



Vetenskapsrådet

GOOD RESEARCH PRACTICE



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The Swedish Research Council's expert group on ethics

Head: Göran Hermerén

This report is based on Good Research Practice – What is it?, report number 1:2005 in the Swedish Research Council's report series, written by Bengt Gustafsson, Göran Hermerén and Bo Pettersson.

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PREFACE

One of the functions of the Swedish Research Council is to take initiatives to ensure that ethical issues receive attention in research and to disseminate information on such issues. Since 2001, the Council has had an expert group on ethics, which monitors and encourages the debate on overarching research ethical matters.

The expert group has written this book, and stands for the perspectives and considerations presented here. The intention is to establish 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.

I would like to express my heartfelt thanks to the expert group for its work on this valuable book.

Stockholm, March 2011

A handwritten signature in black ink, appearing to read 'Mille Millnert', written in a cursive style.

Mille Millnert
Director General
Swedish Research Council

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SVENSK SAMMANFATTNING

Forskningsetiken är inte statisk. När det vetenskapliga landskapet ändras, ändras ibland också den forskningsetiska debatten. Nya principer kan tillkomma, gamla kan behöva tolkas om eller tillämpas på ett annat sätt.

Forskningsetiska överväganden handlar i hög grad om att hitta en rimlig balans mellan olika intressen som alla är legitima. Kunskapsintresset är ett sådant. Integritetsintresset liksom skydd mot olika former av skada och risk för skada är andra legitima intressen. Men ibland kan ny kunskap bara erhållas om forskningspersoner och medverkande utsätts för viss risk. De skador och risker det kan vara fråga om varierar betydligt mellan vetenskapsområden. Därför aktualiserar forskning av olika slag också olika typer av överväganden. Risk-vinstbedömningen görs på skilda sätt, och de etiska regelsystemen – som syftar till att främja kunskapssökande och tillvarata medverkandes intressen – ser inte heller riktigt ut på samma sätt inom olika forskningsområden. Det forskningsetiska regelverket är omfattande och vad som är tillämpligt kan således variera. Ambitionen med denna bok har dock varit att i så stor utsträckning som möjligt diskutera mer övergripande forskningsetiska problem som kan dyka upp under forskningsarbetets gång.

I denna bok diskuteras relevant lagstiftning och etiska krav och rekommendationer mot bakgrund av frågor som kan aktualiseras i forskningsarbetet. Allmänt kan frågorna handla om kunskapens värde, om olika tillvägagångssätt, om ansvar, om intressekonflikter, om metoder, om tillförlitlighet, etc. Mer specifikt är det angeläget att veta att viss forskning kräver tillstånd, bl.a. forskning som avser människor och forskning som innefattar djurförsök, men också vissa andra typer av forskning. Då integritetskänsligt material hanteras reser sig ofta frågor om olika intressen (forskarens, medverkande personers, andra forskares etc.), vad forskaren kan lova de medverkande, vem som äger ett forskningsmaterial o.s.v. Utgångspunkten för den etiska problematiken är även här konflikten mellan olika intressen.

I den pågående förändringen av forskningens villkor och organisering, nationellt och internationellt, ställs nya forskningsetiska frågor, medan andra ges en ny vinkling och prioritet. Mot denna bakgrund diskuteras bl.a. forskningsetiska överväganden i samband med ansvarsfrågor i multicenterstudier och stora internationella projekt. En tydlig ansvarsfördelning är viktig och den koordinerande forskningsledare på nationell och internationell nivå har ansvar för att gå igenom möjliga problem som kan dyka upp under forskningsarbetets gång och vidta åtgärder för att förhindra eller förebygga dem.

Publicering av forskningsresultat 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.

Ett forskningsetiskt problem som ofta uppmärksammas, också i medierna, rör vetenskaplig oredlighet. Det kan röra uppenbara övertramp som fabrikat, plagiat 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 finns således 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.

