more detail in the next section.

5.6 Issues of responsibility in multinational research projects

5.6.1 Starting points

Issues of responsibility in multicentre and large international projects involving research groups from many different countries create a number of specific problems. There is not much discussion of these issues in literature dealing with research and professional ethics, but they have been addressed in connection with investigations of research misconduct. Who bears the responsibility for inconsistencies, or for intentional or unintentional mistakes made?

The fundamental question is: What responsibility does the coordinating research director (see terminology list below) in international multicentre studies have for what happens in the project, and what is the allocation of responsibility between this person and the local research directors; that is, those in charge of the respective participating research groups?

This question arises due to the current development within research and research funding. Large funding bodies, such as the EU and the ERC (European Research Council) often invest in projects involving the collaboration of many research groups in several different countries. In such cases, it can be practically impossible for the coordinating research director to supervise the activities of all the research groups. A certain degree of conflict can arise between common practice and what is ethically or legally required (see also Section 5.6.3 below).

For clarification purposes, it may help to identify the actors and those affected by these projects, and establish a common terminology to more clearly distinguish between research directors of various types. Besides funders, participants and collaborators in the research project, there are also research directors of various types:

- the local research director or supervisor of a laboratory or research unit (suggested term: *locally responsible investigator/research director*)
- the director of a clinic whose patients are participating in a research project
- the national research director who coordinates activities and reports from several local research groups in the country (suggested term: *national coordinator*)
- the international research director – in EU terminology “the coordinator” (suggested term: *coordinating research director* or *principal investigator*, “PI”)
- the project’s “board of directors”, which the coordinating research director usually chairs.

A reasonable starting point is that each research director is responsible, at his or her individual level, for ensuring that the control mechanisms at this level are actually used. The task of supervision can be delegated to others – and, as regards quality management, is regulated by the EU’s Clinical Trials Directive.

The coordinating research director should be the one who bears the overall responsibility for what happens within the project. This means that he or she is the one responsible for ensuring that everyone is qualified to perform their task, that they receive correct instructions and have had time to absorb them and, when applicable, that they have been able to practice their application.

If a researcher consciously does something wrong, he or she is reproached. However, research directors at various levels can also be reproached, if their instructions have proven to be faulty. This fundamental aspect may need to be nuanced through a distinction between several specified terms of responsibility, types of responsibility (especially moral and legal) and responsibility for different issues.

What would you do in the following situation?

A large multinational research project, partly funded by a medical technology company, is testing a technology this company is marketing and is criticised for this in medical trade journals. It turns out that researchers in different countries have used different methods to round off numbers – in all cases to the benefit of the funding company.

You suspect that someone has made a mistake, possibly unintentional, but perhaps to benefit certain interested parties. Should you report this? To whom? The project employs a considerable number of researchers at your department and has received a great deal of international attention.

What do you do? If your report turns out to be unfounded, the careers of many researchers’ may be damaged. But if you do not report it, you could be contributing to the research being misleading and the medical technology device being used incorrectly and causing harm, or even risking people’s lives.

5.6.2 Conditions of responsibility

What conditions must be met in order for responsibility to arise? This question can have both a descriptive and a normative sense. In the first case, it refers to the conditions that do apply in various contexts, while in the second, it refers to the conditions that should apply – perhaps with reference to the guidelines according to which the research is conducted.

Points of departure for a discussion of this problem include varieties of causal conditions and predictability standards. According to the causal conditions, one of the conditions for responsibility is that the person who is held accountable must be able to influence or prevent things for which he or she is held responsible. Predictability standards refer to the aspect that he or she should be able to predict what might happen.

Causal conditions for responsibility should at times be supplemented with other conditions. In some cases, it is not sufficient that a person is held accountable for something that has happened by means of the fact that he or she has influenced or neglected to influence the events. It is also a requirement that he or she had realised the consequences of these actions. Knowledge and intent clauses can thus sometimes be needed as a complement to causal conditions.

Normative clauses on negligence may also be necessary in such a situation, based on the point that it was actually a person who influenced what happened. Suppose a research director created conditions for misconduct by neglecting to act to prevent it, though he or she neither realised he or she was doing so, nor intended to do it. But he or she should have realised this. In this case, a negligence clause can be cited.

It might be sensible to clarify carefully the responsibility of persons further down in the hierarchy as well. This may encourage openness, which is healthy and contributes to increased clarity and transparency in the research. It can also help to reduce the risk of various forms of power abuse; but to say this is not to suggest that it is necessary to reduce the leadership capacity of international and national research directors.

What would you do in the following situation?

An investigation reveals that a researcher has broken international regulations and thereby proven herself unsuitable to continue as research director and supervisor. However, the vice-chancellor of the university where the researcher works chooses to ignore this, and lets her continue in as research director and supervisor. A number of colleagues who question this are themselves subjected to an investigation and other reprisals. Silence spreads among those working at the university.

What do you do? Do you remain silent and thereby support and defend the vice-chancellor?

Quite a lot of inquiry and legislation work of importance to good research practice is currently in progress. Briefly can be mentioned Ds 2016:46, En ny organisation för etikprövning av forskning ("A new organisation for ethical review of research"). This report presents a proposal for re-organisation that entails the current regional ethics review boards being converted into a single unified public authority, the Ethics Review Authority. According to its directives (Dir 2016:65), the inquiry into the ethics review system shall also carry out a review of the regulatory frameworks for research ethics and the borderline area between clinical research and health and medical care (SOU 2017:50). The research data inquiry (Dir 2016:65) will be analysing the adaptations necessary to the Act concerning the Ethical Review of Research Involving Humans (SFS 2003:460) based on the new EU regulation governing personal data handling.

Of particular importance to the handling of personal data for research purposes is the General Data Protection Regulation adopted by the EU (EU 2016/679), which comes into force on 25 May 2018. In general, this reinforces the protection of integrity via the various requirements set by the Regulation to ensure the personal data handling is legal. It applies to areas such as the obligation to inform, and technical and organisational protective measures, etc. At the same time as the new regulatory framework is comprehensive and complicated, it should be noted that research receives favourable treatment in several different respects, such as the issues of handling sensitive personal data. In addition to the EU General Data Protection Regulation, which will apply with legal force in Sweden, work is in progress on national supplementary legislation, and a further special regulation focusing on the handling of research data. Ultimately, it concerns the requirements set for permitting personal data handling for research purposes.

5.6.3 Moral and legal responsibility

Researchers' moral responsibility is based on more or less general values within our culture. This allows for different interpretations among people with varied backgrounds and experiences. One person's idea of how far-reaching our personal moral responsibility is can be significantly different from another's. In addition to this moral responsibility, a legal responsibility may also sometimes arise or be required.

What rights and obligations do the various actors have, and what does current law have to say on the subject? To answer this question, one has to determine which legislation is applicable and how it should be interpreted. In this context, it is primarily a matter of international and national legislation, for example the EU's Clinical Trials Directive, the Medical Products Act and the Act concerning the Ethical Review of Research Involving Humans. These texts define or specify our legal responsibility – naturally along with other laws that may apply.

Two important paragraphs in the Act concerning the Ethical Review of Research Involving Humans are Sections 11 and 11 a, which state that research may only be approved if it is to be conducted by, or under the supervision of, a researcher who possesses the necessary scientific competence, and that during ethics review of clinical trials on humans of the characteristics of a medication (clinical medical trial), in addition to what follows from this Act, Chapter 7 Sections 6 and 7 of the Medical Products Act (SFS 2015:315) shall apply.

Besides the moral and legal responsibilities, we have discussed thus far, there is a third category, based on 'soft law'. This category includes international guidelines, which are not legally binding, but nonetheless carry moral weight and can be cited in legal contexts (see Chapters 1 and 9). Here, there is significantly less flexibility than in the case of views on one's personal moral responsibility. Important documents in this context

are the Declaration of Helsinki, as well as the research ethical guidelines the ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Beings) and CIOMS (Council for International Organizations of Medical Sciences) have adopted.

5.6.4 The extent of responsibility

In a research project, a distinction can be made between a number of stages, such as planning the research and conducting the project – which includes collecting, interpreting and analysing data – as well as testing or generating hypotheses, publishing the research results and applying them. Collecting and analysing data is different from drawing conclusions based on them, writing a research report or publishing the report.

The coordinating research director has a comprehensive responsibility that covers all these aspects. During the planning phase, this responsibility is obvious. If a research group claims to have equipment or competence it later turns out to lack, it can be reproached both legally and morally. But the coordinating research director is responsible for choosing the research group and ensuring that its members have understood what is required of them. He or she can therefore also not escape reproach (at least morally, and perhaps even legally), if crucial information turns out to be wrong.

For projects that entail research on human embryonic stem cells, for example, the EU requires that information be provided on where the stem cell lines come from, when they were created, etc. It is not reasonable to require that these details or similar information be verified by the coordinating research director; in principle, one must be able to assume that the information provided is correct. However, it can be reasonable to require research directors to choose to work with researchers they know they can depend on – who they have good reason to believe are trustworthy.

The coordinating research director is also responsible for organising meetings with the various research groups within the project on a regular basis, and for ensuring that the groups' work is reported at these meetings, as well as providing the opportunity to discuss how data and results have been obtained, as well as how reliable they are. Alternative interpretations of conclusions and other questions of fact and method should also be addressed in such discussions.

The same applies to the all-important publishing phase. There are a number of international guidelines to follow here, for example the *Vancouver rules*, the *Uniform Requirements*, which are discussed in other parts of this book. The coordinating research director has to ensure that there is agreement on which rules to follow, that they are made known to the research groups working on the project, and that any necessary agreements are established – to prevent future conflict and problems within and between research groups.

If the responsibility for certain issues within a project is delegated, the division of responsibility must be clear, and everyone affected by it needs to understand what they are responsible for. However, such a delegation does not absolve the coordinating research director from ultimate responsibility. He or she must speak up if there are indications that the division of responsibility is not working as intended, and ensure that the shortcomings are corrected.

Within a research group, everyone has a certain degree of responsibility to make sure that certain things happen (or do not happen). Experimental researchers in a group should use logbooks of the same type and use the same principles to record information in them on the experiments they conduct and the data they obtain.

Coordinating research directors at national and international levels are responsible for presenting the potential problems that can arise, and for taking action to hinder or prevent them through clear instructions. A clear division of responsibility is necessary to avoid problems, and preventive work to this end should be encouraged.

What would you do in the following situation?

An investigation reveals that a researcher has in many ways proven himself unsuitable to continue as research director and supervisor. Can he be removed from these positions?

What do you do, if you have the possibility to influence the case? How do you justify your decision? Is there common practice or some rule you believe you can cite?

References

1. Council for International Organizations of Medical Sciences (CIOMS). International ethical guidelines for biomedical research involving human subjects. Geneva, CIOMS, 2002.
2. Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, (Oviedo Convention), European Treaty Series No 164, Strasbourg, 1997.
3. European Code of Conduct for Research Integrity Revised Edition. ALLEA, All European Academies, Berlin 2017
4. Directive 2001/20/EC of 4 April 2001, of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
5. International Committee of Medical Journal Editors (ICMJE). Uniform Requirements for Manuscripts Submitted to Biomedical Journals, (Vancouver Rules), ICMJE, updated 2010.
6. Lag om etikprövning av forskning som avser människor (SFS 2003:460).
7. Läkemedelsverkets föreskrifter om kliniska läkemedelsprövningar på människor (LVFS 2011:19).
8. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). E6(R1): Good clinical practice: consolidated guideline, adopted by CPMP, July 1996, issued as CPMP/ICH/135/95/Step5, Geneva, 1996.
9. World Medical Association. Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, latest revision by the WMA General Assembly, Seoul 2013. Ferney-Voltaire, France, World Medical Association, 2013.

6 PUBLISHING RESEARCH RESULTS

6.1 Why publish?

Researchers are generally considered to have a duty to publish their results. Not withholding their findings from society and other scientists is a fundamental principle, stressed already by Robert Merton (see Chapter 1).

Publication is an integral and essential part of the research endeavour. Researchers must therefore be careful, as discussed earlier (see Chapters 2 and 5), when accepting commissioned work, to make no undertakings to refrain from publishing their results, to restrict their publication or to publish them only if a particular outcome is obtained.

Research results are normally reported in writing, either in book form or as articles in scientific journals. In many fields of research, such as medicine and the natural sciences, it is now common for a doctoral student to present a thesis incorporating a number of such articles. Where this format is chosen, the articles are preceded by an introductory narrative, which provides a background and summary and shows how the articles are related to one another. The individual articles may have several authors, but the introduction should be the work of the doctoral student alone.

In the humanities and social sciences, the monograph – a single, coherent text, written by the doctoral student alone – is currently the normal form of publication used for doctoral theses. After completing their doctorates, too, researchers in these fields often publish their results in book form and as sole authors.

Publication serves several purposes. Only if the results are made public does the research conducted contribute effectively to the dissemination of new knowledge to the wider society. What is more, publication is often essential if others are to build on the researcher's ideas or to develop practical applications. But it is also necessary to enable the scientific community to scrutinise and discuss the results achieved. The report that the researcher presents consequently has to meet a number of quality standards.

In addition, publication serves as an announcement of what the researcher (or group of researchers) concerned has accomplished. The work published is thus of importance when it comes to assessing the worth of a contributing researcher, for example when he or she is applying for a position. The citation of published work nowadays also influences the distribution of governmental research funding to different universities and colleges.

When projects are funded by public agencies, researchers are required to make their results available to others (open access). According to the Swedish Research Council general rules for research grants, a researcher may currently not allow an agreement with a commercial actor or other stakeholder to delay publication of results for more than two months, unless a patent application is planned, in which case publication may be delayed by up to four months.

6.2 Disclosure of financial and scientific dependence

A researcher publishing results must clearly disclose any ties or dependencies that may exist. Details should also be given of any individuals or bodies providing financial support for the work, and if the research is commissioned, the commissioning organisation should be named.

A researcher often builds on other people's results, uses ideas, concepts, theories and methods drawn from their work, or develops his or her arguments in dialogue with others. It is important to describe such relationships too, to make clear what the researcher's (research group's) own contribution is.

6.3 Background, materials and conclusions

When a researcher publishes research results, he or she must fulfil a number of crucial requirements. If these are not met, other researchers will not be able to scrutinise the results, and the research community will not be able to assess the quality of the project or the significance of the results.

An honest and clear account of the background to the study should always be included in the published report, which will involve quoting and referring to relevant earlier publications. Materials and methods must be described with sufficient clarity and detail to allow a reasonably well-informed reader to assess the scientific quality or significance of the results.

Where research is based on empirical data and statistical methods, for example, any dropout and excluded observations must be reported, along with the reasons for the latter. The statistical analysis must be clear and adequate for the method used. Experimental studies must also be presented in such a way that their reproducibility can be tested. The researcher should report all variables and conditions included in the study, and the deliberations carried out in order to determine the sample size. In empirical, non-experimental studies, for instance within the historical disciplines, source material and support for any claims made must be presented. These standards have to be met if it is to be possible for other researchers to check the results and assess the quality of the research and the significance of the results.

It is important that the presentation of the results and conclusions is balanced and fair. When publishing research findings, issues such as the underlying assumptions for the conclusions drawn, the limitations of those conclusions and the area in which they apply, and a discussion of possible objections are crucial quality factors.

Several scientific journals are open to researchers pre-registering their studies. This means that before the study is carried out, the journal approves the background and the question addressed, the design and analysis of the research, and also guarantee publication, whatever the outcome.

Several scientific journals also require that the study plan is registered in a public database before any research subjects are included.

6.4 The third task and the media

According to Chapter 1 Section 2 of the Swedish Higher Education Act (SFS 1992:1434), one of the main tasks of the country's universities is to cooperate with society and inform the general public about research. This usually is called the "third task", and is often achieved through the media.

It is important for researchers to understand that the task of the media is to discover and transmit what goes on, openly or below the surface, or what is under development. An urge to be the first to report things that could challenge the established wisdom and a tendency to stress the dramatic are part of the basic strategy in most media.

Some researchers may be put off by the media and what can be felt to be a blunt and oversimplified way of presenting important research problems, while others may be tempted to succumb to this media pressure and announce results prematurely, or even to exaggerate their importance. Both these extremes can have harmful effects.

The public's trust in research is the very foundation for public funds being used to support research. Therefore, researchers should make it a point of informing the public about new research results, but also of discussing topical scientific issues brought up in the general news flow, and in societal debate. Keeping things secret or remaining silent fosters misunderstanding and suspicion.

However, preliminary and unverified results should not be made public, even if they may make for interesting news. If, at a later date, and on closer scrutiny, the results announced prove incorrect, then misgivings or false hopes will have been raised among the various people directly or indirectly affected by the study, for instance patients or relatives of patients with the disease being studied. Well-founded alerts to newly discovered problems should of course be published as soon as possible, but the researcher must guard against exaggeration, for example by securing independent peer review of the results.

What would you do in the following situation?

In a science programme on the radio, your professor gets his facts wrong, and not for the first time. He expresses himself, with great self-assurance, on matters far beyond his field of expertise. You raise the matter with him (again, not for the first time), but this time he does not simply shrug his shoulders, but tells you to get in touch with the producers to do a piece of your own and "have the fight out in the open". Next term he will be deciding on an extension of your postdoctoral fellowship.

What do you do? Would things be different if he didn't have a say in your situation – or if it was the first time this had happened? Does it depend on what type of issue he talked about?

6.5 Open access

Open access to scientific publications has a number of advantages. For researchers, it is an excellent way of rapidly presenting their findings, and making their texts easily accessible. This makes work available to researchers, whose departments cannot afford to subscribe to scientific journals, and to students and teachers who can use them freely for educational purposes. The more readers a text has, the greater the chance is that it will be of benefit. The OECD, the European Commission and other organisations have stressed that scientific work financed by public funds should also be openly accessible to all. The disadvantage, to the individual author, of the additional costs of making a research article openly accessible must be weighed against the advantage of avoiding expensive subscription fees.

Many actors in Sweden – among them the Swedish Research Council and the Association of Swedish Higher Education – follow the 2003 Berlin Declaration on open access to scientific knowledge. The signatories to this declaration intend to encourage researchers to publish their results on the Internet, to develop methods for safeguarding the quality of online publication, and to work towards open publication being counted as a merit in the evaluation and recruitment of researchers.

Since 2010, researchers granted funding from the Swedish Research Council are obliged to publish their results according to the principle of open access (open access journal, hybrid or self archiving; the concepts are explained in the next section). Research articles lodged shall be made openly accessible within six months. For researchers with grants within educational sciences or humanities and social sciences, open access has to be made available within twelve months. The Swedish Research Council's rules concerning open access currently only apply to scientifically reviewed texts in journals and conference reports, and not monographs or book chapters.

Journals often publish material electronically, but it is important to remember that this does not automatically entail that it becomes openly accessible. In order to publish according to the requirements for open access, there are three options:

- 1) In an open-access journal – these, just like traditional scientific journals, use peer review to assess the quality of the research articles.
- 2) Hybrid publication – the research article is published in a subscription-based journal, which offers the author the choice of open access, against a fee.
- 3) Self archiving – which means that the researcher, in addition to publishing the research article in a subscription based scientific journal, also deposits it at the time of publication in an open repository, and is made openly accessible within six or twelve months.

The legal room surrounding self archiving is dependent on the policy of the journal/publisher. To help researchers in handling rights issues, the EU Commission's framework programme for research and innovation, Horizon 2020, has produced an appendix to the publication agreement. This appendix guarantees that the researcher retains the right to deposit the work in an open archive, and thus make it freely accessible. An accompanying letter that researchers can use in their contacts with publishers has also been produced, see the website sparcopen.org. Despite this, self archiving is regarded as complicated, and for this reason the major journal publishers are offering the option of hybrid publication, which replaces the need for an appendix to the publication agreement and avoids the risk of several different versions of the work being published.

Developments in technology have entailed a fundamental change within the area of scientific publication area. To follow this development, see for example the website kb.se/openaccess, which has information on current developments and a discussion forum. A discussion is also in progress on the existence of a so-called "copyright teacher exemption", which would give the university both the right to use and a certain right to process educational materials.

6.6 Publication as a measure of worth

Since the number of published works play a major role when the merits are compared, for example in recruitment, there is a temptation to break research results down into “smallest publishable units”, to enable a larger number of titles to be presented. Such a proceeding is contrary to good research practice. It makes it more difficult to check the results of the research, with each individual article only providing some of the information that a more comprehensive one could convey.

Research has shown that this can lead to misleading results. Readers could get the wrong impression that results presented in a number of different publications come from different studies, when they were actually obtained in a single study. In overview articles they will then be added up, with misleading consequences.

Generally speaking, a complete presentation of the results should be given, and published reports should not be fragmented in such a way that subsets of results from the same study are presented in different publications. If this nevertheless occurs, there must be clear reasons for it, and cross-references must be given to where other results from the same or very closely related studies are published.

Duplicate publication, i.e. the publishing of articles very similar in content, perhaps with different titles, should also be avoided. If there is good reason to do this, however, for instance when an article is included in an anthology or translated into a more internationally accessible language, it should be stated that it is a case of duplicate publication and a reference to the previous publication should be included.

In peer reviews, it should be the quality of the research that is evaluated. Various publication tricks are easily spotted, with the likely consequence that the author’s credibility is called into question. The number of a researcher’s publications in itself also has no significance in the bibliometric model that is used in the distribution of some governmental funds to universities; instead, it is the number of citations that is decisive. Here, a distinction must of course be made between own citations and citations by other authors. A publication with no citations has no value whatsoever in the bibliometric model.

In summary, a merit list is not necessarily better simply because it contains a large number of publications.

What would you do in the following situation?

For far too long now, in your applications to the research council and at various international conferences, you have been talking about a major work that is soon to be finished, and of which you are rightly proud. Now you are finally going to publish it – and not before time, because you have heard that a group in Hamburg has a similar publication in the pipeline.

Then one of your colleagues discovers an irritating error in one of your computer programs. It is probably of no significance, but it will take at least six months to fully investigate the consequences. If your work is not published before the next application round, or the Germans beat you to it, the livelihoods of a postdoc scholarship holder and a postdoctoral research fellow funded from your council grant will be put in jeopardy.

What do you do?

6.7 The author

The author is responsible for the contents of a book or article presenting his or her research. That includes everything related to the actual project – methods, validity and reliability of the results, etc. – but also the quality of the manuscript. It is also the author’s responsibility to check a journal’s or publisher’s terms regarding parallel publishing before one and the same manuscript is simultaneously submitted to or published in several different journals. Another responsibility is of course to make sure that the references and quotations in the text are correct.

In the case of research based on statistical analysis, a scientific interpretation has to be undertaken, taking careful account of all the basic assumptions and limitations of the procedure used to test the hypothesis. The results also have to be interpreted in the light of previously published findings, and other investigators’ results cited where relevant.

Researchers studying, for example, the links between gender and absence from the workplace, the incidence of crime in different groups in the community, or the economic situation, genetics and dietary habits of

different ethnic groups, must make sure they present their statistical interpretation of the data, in relation to their scientific hypotheses, and explain what that interpretation shows and what underlying assumptions have been made, not least when the results are published outside traditional academic circles. If the author foresees a risk of over-interpretation in the media, he or she has a responsibility to try to preclude or prevent that risk, especially if it might cause harm to the research subjects or any third parties.

A good scientific presentation will include an active discussion of the results by the author. This means that the author should not only cite or refer to works which support the proposition advanced. It is also necessary to present possible arguments against it, and try to respond to them in the text.

6.8 Multiple authors – responsibility – publication rules

Why is the question of authorship important?

One reason is that the authors' names are, rightly or wrongly, seen by colleagues in their field as an indication of the quality of a publication. Consequently, it is important to know who actually did the work, so as to be able to evaluate the results. A second reason is that researchers applying for positions are assessed to a large degree on the basis of their publications. Obviously, therefore, it is important that no one is listed as an author who should not be, and that no one who should be so listed is omitted. A third reason is that it must be apparent who bears the responsibility in the event of an investigation into research misconduct.

Two questions thus need to be asked:

- Who should be designated as the author or authors of an article?
- In what order should multiple authors be listed?

The first question has been discussed at length internationally. An influential group of journal editors decided to attempt to draw up general guidelines on co-authorship. The result was a set of criteria described in the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, the *Vancouver Rules*, mentioned in Chapter 9. An increasing number of influential journals in more and more research areas are adopting these rules, which, among other things, state:

Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.

To be credited as an author according to these criteria, it is not sufficient, for example, to collect patient data or provide a limited input – such contributions can be acknowledged in other ways, for example in notes or a preface. Such an acknowledgement should, however, be approved in advance by the person in question.

An alternative to the approach just described is simply to list everyone who has been involved in the work in some way and to state what they have done, roughly in the manner of the closing credits of a film or television programme. Some journals have moved in this direction as a complementary practice. If the aim is to reduce the number of people listed as authors, the *Uniform Requirements* criteria are to be preferred; but if the goal is a system that reflects what contribution everyone has in fact made, the second approach is better.

As regards the order of authorship, too, practices vary. One common tradition is to list the authors in alphabetical order, unless one of them has had a clearly dominant responsibility for the work presented. If the order is other than alphabetical, the first author will generally have made the most important contribution. Appearing first in the list will then carry most credit (assuming it is a good article). Names that come later in the list will often carry descending credit reflected by their distance from the first name, except for the author listed last, who is often the one who bears overall responsibility.

Some journals allow a statement on a text's title page that all authors have "contributed equally". It should be noted, however, that measures of worth based on bibliometric methods often do not consider the order of the author list; as practices vary depending on research area, this is not possible. Thus, differences between the contributions of the various authors are not taken into account either. If the trend of using bibliometric evaluation systems continues, the order of the author list and different authors' respective contributions will likely become less important.