INTRODUCTION

Research ethics is not static. New ethical issues surface when new scientific questions are asked, when new methods are used and when new material is analysed. The early focus of research ethics was to protect patients and research subjects from abuses in the name of science. Later, through the development of epidemiological as well as register data research, other issues have come to the fore. In recent years stem cell and nano research have attracted a great deal of interest, as have the commercialization of research and the effects of research on the environment and society from a more global perspective.

Ethical considerations in research are largely a matter of finding a reasonable balance between various interests that are all legitimate. One such interest is our quest for knowledge. New knowledge is valuable in many ways and can contribute to the development of the individual as well as 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 gained if research subjects and participants are exposed to a certain degree of risk; this is most obvious in medical research. If there is to be no risk, the possibilities to make advances are also greatly reduced, with negative consequences for various groups of patients.

The harm and risks involved may vary considerably depending on the disciplinary domain. Thus different kinds of research call for different types of considerations. Risk-benefit assessments can be performed in several ways, and ethical regulatory systems – whose purpose it is to promote the quest for knowledge and to look after the interests of participants – are not identical across research fields. Early on, medical doctors and researchers as well as psychologists called attention to ethical issues, and since then others have followed their lead.

This book was initially intended to be an updated version of the book *Good Research Practice – What is it?*, published by the Swedish Research Council in January 2005. However, the changes in the field of research policy since then have been so extensive that the expert group has chosen to make more thorough revisions during the course of their work. So, while some sections from the previous book have been included after only a minor facelift, most of this book is new or rewritten. With this in mind, the title has also been changed to *Good Research Practice*.

Of the three professors behind the previous book, two have been especially active in this one as well: Göran Hermerén and Bo Petersson. While

Bengt Gustafsson has not collaborated on this publication, we wish to extend a special thanks to him as his ideas and formulations in the previous book have served as inspiration and in some cases have been repeated; not least in the summarized rules on page 12, the sections on pages 34-35, 41-42, 73-74, 78-79, and the introduction of the examples used in the book as well as eight of these examples – on pages 79, 91, 93, 96, 97, 102, 112 and 115.

The Swedish Research Council's expert group on ethics is responsible for this book. The group includes: Head, Professor Em. Göran Hermerén; and members Justice of the Supreme Administrative Court Karin Almgren, Dr. Per Bengtsson, Professor Barbara Cannon, Associate Professor Peter Höglund, former Editor-in-Chief Olof Kleberg, adjunct professor Margareta Möller, Professor Bo Petersson, adjunct professor Nina Rehnqvist and university lecturer Helena Röcklinsberg. Associate Professor Stefan Eriksson, editor of the CODEX website, served as an adjunct member of the expert group during its work on the book. From the Swedish Research Council, analyst Margareta Larsson has participated as secretary and Communications Officer Pamela Werner as information responsible. Most of these contributors have held the pen for shorter or longer passages, and all have participated engagingly in lively discussions on both the book's content and its form.

ABOUT THIS BOOK

Research has an important place in today's society, and high expectations are placed on it. But with these expectations, researchers themselves also come into focus. They have a particular responsibility towards the people and animals that participate in research, but also towards everyone who, even indirectly, can be affected by and benefit from the research results. The researcher is expected to do his or her best to conduct research of high quality, be free from outside influence and manipulation, and should also not act based on personal motives or those of interested parties. A successful future for researchers and research depends on a well-founded trust from society.

The various demands placed on a researcher's behaviour are part and parcel of the researcher role as it is conceptualized today; they are built into the research process. But these demands are based on society's usual ethical norms and values. As you read the recommendations in this book, you will discover that a great deal of what is said can be summarized in a number of broad rules that all correspond to more general life rules. You should:

- tell the truth about your research.
- consciously review and account for the purpose(s) of your studies.
- openly account for your methods and results.
- openly account for commercial interests and other associations.
- not steal research results from others.
- keep your research organized, for instance through documentation and archiving.
- strive to conduct your research without harming people, animals or the environment.
- be fair in your judgement of others' research.