The basic principles are that every person listed as an author of a scientific text should meet the requirements for inclusion, and that no one who meets these requirements should be excluded.

Another problem can arise when someone makes a significant contribution to the work effort during the research itself, but is not given the option of being included on the author list. It is even more problematic when someone contributes a great deal, not only to the research but also to the writing, and yet is not given the option of approving the final version of the text. This means that he or she does not meet the authorship requirements and can thus, according to the rules, be left off the author list.

Should the principle be that everyone who contributes to the research to any significant degree should also contribute to the writing? This is not a given, but it seems that in most cases the two aspects should go together. If a person is not allowed to be included on the author list due to personal conflict with the research director, this is of course not ethically acceptable. If, on the other hand, it is because his or her contribution is deemed to be too insignificant, and it is a case of one person's word against the other's, it is hard to come up with proof. This again highlights the importance of clear agreements about the conditions for authorship. Such agreements should not be jeopardised by personal conflict; if this happens, it is a violation of good research practice.

What would you do in the following situation?

Prior to a meeting of a PhD examining committee, one of the members discovers that three of the articles making up the thesis have a co-author who died three and a half years ago. The articles concerned were published this year, or have recently been submitted. In other words, the author in question had been dead for at least two years before the papers were completed. The data were collected around five years ago, however.

Thus, the person concerned may have had a hand in planning the project and collecting the data, but hardly in their analysis and interpretation. Still less could this co-author have been in a position to influence the drafting of the articles, to have accepted the contents or the final versions of the articles.

Is it right for the deceased researcher to be listed as a co-author? What arguments could be advanced for and against his inclusion? What course of action could have been chosen instead?

6.9 The responsible publisher and the editor

The responsible publisher of a scholarly journal has a responsibility to ensure that existing rules in the area of research ethics and current legislation relating to research are followed. Leading international journals now insist on review of a project by an ethics committee or the equivalent as a condition for publishing the results. This is something that every scientific journal in a field involving research on humans or animal experimentation should require (see Chapter 3).

The editor of a journal has the overall responsibility for its scientific quality. That means, among other things, that he or she should request clarifications of methods, results or interpretations, for example, if they seem unclear. Alongside the author, who obviously has the main responsibility, the editor is also responsible for making sure a published article provides accurate references to relevant earlier research, and that the choice of references is not improperly influenced by rivalry or a conflict of interest. The editor should also provide space in the journal for debate about published manuscripts.

Researchers have found that it can be difficult to get negative results published. But what constitutes a negative result depends on how the hypothesis is framed. The editor should ensure that it is also possible to publish articles showing that a certain hypothesis does not have scientific support. If the hypothesis is one that is currently under debate, then such negative findings are important and space should be made available for them.

What would you do in the following situation?

As a journal editor, you have received a manuscript from a very well-known, older researcher. You see that he has published over 50 articles in your journal, long before you became its editor, and that many of them are now classics.

But his new article seems to be mostly a rehash of old material, and is also quite poorly structured. The referee recommends rejection. You are considering giving him special treatment by going through his paper carefully and suggesting a number of specific changes.

Would you do this?

References

1. Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities. Berlin, 2003, <https://openaccess.mpg.de/Berlin-Declaration>.
2. Helgesson, Gert & Eriksson, Stefan, Publiceringsetik. Studentlitteratur, 2013.
3. Horizon 2020, http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-pilot-guide_en.pdf
4. Högskolelag (SFS 1992:1434).
5. International Committee of Medical Journal Editors (ICMJE), Uniform Requirements for Manuscripts Submitted to Biomedical Journals, (Vancouver Rules), ICMJE, updated 2010.
6. Organisation for Economic Co-operation and Development (OECD). OECD Principles and Guidelines for Access to Research Data from Public Funding. Paris, OECD, 2007.

7 OTHER ROLES OF THE RESEARCHER

The requirements on quality and integrity are also relevant to discuss in connection with tasks associated with the researcher role. This relates to the roles of supervisor, teacher, expert and reviewer.

7.1 The supervisor and postgraduate supervision

7.1.1 The tasks of the supervisor

There are many ways of being a good supervisor. In general, someone who is appointed as a supervisor has a responsibility to create conditions that will help to develop the doctoral student's knowledge and skills. Through discussions, teaching and their own example, good supervisors transfer knowledge, skills and experience to their doctoral students, and guide the research which they are undertaking.

One important task is to work with the research student to define a suitable thesis project, and to draw up an individual plan of study consistent with the general guidelines laid down by the faculty and the department. The extent to which doctoral students are able to choose and shape their research topics can vary, however. In some research areas, research students will often be offered a place in an existing project group, where the problems to be investigated will already essentially have been formulated, whereas in other areas they will have more opportunity to influence their research tasks. It is therefore important for the supervisor to discuss the basic prerequisites for the research work with the doctoral student before a topic is chosen. Where more than one supervisor is appointed, the different supervisors' functions and relationships to the research student should be clearly defined from the outset.

In the supervision, the supervisor serves as a support, a contributor of ideas, a critic and a discussion partner. The supervisor is the person the doctoral student can test his or her ideas on, the person who provides encouragement, but also the person who reads with a critical eye the texts that the student produces. The supervisor has to give opinions on methodology issues, as well as on questions of interpretation and results, and thus acts as both adviser and critic. The role of constructive critic is both important and difficult. Criticism on a scientific point must not be withheld out of a misguided concern not to hurt feelings; the consequences for the doctoral student at a later stage could be devastating.

Although supervisor and doctoral student often work very closely together and it is natural for them to see each other as friends, it is important that the professional relationship takes precedence. The supervisor has a responsibility to ensure that no circumstances arise that could jeopardise this relationship. If this happens, the supervisor may have to hand over the task to someone else.

7.1.2 Whose ideas?

In discussions between the supervisor and doctoral student, different arguments and approaches are tested, and views and ideas exchanged. Sometimes it is also important in such discussions to consider how justice can best be done to the contributor's input as the work continues and the results are published. In the thesis, the doctoral student should account for any contributions by others, including his or her supervisor.

But it is also important that, if the supervisor uses or develops ideas originating from the student, this is done in consultation with the student and no attempt is made to conceal their origins. Ideas that the supervisor suggests to the doctoral student for further investigation, however, do not thereby become the latter's property. The supervisor, too, must be able to continue to work on these ideas in his or her own research without jeopardising the student's research work.

7.1.3 The thesis and its presentation

The ultimate goal of the doctoral student's research is to produce knowledge, formulated in a scholarly dissertation and reviewed at presentation. The supervisor decides, in consultation with the student and the examiner, when the work can be considered complete and its public defence arranged. A host of different factors will be considered in reaching this decision, including purely financial considerations, the future prospects of the student, undertakings regarding completion time, and the personal wishes of the student.

But the supervisor's personal wishes, for example to see a postgraduate gain his or her doctorate as soon as possible, can also figure. The primary considerations in this context, however, must be the student and the research programme undertaken. It is unethical to force the pace of completion, for example to collect "PhD points" for the department.

7.1.4 Responsibility for ethical and legal compliance

Ethical and legal rules vary depending on the kind of research being conducted. As the leader of the specific research project on which the doctoral student is working, the supervisor is responsible for ensuring that the necessary approvals have been obtained and that the project complies with the ethical standards relevant to the type of research involved.

He or she must consequently keep abreast of the basic documents setting out the fundamental rules and guidelines for research ethics that may be topical. The supervisor should discuss the relevant documents with the doctoral student, and try to create an awareness of what their application entails in specific situations and, in particular, in the student's own research. Examples of documents that apply in various situations are discussed in Chapter 9.

Since the responsibility for the ethical aspects of the doctoral student's project rests with the supervisor, it is the supervisor who has to ensure, for instance, that experiments in medical research are terminated if patients or healthy subjects suffer unexpected harm. The same applies if the ratio of risk to benefit is not consistent with the risk-benefit assessment arrived at when the research was planned and approved by the regional ethics review board, or if other undesirable complications are reported.

7.2 The teacher

A role often combined with academic research is that of teaching. The role of teacher carries special responsibilities, towards the students and towards the department offering the courses. An academic teacher may be obliged to teach on a broad spectrum of courses.

Students have a right to set high standards for their teachers to be competent and to stay informed on developments within their field. To uphold good quality, a teacher must not only maintain his or her knowledge and skills, but also seek to broaden them. Teaching staff should not – at least not without declaring their limitations – address problems in their lectures and classes which do not fall within their field of expertise. Basically, these standards are no different from those placed on many other occupations. For instance, who wants to see a doctor or hire a computer consultant who hasn't kept up with current developments since graduation?

It is important to be aware that the teacher is in a position of power in relation to the students; a position which must not be abused. Certain departments and other course providers have special ethical rules for teachers. In addition, the Swedish Association of University Teachers (SULF) has adopted ethical guidelines for university teaching staff (*Etiska riktlinjer för universitetslärare*, 2005). Those working as teachers should be familiar with and seek to comply with such documents.

7.3 Assessing applications and proposals

Researchers are frequently called upon to review colleagues' research proposals or to act as external assessors in conjunction with appointments. It is important in such contexts to decline invitations to provide an assessment when a conflict of interest might arise. It is sufficient that a circumstance exists that, seen from outside, *may* reduce the confidence that the researchers will make an objective assessment. If you are uncertain whether a conflict exists, you should disclose this to the party requesting your participation. Provisions relating to conflict of interest are included in the Administrative Procedure Act (for national public authorities) and in the Local Government Act (for municipalities). To help in the interpretation of conflict of interest rules in research funding, the Swedish Research Council has produced a policy on conflicts of interest (2014).

It is also important to base assessments of this nature on an objective and careful analysis of the documents and qualifications presented, and to maintain a critical stance towards unfounded claims and opinions aired by others. It should go without saying that the analysis in any assessment should be well founded.

7.4 Reviewing manuscripts for publication

Another situation where ethics may be tested is when a researcher reviews an article or a larger manuscript submitted to a journal or publishers for publication. It is very common in the academic world for a researcher's work to be assessed by his or her colleagues. Since such assessments presuppose expert knowledge in the field concerned, there are few alternatives to this system, which is generally referred to as "peer review". Thus, clear rules to counteract various types of conflict of interest are crucial.

One reason the system has been challenged is a number of flagrant cases of peer reviewers abusing the trust which being given access to a colleague's work to assess it entails. Such abuses have included reviewers stealing ideas from submitted manuscripts (this is addressed in Chapter 8), "sitting on" manuscripts for a long time to enable researchers in their own groups to publish their results first, or trying without just cause to prevent the publication of colleagues' work.

Often, the journal reviewers know the identity of the authors, while the authors do not know the identity of the reviewers. Temptations to abuse the system in conjunction with such tasks could be reduced if the system was either entirely open, or else double-blind.

Another important reason why the peer review system has been questioned is that the volume of manuscripts submitted to journals is now so great that it can be difficult to find willing and competent reviewers. There is good reason to consider awarding greater merit than is given today for the arduous work of reviewing texts (not only when it comes to journal publication, but also in advisory groups and in the case of thesis defence and the awarding of positions).

For the system of peer review to continue working, as referred to above, at least three criteria must be met: reviewers must submit their reports as quickly as possible, they must not use information in the manuscript for their own purposes without referring to the source – and if they do wish to use it, they must first contact the author and ask whether he or she has any objection – and they must be guided only by objective reasons in deciding whether or not to recommend publication.

The system of peer review is used also in other contexts, such as when awarding positions and allocating grants.

What would you do in the following situation?

You are reviewing an article and discover that the authors have made a major issue of a discovery that you yourself made 20 years ago, but never wrote clearly about at the time – only a parenthesis buried in a long article. Now they are claiming credit for the discovery. However, you currently have an article of your own at the proof stage, and are now considering adding a section about your old discovery to underline your ownership of it.

Would it be right to do so?

7.5 Committee work

Researchers may also be appointed to serve on various committees or boards. It is perhaps appropriate to distinguish between memberships related to research councils, research foundations and the like, and those of a more commercial nature, such as a position on the board of directors of a company.

Researchers serving on committees and boards within the research community are subject to very similar ethical standards to those acting as reviewers or external assessors. They are all involved in decisions and appraisals concerning other people's research. To maintain the research community's confidence in these decisions and appraisals, it is particularly important that committee members make every effort to be independent of their own research community and affiliations, to avoid showing special favour to their own discipline, university or department, colleagues or students. In practice, this can be very difficult, not least because they may be seen by their close colleagues in the research community as "the representative of their discipline" on the body concerned. The research community needs to have an open discussion about what membership of a given committee or board entails; that the member represents the entire research community if no other terms have been specified. Appointments to committees of this kind are to be regarded as positions of trust. When the members of a decision-making committee with a research council is involved in making a decision, their decision-making must comply with the rules that apply for such decisions, such as the

Administrative Procedures Act, the Government Agencies Ordinance and the Government's Instruction to the research council.

As a member of a board or committee outside the research community, it is important to realise that, whether you like it or not, in this context it is in fact the research community you are representing. You will usually have been appointed because you represent a certain desired area of expertise. Consequently, here too the researcher has a special responsibility. Your membership should not result in you lending scientific legitimacy to a company's operations or production, for example, when the scientific evidence is in fact unclear or points in the opposite direction. Your task, rather, is to communicate the results and possibilities of research, without exaggerating, diminishing or concealing.

References

1. Vetenskapsrådet, Jävspolicy för Vetenskapsrådet, 2014.
2. Sveriges universitetslärarförbund (SULF), *Etiska riktlinjer för universitetslärare*, 2005.
3. Livsmedelsverket, Läkemedelsförmånsnämnden, Läkemedelsverket, Statens beredning för medicinsk utvärdering, Smittskyddsinstitutet, Socialstyrelsen och Statens folkhälsoinstitut, Hantering av jäv, intressekonflikter och bindningar när externa experter anlitas, 2008.

8 RESEARCH MISCONDUCT

8.1 Introduction

The occurrence of research (or scientific) misconduct undermines *confidence* in published scientific results, in the research community as well as in society at large. It also risks eroding the trust between researchers, providers of funding and the people who participate in research, for example as subjects.

In many types of research, there is another angle as well. Research findings are used to make choices in the treatment of patients, to select construction methods for tunnels, bridges or aircraft, as an input into the planning of health care, social work, road safety or education. If those findings are based on research misconduct, people could suffer *harm* as a result of poorer treatment, collapsing bridges and tunnels, and incompetent planning.

Research misconduct also has negative consequences on the academic merit system. A researcher who presents falsified merits, for example producing work containing undetected elements of plagiarism, or through another form of misconduct, can cause other applicants to be passed over. Misconduct thus causes *injustice* in the research community, often resulting in lower quality research when a fraudulent researcher is chosen over better ones.

If research misconduct occurred on a regular basis, researchers' trust in the merit system would also diminish and become completely useless for determining who is most competent. It is also likely that researchers, knowing or having the impression that others do not take good research practice seriously, can themselves be tempted to turn to such methods. The toleration of plagiarism and other types of misconduct would be devastating to research in the long run.

It is difficult to say how common research misconduct is; the answer depends, of course, on how it is defined. There are no large, thorough studies on the subject, although some statistics and interesting yet limited studies can be found. However, these are based on somewhat different definitions of misconduct. At any rate, few reports of suspicion result in action being taken, for instance the retraction of journal articles. In the USA during the period 1994-2006, the *Office of Research Integrity* received a total of 3,571 reports. Misconduct – there, defined as fabrication, falsification or plagiarism – was demonstrated in only 165 of these cases (Office of Research Integrity, ORI, Annual Report 2007).

Various surveys indicate, however, that the number of cases reported are just the tip of an iceberg. In a study from 2007, for example, 18 per cent of participating US research project leaders (a total of 1,645 individuals) said that they had had direct experience of misconduct in the latest year (Pryor et al. 2007). In another study, 20 per cent of practicing researchers who were asked answered that they had consciously changed the design, method or results of a project when pressed to do so by their funding body (de Vries et al. 2006, "Normal Misbehavior: Scientists talk about the ethics of research"). What has also become evident is that there is a widespread *perception* in the research community that others are acting dishonestly, or bending the rules (de Vries et al. 2006, "Scientists' Perceptions of organizational justice and self-reported misbehaviors").

What would you do in the following situation?

A doctor carried out a study to establish whether high-dose chemotherapy followed by bone marrow transplantation could improve the survival rate of a certain group of patients with breast cancer. The results were questioned, however, and the doctor was unable to produce the patient records and source data to confirm them. Other researchers then tried to repeat the results, without success. It is one person's word against another's, but primary data that could clear the doctor's name are not available.

What should the next step be? Who should do what?

8.2 Questions of definition and scope

What is research misconduct? It can be defined in several ways. In a narrow sense, it refers to obvious violations involving the theft of other people's ideas and data, manipulation (or falsification) of data, and plagiarism of other people's texts. In a wider sense, it also includes other forms of reprehensible behaviour, such as dishonesty towards funding bodies, exaggeration of one's qualifications in applications, publication of

the same study in multiple contexts, sexual harassment, defamation of colleagues, sabotage of colleagues' work and so on.

The choice between wide and narrow definitions is not only a matter of linguistic usage. It also has consequences, for example, when it comes to applying rules on sanctions for research misconduct. With a narrow definition, only certain phenomena can be acted on; with a wider one, others can as well. The requirements of due process suggest that we should concentrate on central, reasonably well-defined transgressions such as plagiarism, fraud (falsification, invented data) and manipulation of data, and deal with other forms of inappropriate behaviour in other contexts and under other headings.

Another problem that is not always easy to handle is how to distinguish between intentional fraudulent behaviour on the one hand, and carelessness, rushed work and incompetence on the other. Research misconduct can be intentional behaviour, or as something that can also be perceived as being independent of the researcher's intention, that is to say something that can be established without any need to speculate on whether the author intended to deceive.

The definition of research misconduct used by the Swedish Research Council was formulated by Birgitta Forsman (2007), and uses the current terminology of the scientific community. It states that

Research misconduct entails actions or omissions in research, which – consciously or through carelessness – lead to falsified or manipulated results or give misleading information about someone's contribution to the research.

This definition thus limits itself to the narrower concept of research misconduct, in which it directly concerns the scientific work. Sexual harassment, defamation of colleagues and the like are not included here, even though they are unethical in other ways. The reference to “consciously or through carelessness” means that the definition not only encompasses fraud, the fabrication of data and plagiarism – that is, actions we regard as evidence of an intention to deceive; it also encompasses actions such as iterated carelessness, for example when a researcher would have been immediately able to realise that the results were distorted, or when his or her own contribution is described incorrectly.

In order to enable a nuanced description of the situation, to avoid the juridification of research ethics and avoid one person's word standing against another's – and to avoid the matter therefore being dismissed due to lack of evidence – a proposal has been made to differentiate between parallel and disjunctive definitions. For parallel definitions, two main questions are asked: Has the author diverged from good research practice? Has the author intended to deceive or mislead his or her readers? One may exist without the other, and each of the two questions can be answered with “yes”, “no” or “unclear”. If the answers are combined, a more nuanced picture of the situation is obtained in each individual case.

8.3 Fabrication and falsification

The most obvious case of research fraud would be a researcher simply fabricating data or results – making them up – and then representing them as genuine. Falsification, however, is a more multifaceted phenomenon. The concept comprises all the possible ways of manipulating the research process, equipment, material or data that make it impossible to present a research project in a trustworthy way. The same can happen if certain data or experiments are left out of the report. It is also possible to manipulate the research report itself, for instance through changing diagrams and other pictures. New technology has made manipulation increasingly easier.

Another issue that has been discussed at length is whether “outliers” (notable individual deviations from the other results) should be included in the statistics the researcher presents, and when it can be justified to call them anomalies or mistakes, and therefore exclude them from the report.

Manipulation of research – as opposed to cases of fabrication – can be the unintentional result of carelessness or ignorance, and it can be difficult to determine whether intentional misconduct has occurred. This further supports the need for the concept of research misconduct to encompass both intentional and unintentional behaviour.

8.4 Plagiarism

Plagiarism is the form of scientific misconduct that, in the experience of the Swedish Research Council's expert group on ethics, seems to be the most common. In the definition of scientific misconduct discussed above, it is the final mention of "misleading information about someone's contribution to the research" that especially refers to plagiarism. The term plagiarism concerns a researcher presenting text excerpts, ideas, data, results, etc. in such a way that they appear to be his or her own, when they have in fact been created by someone else. Doing this is a form of lying, and in many cases is also considered theft. A definition of plagiarism can thus be formulated as follows:

Plagiarism in research entails a researcher using material (texts, ideas, hypotheses, "designs", methods, data, results or conclusions) – consciously or through carelessness – in such a way that it presents a misleading picture of the researcher's contribution to the project at hand.

Thus, plagiarism can concern various aspects of research and its contents, and is not limited to the copying of text. Normally, it is a case of a researcher (or a research group) plagiarising someone else; but, according to the definition, it can also happen that a researcher uses his or her own material in a misleading way.

It is not until stolen material is presented by a researcher as his or her own that it is a matter of plagiarism. If a researcher steals data from another researcher and then publishes them as his or her own, it is not the theft of the data that makes it plagiarism but rather the fact that the researcher, through publication, has claimed that they are his or her own product. Stealing someone's data is of course unethical and a violation of good scientific practice, but plagiarism doesn't come into the picture until these data are presented in a way that hides their origin. Thus, a researcher's presentation in an article, report or conference paper, for instance, is especially interesting when questions of plagiarism arise.

Research often involves the researcher building further on the results, ideas and methods of others. The researcher bases his or her work on knowledge that already exists and uses available data – his or her own or others – and borrows useful concepts and theories, or looks at them with a critical eye. Therefore, it is crucial that the researcher clarifies who has done what. See also the discussion of Merton's CUDOS norms in Chapter 1.

Publication should also not be delayed. As the researcher has no control over the material after publication, it is important that its origin is still made known. It is important to have one's contribution acknowledged, not only for a researcher personally, but also for the research community, and to ensure the academic merit system continues to work.

A published line of reasoning, a certain formulation of words, etc. is regarded as the author's own if nothing else is specified. Therefore, an author who uses material from other authors must make the reader aware that the idea or formulation is not his or her own. Avoiding plagiarism is normally very simple. In general, a person using another author's data, methods, ideas or formulations should state the author and usually also the printed source, if a specific text is used.

Good conduct in this area dictates that the following basic principles be observed: When using other authors' texts, be it in the form of paraphrase, summary, reference or quotation, one should always name the author and refer to the original text. In the case of a quotation, a detailed source reference must be included, and the quotation must be presented as such through the use of quotation marks, indentation or the like. When a researcher uses the ideas, hypotheses, distinctions, concepts, etc. of others, it usually suffices to state from whom the material has been borrowed to avoid accusations of plagiarism. But, if it is crucial to the context, its origin should also be supplied. This can apply to a conversation, presentation, article, book, etc.

However, there are ideas – theories, methods, concepts – that are so widely known that mentioning them hardly runs a risk of creating misunderstanding. In such cases, it is not necessary to point out that they are not an author's own material. Sometimes it is no longer known who coined an expression, for instance; thus, using the formulation does not risk misleading the reader. Using such a formulation cannot mislead the reader in this case. Additionally, it is common practice within a number of subject areas to use standardised formulations in a text's method section, and this is done without the use of quotation marks. Different opinions can be expressed on this practice, but the main point is that this is such a well-known approach that no one draws benefit from it, and no one is misled.

8.5 Unpublished material and self-plagiarism

In the research community, researchers partake of others' results and ideas in various ways. Publication means that a text is available to the general public and can thus be used legitimately by others. However, a researcher may also have access to material before its publication, for instance through lectures, presentations, congresses and other meetings, or in conversations with other researchers. Before a researcher uses someone else's material that was accessed in such a way, he or she should think about the situation in which access was provided.

As a guideline, one can say that lectures given at major conferences, or by established researchers, can be regarded as published, and that their content may be used in accordance with the rules presented above. However, one should be more careful with presentations or lectures at small conferences, seminars and the like, as well as lectures given by doctoral students. Doctoral students often talk about their own projects, which are as yet not completed, and normally participate in conferences to get feedback to improve their ongoing work. It is not a given that such a lecture should be regarded as a publication – often, it should not. To avoid causing any harm to the doctoral student, interested parties should contact him or her directly and ask whether specific ideas or other aspects of the lecture may be used, naturally citing the source, or if this should wait until the material has been published in a journal or in connection with the student's thesis defence.

If someone has access to material in the role of external assessor, for example reviewing a manuscript for possible publication in a journal, or as a member of an examining committee or a faculty opponent, this material should be considered confidential until it has been published. Using parts or ideas from it or publishing it without supplying the source is not only plagiarism, but also theft of material, and places the entire evaluation system at risk.

It is very common for a researcher to refer to his or her earlier results or mention problems previously dealt with. If the purpose is to confirm or repeat previous results, the earlier account should be presented to the reader. It also happens that researchers want to reuse earlier formulations. Nothing prevents this, but it is actually a quotation from the researcher's previous work and should be presented as such. It is also completely acceptable to use complete sections of text, for instance a whole chapter from a book, as long as the researcher states that that text has appeared in an earlier context. This can easily be done in a preface or a note in the chapter itself. Neglecting to take these precautions is called self-plagiarism. There is currently a debate in the scientific community concerning whether this concept is accurate, or if it should instead be called double publication (see also Chapter 6). At any rate, it is a violation of good publication practice.

8.6 Establishing plagiarism

How, then, can it be established that plagiarism has been committed? First of all, a very clear congruence between the work in question and the suspected source must exist. In texts, this can be a congruence between formulations, perhaps even partly verbatim congruence. It can also be a case of detailed agreement when it comes to arrangement, structure, terminology or concept formation. In certain types of texts, formulation congruence can now be established using the Internet or databases created for this purpose. Here, however, one should beware of false congruence. There are only so many ways to express something, and some degree of phrasing congruence can nearly always be found.

As regards plagiarism of ideas, the congruence should not only exist in the actual content of the idea but also in the argument for it. However, considerations of similarities between a work and a suspected source can never serve as the sole evidence of plagiarism; even extensive congruence can be coincidental. It can be natural to present certain premises within a given field, and it can happen that two researchers do so independently of each other. The history of science provides many examples of the "same" discovery being made by different researchers at approximately the same time, without their having had anything to do with each other, and with no possibility of plagiarism.

Therefore, it is necessary to evaluate how likely it is that the suspected source actually is a source. An assessment must be made of whether it could have been available at all to the accused researcher, as well as of how likely it is that he or she in that case would have known of it, and had access to it. For instance, is there anything that suggests the researcher might have owned, read or spoken of the suspected source? Was the source published in a journal that those in the researcher's field usually read? Plagiarism of an idea can possibly be established if there is a high probability of determining that the source was available to the researcher, and if there is a great deal of congruence between a text and a suspected source. In an actual investigation, it is

naturally important to consider the researcher's own explanation for the similarities, and of his or her relationship to the suspected source.

What would you do in the following situation?

A doctoral student, Eric, sends his thesis to fellow postgraduate Nicole at another university to get her feedback. They work in the same field and have previously met at a seminar, at which they got on well. Nicole uses some of the data and ideas from Eric's work in her own thesis, which she presents before Eric completes his. Eric is accused of plagiarism.

What should the doctoral students, their supervisors, heads of department, vice-chancellors and their colleagues do?

8.7 Prevention

Researchers operate in a highly competitive environment. Publications are the most essential merit for applicants to university positions – there is often talk of a “publish or perish” culture. This can tempt researchers to strive for quantity rather than quality; and the same applies in the system of research funding.

If the results of a US study can be applied to a Swedish context, there is mistrust of the career system among researchers in Sweden as well. In the US study, nearly four of five researchers asked felt that the most successful members of their field had achieved their positions by successfully “working the system” (de Vries et al. 2006, Normal Misbehavior...).

What can or should be done to counteract and prevent research misconduct? The discussion above suggests a number of possible long-term changes. But right now, there is a need to address research misconduct within the merit and career systems in place today. The most crucial issue is to work to create a good research environment, characterised by a culture that does not tolerate research misconduct and that nurtures good practice. The individual researcher, as well as department and faculty heads, can contribute to creating such an environment (see ALLEAS's European Code of Conduct for Research Integrity Revised Edition).

A university's vice-chancellor has a special responsibility to ensure that ethics awareness is kept at a high level amongst its researchers. According to Chapter 1 Section 16 of the Higher Education Ordinance (SFS 1993:100), a university, which through a report or in some other way is made aware of suspicions of misconduct in research, artistic work or other development work at the university, must investigate these suspicions. The vice-chancellor is ultimately responsible for all activities at a higher education institution, and is thereby also ultimately responsible for investigating suspicions of misconduct. The equivalent applies to research conducted outside universities, for instance at a county council or an independent research institute, or within industry. Here too, the person who is ultimately responsible for the organisation's activities has a special responsibility to see to it that a high level of research ethics is maintained.

A good research environment is open to and encourages the discussion of issues around good research practice. Cases of misconduct that are revealed nationally or internationally can be followed and discussed. How could the misconduct have been prevented or discovered sooner? The supervisor is responsible for ensuring that the young researcher is familiar with correct practice, and has thought about what this means in his or her own work. The supervisor should also serve as a good example of how to behave.

Recurring discussions and information at a department are a way of creating and maintaining good research ethics. For doctoral students, the supervisor's input can be supplemented with classes in research ethics and professional ethics that address issues of research misconduct in its various forms. Already during undergraduate studies, issues of at least plagiarism should be brought up, as these problems already exist at this level, for instance in connection with students' essay work.

In addition to preventive work and creating a good environment, something else that can discourage research misconduct is research colleagues taking a clear stand against it. A researcher who might be tempted to plagiarise or cheat in some other way can return to the right path if he or she knows that the risk of being discovered is great. An environment where researchers' work is normally open, allowing everyone to know what their colleagues are doing, how their work is progressing, how their texts look while under production, etc. offers fewer opportunities for misconduct than one where everyone works in isolation without any exchange of ideas or texts. Thus, active work with seminars at department level can be a way of reinforcing research ethics. If I am aware that my colleagues want to know something about my research, material, texts –

i.e., how the work on my research project is progressing – this in itself will be an inhibiting factor if I were ever tempted to cheat.

A great deal of cheating is revealed by chance. Perhaps it is a matter of an experiment that cannot be repeated, or a test that cannot possibly have been conducted as described. Values or data can seem too perfect. Research subjects cannot have been available in the way stated. It may also be a case of undergraduates, postgraduate students or researchers simply happening to read an article or a presentation, where they recognise their own (or others') ideas, results or formulations. Plagiarism can be discovered by colleagues, who may be surprised when a researcher publishes something in an area or about an issue they didn't know he or she was working with, even though they belong to the same department or work closely in some other way. It has also happened that faculty opponents, in preparation for an upcoming thesis defence, have found that large parts of the thesis text have been taken from others' work. Others who may discover research misconduct in similar ways include reviewers at journals and experts working with applications for positions in academia.

8.8 Sanctions for misconduct

An accusation of research misconduct is very serious and can have grave consequences for the researcher. It is therefore a delicate task to take a stand and state that something has come about through research misconduct. Many components must be investigated and clarified.

If it is established that misconduct has occurred, it is important that this is made known: that it has happened, how it happened and where it happened. Going public with established cases of misconduct is also a crucial discouraging factor. Departments and other research environments do not want to be associated with such cases any more than researchers themselves or research principals do.

It is also important that established misconduct be followed by sanctions, to mark that a violation of research ethics is a serious matter. If it is discovered, for instance, that someone has committed plagiarism and nothing happens, it can be interpreted that plagiarism is not a particularly serious offence. There are labour law measures that employers can take in the event of established misconduct.

Research misconduct shall simply not occur in research. As part of this effort, the Swedish Research Council wants to stimulate departments, higher education institutions and universities to develop into such excellent environments as described above. The Swedish Research Council is government agency that awards grants to research following careful quality control. Payment of a grant may be stopped if any misconduct is established.

What would you do in the following situation?

You discover that one of your older colleagues in the department has falsified a series of measurements in a minor publication, with no very sensational results. He is close to retirement. When you raise the matter with him, he breaks down crying and blames the head of department's demand for "at least one paper a year". If he fails to meet that target, he will not get a share of the "special research resource" and will have to teach 400 hours a year. The man is in poor health and has no great talent for teaching.

What do you do?

8.9 Addressing issues of misconduct

According to the Higher Education Ordinance (SFS 1993:100), it is mandatory for universities and higher education institutions to investigate any suspected research misconduct. No equivalent requirement exists for research conducted outside academia. The Ordinance does not, however, regulate how investigations should be conducted; this is up to each higher education institution.

It is common practice that suspicions of research misconduct are reported to the organisation – the department, university, etc. – where the suspected researcher works. For instance, if someone discovers that a colleague has committed plagiarism, this person must report this to the department head or the dean of the university, who should in turn report this to the vice-chancellor. The vice-chancellor is under obligation to process the report and ensure that the case is investigated, and, if the accused researcher is found guilty of research misconduct, determine the labour law sanctions to be imposed. It is thus primarily the learning institution itself that investigates and decides on the case.

However, the vice-chancellor does have the possibility to get an external statement. Since 1 January 2010, the CEPN has had an expert group on research misconduct, which on request can provide assistance in these matters. The group is completely independent, with no ties to universities or other research institutions. This ensures an impartial evaluation; something that is sometimes called into question when a university investigates an internal matter itself.

The individual – either the person who submitted the report or the reported person – can also submit a request to the vice-chancellor that the expert group handle the investigation. If the person who reported the suspicion of misconduct, or the person suspected of misconduct so request, the university shall obtain such a statement. However, no statement needs to be obtained if the university decides it is clearly unnecessary. The expert group thus investigates whether research misconduct has been committed, or not. The CEPN does not suggest consequences, however; this is the responsibility of the vice-chancellor as the employer.

When misconduct has been established in connection with a journal article, good practice dictates that this should be brought to the attention of the journal's editor. The journal should then publicise the situation in a prominent place and state its regrets and an apology for the publication. The article shall then also be retracted.

There are some international guidelines for how accusations of misconduct should be handled. For example, the *Office of Research Integrity*, mentioned earlier, has drawn up a set (ORI 2009). Also in 2009, the OECD presented a practical guide for how to go about in the case of international collaboration projects. The OECD guide stresses the importance of those involved establishing, in a formal document produced before the research starts the rules and procedures to be followed in the case of accusations of fraud, or if fraud is actually found. Specific individuals should be assigned the responsibility of putting these formalised rules into practice. It also provides a template for such a document. In the case of accusations of misconduct, investigations should be conducted fairly and confidentially, and with integrity.

It has happened that researchers have deliberately and wrongly accused colleagues of misconduct. This is, of course, unethical.

8.10 A broader perspective

The focus of what could be called the “classic definitions” of scientific misconduct is on deliberate fraud, fabrication of data and plagiarism, but as mentioned above, the concept of negligence broadens the definition.

This book was revised in 2011, and during the five years that have passed since then, a tendency can be noticed of the previously narrow definitions becoming ever broader. Specific concepts, such as fraud, fabrication and misconduct are still central, but the research and research ethics discourse on what is good practice has become considerably more general. This has both advantages and disadvantages, of course.

In the European Code of Conduct for Research Integrity, the All European Academies (ALLEA) has chosen for good reasons to take the broader view. This code was revised most recently in 2017 (European Code of Conduct for Research Integrity Revised Edition). ALLEA emphasises that, besides avoiding FFP, there are a number of ethics principles with which all researchers should comply. Worth mentioning are (in the most recent version, the number of principles has been slightly reduced):

- honesty
- reliability
- objectivity
- impartiality and independence
- open communication
- obligation to safeguard the interests of research subjects
- fairness
- obligation to nurture the next generation of researchers.

It cannot be said that these principles are each one clearly defined. But together they create a multi-dimensional moral space within which the researcher shall work - they stake out the borders for what can be regarded as good research practice.

It is the researcher's obligation to present the purpose and the aim of his or her research honestly, and it is crucial that the scientific findings are reported in a reliable and defensible way. A prerequisite for research that it worthy of its name is that it is possible to scrutinise data, the scientific argumentation and not least the

conclusions. To make this possible, the results have to be made available and communicated in a trustworthy manner to colleagues and the general public. Open communication is crucial.

ALLEA underlines the importance of research not being improperly influenced by ideologies, political pressure or financial interests. ALLEA also emphasises our obligations as researchers to give guidance on these issues to future generations, and to monitor them collegially, which for example includes taking measures against all forms of harassment.

In a report from 2016, Science Europe has moved in the same direction; that is to say emphasising the importance of researchers receiving good instruction in research ethics and researcher ethics, and that the values mentioned above are discussed and taught. This research and researcher ethics training shall start already during the first cycle, and the knowledge shall then be updated and expanded in width and depth throughout the career.

The European Code of Conduct for Research Integrity (2017) is an important document that clearly indicates a code of conduct in a wider sense than the more narrow definition of misconduct emphasised by Good Research Practice. If researchers complied with this code, a large proportion of the current misconduct would probably be avoided. The few pathological cases of misconduct would not be prevented through this type of code of conduct, for which severe sanctions would instead be required. However, this entails a problem: if issues of research ethics are dealt with in legislation, and the concept becomes too comprehensive or multi-dimensional, the legal codification will be difficult to handle. Instead, the definition of good research ethics should be seen as a code of conduct that covers a more narrow legal description of misconduct.

References

1. Danish Committees on Scientific Dishonesty, *Annual Report*. Copenhagen, Danish Research Agency, 1993–.
2. European Code of Conduct for Research Integrity Revised Edition. ALLEA. All European Academies, Berlin 2017
3. Forsman, Birgitta, *Vetenskap och moral*. Nora, Nya Doxa, 2002.
4. Forsman, Birgitta, *Forskningsfusk och vetenskaplig oredlighet*. Lund, Enheten för medicinsk etik, 2006.
5. Forsman, Birgitta, *Begrepp om forskningsfusk*, rapport till Vetenskapsrådet, 2007.
6. Forsman, Birgitta, *Forskarens frihet: Om makt och moral*. Lund, Studentlitteratur, 2009. Högskoleförordning (SFS 1993:100).
7. Hermerén, Göran, *På Minervas bakgård. Om vetenskaplig oredlighet: Definitioner, metoder, sanktioner*, KHVA Årsbok 2014.
8. Hermerén G. *Definitions of Fraud and Misconduct Revisited*. *Jahrbuch für Wissenschaft und Ethik*, 18(1), 2013: 85-121.
9. National Science Foundation (NSF), Research Misconduct Regulation, Key Regulations 45 CFR 689, 1982.
10. Office of Research Integrity (ORI), *ORI Annual Report 2007*. Rockville, ORI, 2008.
11. Office of Research Integrity (ORI), *ORI sample policy and procedures for responding to research misconduct allegations*. Rockville, U.S. Department of Health and Human Services, 2009.
12. Organisation for Economic Co-operation and Development (OECD), *Investigating research misconduct allegations in international collaborative research projects. A practical guide*. Paris, OECD, 2009.
13. Pryor, Erica R. & Habermann, Barbara & Broome, Marion E., "Scientific misconduct from the perspective of research coordinators: A national survey", *Journal of Medical Ethics*, 2007, 33; 6:365–369.
14. de Vries, Raymond & Anderson, Melissa S. & Martinson, Brian C., "Normal misbehavior: Scientists talk about the ethics of research", *Journal of Empirical Research on Human Research Ethics*, 2006, 1; 1:43–50.
15. de Vries, Raymond & Anderson, Melissa S. & Crain, A. Lauren & Martinson, Brian C., "Scientists' perceptions of organizational justice and self-reported misbehaviors", *Journal of Empirical Research on Human Research Ethics*, 2006, 1; 1:51–66.

9. KEY LEGISLATION AND OTHER REGULATIONS WITH WHICH RESEARCHERS SHOULD BE FAMILIAR

There are numerous laws, directives, ordinances, directives, guidelines and codes of research and professional ethics that researchers need to know in order to carry out their work in both a legal and ethically considered manner. The rules that are particularly important for individual researchers does of course vary, depending on the nature of the research. Here, we present a selection of especially important regulations.

There are many different kinds of regulations, and they are mandatory to varying degrees. This is discussed more thoroughly in Chapter 1. In this chapter, we present some of these laws and other regulations.

9.1 Personal data handling

Research often involves the handling of personal data. Personal data is anything that can be linked, directly or indirectly, to a physical person, such as address, de-coded data where the code key remains, or data that together with other information can identify an individual. Handling is more or less anything that can be done with personal data, such as storing, summarising and transferring. Special rules apply for the handling of personal identity numbers, sensitive personal data and data concerning breaches of the law. Permission from an ethics review board is also needed when handling the latter two in research.

When personal data is handled, there are a number of regulations that must be complied with. There are both general rules – international, at EU level, and national – and also regulations for the handling of personal data for certain types of purposes. In Sweden, the handling of personal data is currently regulated by the Personal Data Act (SFS 1998:204) and the Personal Data Ordinance (SFS 1998:1191), and in a number of enactments with special provisions for the handling of personal data in various situations.

As from May 2018, a new EU Regulation on general data protection⁷ will replace the current Data Protection Directive, which you can read more about in Section 9.1.8, as well as the Swedish Personal Data Act and the Personal Data Ordinance. A consequence of this will also be that all the regulations that govern personal data handling will be reviewed and adapted to the new Regulation.

9.1.1 Legal support for personal data handling

The handling of personal data is governed by the Personal Data Act, but if there are provisions in another law or ordinance that regulates personal data handling, these latter provisions shall apply; see Section 2 of the Personal Data Act. This means that the handling of personal data must be supported either by the Personal Data Act or by another law or ordinance that regulates the handling.

9.1.2 International regulations

Sweden has undertaken to safeguard the respect of fundamental freedoms and rights in an international context, including the right to personal integrity in the handling of personal data. Below follows a brief description of some of the most important ones. The aim is to provide a background to the principles encompassed by the Swedish regulations within the area. Some of the central principles are that personal data may only be collected for one or several stated purposes, that they shall be fit for purpose, relevant, necessary for the purposes for which they are handled, and not be stored for longer than necessary.

⁷ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), EUT L 119, 4.5.2016, p. 1.

9.1.3 The UN's Universal Declaration of Human Rights, etc.

Article 12 of the United Nations' Universal Declaration of Human Rights, etc. establishes that "No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks." Article 29 Item 2 further states that "In the exercise of his rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society."

The Universal Declaration is not binding upon member states, but may be seen as an expression of common law rules within the area.

9.1.4 The European Convention on Human Rights

The Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 ("European Convention on Human Rights") was incorporated into Swedish law on 1 January 1995, and has since then applied as law in Sweden.

Article 8 of the European Convention on Human Rights states that "Everyone has the right to respect for his private and family life, his home and his correspondence". It further states that "There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others". The European Court of Human Rights was established to monitor that the obligations under the European Court of Human Rights are fulfilled.

9.1.5 The Council of Europe's Data Protection Convention

In 1981, the Committee of Ministers of the Council of Europe adopted the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. The Convention came into force on 1 October 1985. All EU member states have ratified the Convention. The Convention is binding on the countries who have ratified it. The Convention is associated with a number of recommendations on how personal data should be handled in various areas. The recommendations are not directly binding.

According to Article 1, the Convention aims "to secure in the territory of each Party for every individual, whatever his nationality or residence, respect for his rights and fundamental freedoms, and in particular his right to privacy, with regard to automatic processing of personal data relating to him ("data protection")". According to Article 2, the Convention's area of application is "automated data files" and "automatic processing" of personal data in public and private activities. Each Convention state may, however, introduce certain general restrictions or expansions of the area of implementation. The central part of the Convention is Chapter II (Articles 4–11), which comprise the fundamental principles for data protection. They include requirements that personal data that is processed automatically shall be "obtained and processed fairly and lawfully", "adequate, relevant and not excessive in relation to the purposes for which they are stored" and "preserved ... for no longer than is required" (Article 5). Personal data "revealing racial origin, political opinions ... health or sexual life", as well as "personal data relating to criminal convictions" "may not be processed automatically unless domestic law provides appropriate safeguards" (Article 6). The Convention also includes provisions governing requirements on safety measures and information to those whose data is being processed.

9.1.6 OECD's Guidelines

The Organisation for Economic Cooperation and Development (OECD) has produced Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data. These Guidelines were adopted by the OECD Council in 1980, simultaneously with a recommendation to the governments of the member countries to consider the Guidelines in national legislation. Sweden has adopted these recommendations, and by this means undertaken to follow the Guidelines. The Guidelines are minimum rules, which means that protection in the countries that have undertaken to follow the Guidelines may be made more comprehensive than the protection given by the Guidelines. The Guidelines include eight fundamental principles to protect personal integrity; for

example, they state that personal data shall be collected for specific purposes, be relevant to the purpose for which they are intended, and shall be correct, complete and up-to-date.

9.1.7 The European Union's Charter of Fundamental Rights

The European Union's Charter of Fundamental Rights was adopted at the meeting of the Council of Europe in Nice in 2000 (the "EU Charter"). The EU Charter states the fundamental rights under six headings: Dignity, Freedoms, Equality, Solidarity, Citizens' Rights, and Justice.

In terms of protection of personal integrity, it states that everyone has the right to physical and mental integrity (Article 3). Everyone has the right to respect for his or her private and family life, home and communications (Article 7), and to the protection of personal data concerning him or her (Article 8). Article 8 also states that personal data shall be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis. The EU Charter is now legally binding through the Lisbon Treaty when EU institutions and EU member states apply the EU's laws and regulations.

9.1.8 The Data Protection Directive

On 24 October 1995, the EU adopted a Directive on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, the Data Protection Directive. The provisions of the Data Protection Directive set the framework for what is possible to do in Sweden in terms of handling personal data. It is therefore not possible to create Swedish legal provisions that are not compatible with the Directive.

The Data Protection Directive includes a number of fundamental requirements that must be fulfilled in the handling of personal data. These rules are largely represented in the Swedish Personal Data Act. As mentioned in Section 9.1, the Data Protection Directive will be replaced by a new EU Regulation on data protection.

9.2 Two important Swedish laws

As mentioned above, in Sweden the Data Protection Directive has been implemented through the Personal Data Act. This is the law that generally regulated the handling of personal data in Sweden. There are also a number of laws that regulate the handling of personal data for specific purposes.

9.2.1 The Patient Data Act

Research may involve the processing of personal data relating to patient within health and medical care. The handling of personal data by caregivers within the framework of health and medical care is largely regulated in the Patient Data Act, (SFS 2008:355). Health and medical care refers to activities as referred to in the Health and Medical Services Act (SFS 1982:763), the Dental Services Act (SFS 1985:125), the Compulsory Mental Care Act (SFS 1991:1128), the Forensic Mental Care Act (SFS 1991:1129), the Communicable Diseases Act (SFS 2004:168), the Act (SFS 1972:119) on the Determination of Sex in Some Cases, the Genetic Integrity Act (SFS 2006:351), and the revoked Castration Act (1 SFS 944:133), Chapter 1 Section 3 of the Patient Data Act.

In health and medical care, personal data may be handled if required to fulfil the obligations stated in Chapter 3 of the Patient Data Act, namely the obligation to maintain patient records and to produce other documentation needed in and for the care of patients, administration relating to patients and aimed at providing care in individual cases, or that is otherwise occasioned by care in individual cases, to draw up other documentation that follows by law, ordinance or other statute, to systematically and continuously develop and safeguard the quality of the activities, administration, planning, follow-up, evaluation and supervision of the activities, or to produce statistics relating to health and medical care; see Chapter 2 Section 4 of the Patient Data Act. The aim of stating purposes is to establish an outer-most limit for when personal data may be collected and then processed. The starting point is thus that only such personal data handling may take place as is covered by one or several of the stated purposes, see Govt. Bill 2007/08:126 p. 228.

9.2.2 The Act concerning the Ethical Review of Research Involving Humans

Since 1 January 2004, the Act concerning the Ethical Review of Research Involving Humans has been in force. It covers research involving living persons, but also research involving deceased persons and biological material from humans, and also research involving the handling of sensitive personal data. The purpose of the Act is to protect the individual person and ensure respect for human dignity in research.

The Act (SFS 2003:460) concerning the Ethical Review of Research Involving Humans shall apply to research involving sensitive personal data under Section 13 of the Personal Data Act, *or* personal data on breaches of the law that includes statutory offences, judgements in criminal cases, criminal procedural coercive measures or administrative deprivation of liberty according to Section 21 of the Personal Data Act. The Act is also applicable to research that involves physical encroachment on a research subject, that is carried out using a method aimed at influencing the research subject physically or mentally, or that entails a clear risk of physical or mental harm to the research subject, that relates to studies of biological material taken from a living person that can be attributed to this person, that involves a physical encroachment on a deceased person, or relates to studies of biological material taken for medical purposes from a deceased person that can be attributed to this person.

By means of the ethics review procedure, support can be created for personal data handling in research projects that are carried out without consent, but the Act gives no support for personal data handling carried out before the actual research process begins.

The Act applies to all such research, regardless of in what institutional setting it is carried out, or how it is funded. The regional ethics review board's review involves an examination of the project description to establish whether it involves any infringement of human rights or hard-to-capture concept of human dignity. An assessment is also made of the relationship between the value of the project and any burdens or risks which it might entail for the subjects of the research. Its value must be judged to outweigh the risks. Great importance is placed on an assessment of how the issue of informed consent has been handled. Regional ethics boards are also able to issue advisory statements on research involving human subjects in the event the research is not covered by the Act (SFS 2003:460) concerning the Ethical Review of Research Involving Humans. Such statements are sometimes required in order to obtain financial support, or to enable publication of results in certain international journals. Reviews by the regional boards are subject to a fee and shall be undertaken within 60 days from receipt of application. More information is available on (epn.se).

9.3 Secrecy

Researchers need to know whether the data handled within the research they carry out is covered by secrecy, and if so, what the secrecy parameters are. A significant factor when determining the secrecy parameters for a task is who is carrying out the activity.

9.3.1 Public principal

The Freedom of the Press Act contains regulations for public documents stored by public authorities. The starting point is that public documents are open to the general public, and that the general public's access to these may only be limited for the purposes listed in Chapter 2 Section 2 of the Act. One of the purposes is the protection of the personal or financial circumstances of individuals. The issue of when data may be covered by secrecy under this exception is regulated in particular in the Public Access to Information and Secrecy Act (SFS 2009:400). This Act contains provisions that apply to the handling of personal data within the framework of health and medical care, in research activities and other activities carried on by public agencies.

The regulations in the Act also entail that those who work at a public agency are automatically covered by professional secrecy rules. It is important to remember that employees have an obligation of professional secrecy under the Act, but cannot have a more comprehensive obligation imposed. That means that if data is covered by secrecy under the Act, it must not be disclosed, at the same time that data that is public must be disclosed on demand.

9.3.2 Private principal

Private actors have no obligation to disclose data, or keep data secret, unless this follows from special legislation covering their activities. Such regulations exist, for example for private caregivers, in Chapter 6 of the Patient Safety Act. If there are no particular regulation, private actors may themselves decide on the secrecy protection that shall apply for a certain task.

This also means that employees of private employers do not have any statutory obligation of secrecy, unless this follows from special regulations, such as those in the Patient Data Act. This must instead be regulated between the employee and the employer in such a way that the private employer ensures that data that shall not be disseminated are kept secret.

If the data is held by a private principal, there is also no right for the general public, including research principals, to partake of data in the system under the Freedom of the Press Act. There is thus greater freedom for a private principal to decide who may partake of data.

9.4 Examples of other legislation

The *Animal Welfare Act* (SFS 1988:534) and *Animal Welfare Ordinance* (SFS 1988:539) apply to research on animals. The Swedish Board of Agriculture provides supplementary guidelines and general advice.

9.5 The CODEX website

The Swedish Research Council maintains a website in collaboration with the Centre for Research Ethics and Bioethics at Uppsala University on which the great majority of documents that may be relevant to the researcher can be found. The site thus includes legislation with a bearing on research.

Also to be found here are various directives and conventions of an international character, adopted for example by the UN, UNESCO, the EU and the Council of Europe. The site also features the full texts of codes of research ethics for different disciplines and fields of research, along with introductions to specific challenges in research, such as informed consent or publication. In addition, there is a section on the use of animals in research. CODEX can be found at www.codex.vr.se.

Note that CODEX is a site that provides information on research ethics; the material presented there does not necessarily reflect the Swedish Research Council's opinions on research ethics issues.

Below, some documents that are central to research in Sweden are commented on briefly. The complete texts can all be found in CODEX, together with many other significant and valuable questions. They are arranged here from the most binding to the more voluntary.

9.6 The Declaration of Helsinki

The *Declaration of Helsinki* is a central guideline for research ethics adopted by the World Medical Association in 1964. The Declaration contains ethical principles for doctors and other participants in medical research.

The Declaration of Helsinki is not legally binding, but has had major impact on national legislation. Since 2000, it refers explicitly to research using identifiable samples and data. One of the fundamental principles of the Declaration is that concern for the individual must always take precedence over the interests of science and society.

Furthermore, the principles state that informed consent must be obtained for research that uses identifiable samples and data – for collection, analysis, storage and use for new purposes. It establishes, however, that situations may exist where it is impossible or unsuitable to obtain consent. In such cases, research may only be carried out if an ethics review board has approved the research project.

The principles further establish that all conceivable safety measures must be undertaken to respect the private lives of participants, and to treat patient information confidentially, and to minimise the impact the study may have on the participants' physical and mental integrity and personality.

The Declaration of Helsinki is mentioned in the preambles of both the Act concerning the Ethical Review of Research Involving Humans and the Biobanks in Medical Care Act (2002:297). The above-mentioned instruction from the Swedish Medical Products Agency states that it shall be followed in clinical trials. It is often a requirement that a medical research project has been carried out in accordance with the requirements of

the Declaration of Helsinki in order to receive research grants or be published. The Declaration has been updated regularly with various new formulations and additions. The current version was adopted in 2013.

The Declaration stated a number of principles that apply, such as a competency requirement on the researcher, a requirement for a balance between the value of the research (benefit) and risks, where the well-being of the patient shall take precedence. It also includes requirements for the informed consent; what the information shall contain, how the consent is given, by whom it is given, and to whom it is given. The Declaration of Helsinki also covers a number of rules that apply when medical research is combined with care.

9.7 Guidelines for Good Clinical Practice (GCP)

For clinical trials of drugs, the relevant guideline is *Good Clinical Practice* (GCP). This guideline applies in the EU, the United States, Japan and Australia, and is included in Swedish law through the Swedish Medical Products Agency's rules and general recommendations (LVS 2011:19) regarding clinical trials using human subjects. It contains a large number of detailed principles, together with a glossary defining relevant concepts.

To aid European research ethics committees, the European Forum for Good Clinical Practice has produced a number of documents that serve as guides when using GCP (www.efgcp.eu). These documents are intended to harmonise with the Declaration of Helsinki but are much more comprehensive, addressing everything from planning and conducting clinical studies to how they should be documented and reported.

9.8 The Council of Europe's Convention for the Protection of Human Rights and biomedicine

The Council of Europe is an organisation that works to uphold human rights in its member countries. The Council's *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine* of 1997 (also known as the Oviedo Convention) comprises a number of articles that directly or indirectly relate to biomedical research. It deals in particular with the protection of individuals undergoing research and with the conduct of research on persons with reduced capacity to give free and informed consent. One article deals with research on embryos *in vitro*.

This document, together with the EU Directive on Good Clinical Practice in the member states, has directly prompted the Swedish Act concerning the Ethical Review of Research Involving Humans. Sweden has signed this convention but has not yet ratified it. In practice, however, it has served as a guidepost for Swedish regulations since its establishment.

9.9 The CIOMS guidelines for research

The Council for International Organizations of Medical Sciences (CIOMS) has, in collaboration with the World Health Organization (WHO), published *Ethical Guidelines for Biomedical Research Involving Human Subjects*, addressing issues of safety and informed consent. Through this document, the Council attempts to apply the principles of the Declaration of Helsinki while acknowledging important differences between the countries of the world. The guidelines contain special sections on research on weaker groups and women. CIOMS has also published guidelines on epidemiological research which are widely referred to.

9.10 Center for Open Science

Recently, researchers have taken the initiative to encourage better research practice. The currently best established and comprehensive initiative is the *Center for Open Science*, which provides resources to increase openness, integrity and reproducibility. (<https://cos.io/>)

9.11 Publication ethics and questions of misconduct

Some important documents on research ethics, such as the *Declaration of Helsinki*, address aspects of publishing ethics. As the Swedish Research Council has signed the Berlin Declaration (the *Berlin Declaration*

on Open Access to Knowledge in the Sciences and Humanities), the Council has since 2010 included a requirement for open access publication in its calls for grant applications.

Two international documents are of particular relevance in this context: one being, the *Editorial Policy Statements* of the Council of Science Editors (CSE), and the other – and most important – the “Vancouver Rules”, published by the International Committee of Medical Journal Editors (ICMJE) under the title of *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*. A point emphasised in both these documents is the clear link between the right to be credited as an author and the obligation to assume responsibility for and have contributed to the intellectual content of the publication.

Shared authorship is addressed in the CSE’s *Recommendations for Group- Author Articles in Scientific Journals and Bibliometric Databases*. Many journals today also refer to the ethical guidelines launched by the British Committee on Publication Ethics (COPE).

Constant departures from these standards have led other actors to intensify their work with publication ethics. Not least, publishing companies themselves have started formulating rules and guidelines. Groups of researchers, editors and funding bodies have also collaborated in drawing up a number of standards, such as CONSORT, STARD, STROBE and STREGA, for how various types of studies should be presented in journals. These and other documents can be found on the CODEX website’s page on publication ethics.

As regards research misconduct in general, perhaps the most important initiative in recent time is the OECD’s *Best Practices for Ensuring Scientific Integrity and Preventing Misconduct*, and another one produced by ALLEA, the *European Code of Conduct for Research Integrity Revised Edition*. The US federal guidelines, *U.S. Federal Policy on Research Misconduct*, have also received a great deal of attention. The European Science Foundation’s contribution is a discussion of Research Integrity in its Briefing no. 30. In Sweden, the Association of Swedish Higher Education has presented guidelines for the handling of questions of research misconduct by universities and higher education institutions in its *Riktlinjer för hantering vid universitet och högskolor av frågor om vetenskaplig ohederlighet*.

The most recent contribution to the documents on misconduct, the *Singapore Statement on Research Integrity*, was drawn up at the 2nd World Conference on Research Integrity.

References

1. 2nd World Conference on Research Integrity. Singapore Statement on Research Integrity. Singapore, 2010. Arkivförordning (SFS 1991:446).
2. Arkivlag (SFS 1990:782).
3. Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities. Berlin, 2003.
4. Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products. European Community, Brussels, 2005.
5. Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, (Oviedo Convention), European Treaty Series No 164, Strasbourg, 1997.
6. Council of Science Editors. Editorial Policy Statements, Wheat Ridge, CO, 2010.
7. Council for International Organizations of Medical Sciences (CIOMS). International ethical guidelines for biomedical research involving human subjects. Geneva, CIOMS, 2002.
8. Council for International Organizations of Medical Sciences (CIOMS). International ethical guidelines for epidemiological studies. Geneva, CIOMS, 2008.
9. Djurskyddsförordning (SFS 1988:539).
10. Djurskyddslag (SFS 1988:534).
11. European Code of Conduct for Research Integrity Revised Edition. ALLEA, All European Academies, Berlin 2017.
12. European Science Foundation. *Research Integrity: global responsibility to foster common standards*. ORI-ESF Science Policy Briefing 30, Strasbourg, 2007.
13. Hälso- och sjukvårdslag (SFS 1982:763).
14. Lag om biobanker i hälso- och sjukvården med mera (SFS 2002:297).

15. Lag om etikprövning av forskning som avser människor (SFS 2003:460).
16. Lag om genetisk integritet med mera (SFS 2006:351).
17. Läkemedelsverkets föreskrifter om kliniska läkemedelsprövningar på människor (LVFS 2011:19).
18. Offentlighets- och sekretesslag (SFS 2009:400).
19. Office of Research Integrity (ORI). Federal Research Misconduct Policy. Federal Register: December 6, 2000, Volume 65, Number 235, Notices, Page 76260–76264.
20. Organisation for Economic Co-operation and Development (OECD). *Best Practices for Ensuring Scientific Integrity and Preventing Misconduct*. Paris, OECD, 2007.
21. Patientdatalag (SFS 2008:355).
22. Personuppgiftslag (SFS 1998:204).
23. Sveriges universitets- och högskoleförbund (SUHF), *Riktlinjer för hantering vid universitet och högskolor av frågor om vetenskaplig ohederlighet*. Stockholm, SUHF, 1997.
24. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). E6(R1): Good clinical practice: consolidated guideline, adopted by CPMP, July 1996, issued as CPMP/ICH/135/95/Step5, Geneva, 1996.
25. Tryckfrihetsförordning (SFS 1949:105).
26. World Medical Association. Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, latest revision by the WMA General Assembly, Seoul 2013. Ferney-Voltaire, France, World Medical Association, 2013.

Reading tips

1. Alexius Borgström, Katarina, *Djuren, läkarna och lagen: en rättslig studie om djurförsöksetik*. Uppsala, Iustus förlag, 2009.
2. Bagni, Julian & Fosl, Peter S., *The ethics toolkit. A compendium of ethical concepts and methods*. Oxford, Blackwell, 2007.
3. Beauchamp, Tom L. & Childress, James F., *Principles of biomedical ethics*. Oxford & New York, Oxford University Press, (1979), Sixth Edition, 2008.
4. Bühler, Axel, (ed) *Hermeneutik*. Heidelberg, Synchron, 2003.
5. Cavalieri, Paola & Singer, Peter (eds.) *The Great Ape Project: Equality Beyond Humanity*. New York, St. Martin's Press, 1994.
6. Chalmers, Alan F., *Vad är vetenskap egentligen?* Nora, Nya Doxa, 2003.
7. Coughlin, Steven S. & Beauchamp, Tom L. & Weed, Douglas L. (eds), *Ethics and epidemiology*. Oxford & New York, Oxford University Press, 2009.
8. Egonsson, Dan, *Filosofiska essäer om människovärde*. Falun, Nya Doxa, 1999.
9. Emanuel, Ezekiel J., et al., *The Oxford textbook of clinical research ethics*. Oxford & New York, Oxford University Press, 2008.
10. Fleischhauer, Kurt & Hermerén, Göran, *Goals of Medicine in the Course of History and Today*. A&W International, Stockholm, 2006.
11. Forsman, Birgitta, *Forskningsetik: en introduktion*. Lund, Studentlitteratur, 1997.
12. Forsman, Birgitta, *Vetenskap och moral*. Nora, Nya Doxa, 2002.
13. Forsman, Birgitta, *Etik i biomedicinsk forskning: En orientering*. Lund, Studentlitteratur, 2005. Forsman, Birgitta, *Forskningsfusk och vetenskaplig oredlighet*. Lund, Enheten för medicinsk etik, 2006.
14. Forsman, Birgitta, *Forskarens frihet: Om makt och moral*. Lund, Studentlitteratur, 2009.
15. Föllesdal, Dagfinn & Wallöe, Lars & Elster, Jon, *Argumentationsanalys, språk och vetenskaps- filosofi*. Stockholm, Thales, 2001.
16. Gilje, Nils & Grimen, Harald, *Samhällsvetenskapernas förutsättningar*. Göteborg, Daidalos, 1993, tredje upplagan 2007.
17. Görman, Ulf & Andrén, Carl-Gustaf & Hermerén, Göran, *Att forma vår framtid: bioteknikens möjligheter och problem*. Lund, Nordic Academic Press, 2009.

18. Hansson, Mats G., *Integritet. I spänningen mellan avskildhet och delaktighet*, Stockholm, Carlsson Bokförlag, 2006.
19. Helgesson, Gert, *Forskningsetik för medicinare och naturvetare*, Lund, Studentlitteratur, 2006.
20. Hermerén, Göran, *Kunskapens pris: forskningsetiska problem och principer i humaniora och samhällsvetenskap*. Stockholm, Swedish Science Press & HSFR, 1986, andra upplagan 1996.
21. Hermerén, Göran, "Vi kommer aldrig att ha forskat färdigt kring de etiska problemen". *Praktik & Teori*, 2007, 2:44–51.
22. Hermerén, Göran, "Challenges in the Evaluation of Nanoscale Research: Ethical Aspects". *Nano Ethics*, 2007, 1:223–237.
23. Hermerén, Göran, Hug, Kristina (red). *Translational Stem Cell Research: Issues Beyond the Debate on the Moral Status of the Human Embryo*. New York, Springer, 2010.
24. Karlsson, Fredrik, *Weighing Animal Lives – a Critical Assessment of Justification and Prioritization in Animal-Rights Theories*. Uppsala, Acta Universitatis Upsaliensis, 2009.
25. Klareskog, Lars & Rönnelid, Johan & Lundberg, Karin & Padyukov, Leonid & Alfredsson, Lars, "Immunity to citrullinated proteins in rheumatoid arthritis." *Annual Review of Immunology*, 2008, 26:651–675.
26. Kodish, Eric (ed), *Ethics and research with children. A case-based approach*. Oxford & New York, Oxford University Press, 2005.
27. Kuhn, Thomas S., *De vetenskapliga revolutionernas struktur* (1962). Stockholm, Thales, andra upplagan, 2009.
28. Loue, Sana, *Textbook of research ethics. Theory and practice*. Dordrecht, Kluwer, 2000.
29. Lynøe, Niels, *Mellan cowboyetik och scoutmoral: medicinsk forskningsetik i praktiken*. Stockholm, Liber, 1999.
30. Lynøe, Niels & Juth, Niklas, *Medicinska etikens ABZ*. Stockholm, Liber, 2009.
31. Macklin, Ruth, *Double standards in medical research in developing countries*. Cambridge, Cambridge University Press, 2004.
32. Merton, Robert, "The Normative Structure of Science" (1942), in Merton, R., *The Sociology of Science*: University of Chicago Press, 1973.
33. Murphy, Timothy, F., *Case Studies in Biomedical Research Ethics*. Cambridge, Mass., MIT Press, 2004.
34. Myrdal, Janken, *Spelets regler i vetenskapens hantverk: Om humanvetenskap och naturvetenskap*. Stockholm, Natur & Kultur, 2009.
35. Newman, W. Lawrence, *Social Research Methods, Qualitative and Quantitative Approaches*. 5th edition. Boston etc, Pearson Education, 2003.
36. Pence, Gregory E., *Classic Cases in Medical Ethics*. New York, McGraw Hill, 2000.
37. Perel, Pablo, & Roberts, Ian & Sena, Emily & Wheble, Philipa & Briscoe, Catherine & Sandercock, Peter & Macleod, Malcolm & Mignini, Luciano E. & Jayaram, Pradeep & Khan, Khalid S., "Comparison of Treatment Effects between Animal Experiments and Clinical Trials: Systemic Review". *British Medical Journal*, 2007, 334 (7586):197.
38. Petersson, Bo, *Forskning och etiska koder*. Nora, Nya Doga, 1994.
39. Petersson, Bo, *Forskningsetisk vägning. Forskningens värde*, Linköping, Centrum för tillämpad etik, 1999.
40. Popper, Karl, *Conjectures and refutations: The growth of scientific knowledge* (1934), London, Routledge, 2002.
41. Pryor, Erica R. & Habermann, Barbara & Broome, Marion E., "Scientific Misconduct from the Perspective of Research Coordinators: A National Survey". *Journal of Medical Ethics*, 2007, 33; 6:365–369.
42. Rydén, Lars (red), *Etik för forskare. En antologi med utgångspunkt i arbetet med Uppsalakodexen*. Stockholm, UHÄ, 1990.
43. Snyder, Peter J. & Mayes, Linda C. & Spencer, Dennis D., *Science and the media: Delgado's brave bulls and the ethics of scientific disclosure*. London, Academic Press, Elsevier, 2009.

44. de Vries, Raymond & Anderson, Melissa S. & Martinson, Brian C., "Normal misbehavior: Scientists talk about the ethics of research", *Journal of Empirical Research on Human Research Ethics*, 2006, 1; 1:43–50.
45. de Vries, Raymond & Anderson, Melissa S. & Crain, A. Lauren & Martinson, Brian C., "Scientists' perceptions of organizational justice and self-reported misbehaviors", *Journal of Empirical Research on Human Research Ethics*, 2006, 1; 1:51–66.
46. Wells, Frank & Farthing, Michael, *Fraud and misconduct in biomedical research*. London, Royal Society of Medicine Press Ltd, 2008.
47. Wendler, David, *The ethics of pediatric research*, Oxford & New York, Oxford University Press, 2010.

Laws, ordinances, directives

1. Arkivlag (SFS 1990:782). Arkivförförordning (SFS 1991:446).
2. Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products. European Community, Brussels, 2005.
3. Djurskyddslag (SFS 1988:534). Djurskyddsförordning (SFS 1988:539).
4. Directive 2001/20/EC of 4 April 2001, of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.
5. Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.
6. Förordning om etikprövning av forskning som avser människor (SFS 2003:615).
7. Förordning om utsättning av genetiskt modifierade organismer i miljön (SFS 2002:1086).
8. Förordning om innesluten användning av genetiskt modifierade organismer (SFS 2000:271).
9. Förordning med instruktion för regionala etikprövningsnämnder (SFS 2007:1069).
10. Förordning med instruktion för Centrala etikprövningsnämnden (SFS 2007:1068).
11. Lag om biobanker i hälso- och sjukvården med mera (SFS 2002:297). Förordning (2002:746) om biobanker i hälso- och sjukvården med mera.
12. Lag om etikprövning av forskning som avser människor (SFS 2003:460).
13. Lag om genetisk integritet med mera (SFS 2006:351).
14. Läkemedelslag (SFS 2015:315).
15. Offentlighets- och sekretesslag (SFS 2009:400).
16. Patientdatalag (SFS 2008:355).
17. Personuppgiftslag (SFS 1998:204).
18. Personuppgiftsförordning (SFS 1998:1191).
19. Ändring i Centrala försöksdjursnämndens föreskrifter (LSFS 1988:45) om den etiska prövningen av användningen av djur för vetenskapliga ändamål med mera (SJVFS 2008:70).
20. Strålsäkerhetsmyndighetens föreskrifter om allmänna skyldigheter vid medicinsk och odontologisk verksamhet med joniserande strålning (SSMFS 2008:35).
21. Tryckfrihetsförordning (SFS 1949:105).

Declarations, guidelines, reports

1. 2nd World Conference on Research Integrity. Singapore Statement on Research Integrity, Singapore, 2010.
2. Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities. Berlin, 2003. Bohlin, Alf, *Offentlighet & sekretess i myndighetsforskningsverksamhet*. Riksarkivet, 1997:2.

3. Brambell, Rogers, F.W. (Chairman), *Report of the Technical Committee to enquire into the Welfare of Animals kept under Intensive Livestock Husbandry Systems*, London, HMSO, 1965.
4. Centrala försöksdjursnämnden, *Författningar, allmänna råd och anvisningar om användningen av djur för vetenskapliga ändamål*. Stockholm, CFN:s skriftserie: 45, 2002.
5. Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, (Oviedo Convention), European Treaty Series No 164, Strasbourg, 1997.
6. Council for International Organizations of Medical Sciences (CIOMS). International ethical guidelines for biomedical research involving human subjects. Geneva, CIOMS, 2002.
7. Council for International Organizations of Medical Sciences (CIOMS). International ethical guidelines for epidemiological studies. Geneva, CIOMS, 2008.
8. Council of Science Editors. Editorial Policy Statements, Wheat Ridge, CO, Council of Science Editors, 2010.
9. Danish Committees on Scientific Dishonesty, *Annual Report*. Copenhagen, Danish Research Agency, 1993–.
10. Den nasjonale forskningsetiske komité for naturvitenskap og teknologi (NENT), *Forskningsetiske retningslinjer for naturvitenskaplig teknologi*. Oslo, 2007.
11. Djurförsöksetiska utredningen, *Etisk prövning av djurförsök: delbetänkande* (SOU 2002:86). Stockholm, Fritzes offentliga publikationer, 2002.
12. European Commission, European Research Area, Science in Society, *European Textbook on Ethics in Research*. EUR 24452 EN, Luxembourg Publication Office of the European Union 2010.
13. European Commission, European Research Area, Science in Society, *Syllabus on Ethics in Research, Addendum to the European Textbook on Ethics in Research*. EUR 24451 EN, Luxembourg Publication Office of the European Union 2010.
14. European Science Foundation. *Research Integrity: global responsibility to foster common standards*. ORI-ESF Science Policy Briefing 30, Strasbourg, 2007.
15. Forsman, Birgitta, *Begrepp om forskningsfusk*, rapport till Vetenskapsrådet, 2007.
16. Hermerén, Göran, *Hanteringen av integritetskänsligt forskningsmaterial*, Vetenskapsrådet, 2007. International Committee of Medical Journal Editors (ICMJE). Uniform Requirements for Manuscripts Submitted to Biomedical Journals, (Vancouver Rules), ICMJE, updated 2010.
17. Jordbruksverket, *Användningen av försöksdjur i Sverige under 2008*. Rapport, Dnr: 31-502/09.
18. Justitiedepartementet, *Offentlighet och sekretess hos det allmänna*, 2009.
19. Livsmedelsverket, Läkemedelsförmånsnämnden, Läkemedelsverket, Statens beredning för medicinsk utvärdering, Smittskyddsinstitutet, Socialstyrelsen och Statens folkhälsoinstitut, *Hantering av jäv, intressekonflikter och bindningar när externa experter anlitas*, 2008.
20. National Science Foundation (NSF), Research Misconduct Regulation, Key Regulations 45 CFR 689, 1982.
21. Office of Research Integrity (ORI), *ORI Annual Report 2007*, Rockville, ORI, 2008.
22. Office of Research Integrity (ORI), *ORI sample policy and procedures for responding to research misconduct allegations*, Rockville, U.S. Department of Health and Human Services, 2009.
23. Office of Research Integrity (ORI), *Federal Research Misconduct Policy*. Federal Register: December 6, 2000, Volume 65, Number 235, Notices, Page 76260–76264.
24. Organisation for Economic Co-operation and Development (OECD). *OECD Principles and Guidelines for Access to Research Data from Public Funding*. Paris, OECD, 2007.
25. Organisation for Economic Co-operation and Development (OECD), *Investigating research misconduct allegations in international collaborative research projects. A practical guide*, Paris, OECD, 2009.
26. Riksarkivet, *Om gallring – från utredning till beslut*. Rapport, 1999:1.
27. Sveriges universitets- och högskoleförbund (SUHF), *Riktlinjer för hantering vid universitet och högskolor av frågor om vetenskaplig ohederlighet*. Stockholm, SUHF, 1997.
28. Sveriges universitets- och högskoleförbund (SUHF), *Övergripande principer för offentlighet och sekretess i integritetskänslig forskning*. SUHF, 2006.


30. Sveriges universitetslärarförbund (SULF), Etiska riktlinjer för universitetslärare, 2005.
31. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). E6(R1): Good clinical practice: consolidated guideline, adopted by CPMP, July 1996, issued as CPMP/ICH/135/95/Step5, Geneva, 1996.
32. Uppsala universitet, *Hantering av allmänna handlingar vid universitetet*. Tredje upplagan, 2009.
33. Vetenskapsrådet, Jävspolicy för Vetenskapsrådet, 2014.
34. World Medical Association. Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, latest revision by the WMA General Assembly, Seoul 2013. Ferney-Voltaire, France, World Medical Association, 2013.

GOOD RESEARCH PRACTICE

Research ethics is not static, neither as a discipline nor as a practice. When the scientific landscape changes, sometimes the debate about research ethics shifts as well. New principles may be added, and old ones may need to be reinterpreted or applied differently.

Ethical considerations in research are largely a matter of finding a reasonable balance between various interests that are all legitimate. The quest for knowledge is one such interest. Individual privacy interests as well as protection against various forms of harm or risk of harm are other legitimate interests. Issues like the handling of integrity-sensitive material raise questions about the interests of the researcher, the study participants and other researchers, but also about what a researcher is able to promise participants and who owns research material.

This book addresses relevant legislation and ethical requirements and recommendations against the background of questions that may arise in research work. The aim is to provide an orientation among the issues and problems, stimulate thought and contribute to the debate on responsibility and challenges. The book primarily addresses researchers, not least the younger generation, to help them make well-reasoned research ethical decisions.



Västra Järnvägsgatan 3 | Box 1035 | 101 38 Stockholm, Sweden | Tel +46-(0)8-546 44 000 | vetenskapsradet@vr.se | www.vr.se

The Swedish Research Council has a leading role in developing Swedish research of the highest scientific quality, thereby contributing to the development of society. Besides research funding, the agency advises the government on research-related issues and participates actively in the discussions to create understanding of the long-term benefits of research.