This book gives a brief, summary account of the area of research ethics. It should therefore be complemented with additional reading if you wish to learn more about the subject. Some documents are described in the text here, but the reader is usually referred to the website "CODEX – rules & guidelines for research" at <http://www.codex.vr.se/en/index.shtml>. The site offers not only a list of rules and guidelines but also short research ethics introductions to various issues, links to national and international documents and a regularly updated news archive.

A researcher needs to be familiar with both relevant legislation and research ethics codes to be able to reflect on his or her project. The need for

research ethics is discussed as an introduction under the heading *What ethics dictate and the law demands* in Chapter 1.

In Chapter 2, *About research – what, why, how and for whom?*, a number of research ethics issues are addressed. These concern the value of knowledge, approaches, responsibility, conflicts of interest, methods and reliability.

Certain research requires approval. This includes research that concerns people as well as research using animals, but also some other types. In Chapter 3, *Ethics review and other approval review*, certain legislation and forms of approval review are described. This chapter also discusses ethical problems and considerations associated with the use of animals in research and with research in foreign countries.

In the handling of research material it is important, already at an early stage, to think about the various interests involved (the researcher's, the participants', other researchers', etc.), what the researcher can promise the participants, who owns the research material, etc. What rules apply? In recent years these questions have been asked so often, by so many, that we have chosen to dedicate Chapter 4 to them. Apart from a slight update, the chapter's text is a direct translation of that which appears in an article by Göran Hermerén, published by the Swedish Research Council in 2007.

In the ongoing changes to the organization and conditions of research, both nationally and internationally, new research ethics questions come up while others are given a new twist and priority. Issues of responsibility in multicentre studies and large international projects are examples that are discussed in Chapter 5, *Research collaboration*.

Publishing research results, looked at in Chapter 6, is necessary if the results of research are to be of any use, either for immediate application or to serve as a puzzle piece in the continued quest for knowledge. The person or people included in the author list is not only important for merit evaluation, but also in questions of responsibility. The roles of reviewer, responsible publisher and editor especially raise ethical questions, as does the researcher's role as supervisor, teacher and expert. These issues are discussed under the heading *Other roles of the researcher* in Chapter 7.

A research ethics problem that often receives attention, even in the media, is *Research misconduct* (or scientific misconduct) and this is examined in Chapter 8. It can involve obvious breaches like fabrication, plagiarism, cheating and the manipulation of data, but also slander, sabotage of colleagues' work, the misleading presentation of one's own merits in applications for funding or positions, etc. A uniform method of investigation for when there are suspicions of misconduct is fundamental, as is a clear and unified sanction system.

The area of research ethics is broad. There are many different laws, directives, guidelines and codes on ethics in research as well as professional ethics that the researcher should be familiar with and follow in his or her work so that it can be conducted in both a legally and ethically sound way. The matter of which documents apply, however, varies depending on the type of research and how it is conducted. Chapter 9, *Key documents researchers should be familiar with*, presents a selection of these documents that the Swedish Research Council's expert group considers especially important to highlight.

In research there are demands on the quality of the work as well as the integrity of the researcher. A well thought-out ethical approach in the researcher's various roles is therefore fundamental. To concretize this, the various presentations also include a number of examples from the research field, many taken from the previous book *Good Research Practice – What is it?* while others are new. These examples are fictive, but not unrealistic. One of the intentions with using them was to show that good research practice, in practice, can entail difficult choices between different courses of action. The question is how one should act in a complicated reality, where different principles and interests can stand in opposition.

1 WHAT ETHICS DICTATE 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. 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. 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 dis-

inction 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 are wrong. By the same token, if knowledge is seen as valuable, we naturally embrace the norm that man 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 summarize 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 with 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 great impact on the discussion around professional ethics. Commonly referred to as the CUDOS (Communism/Communalism, Universalism, Disinterestedness and Organized 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, organized scepticism (OS), requires the researcher to constantly question and scrutinize, 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 organizations 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 rule of *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 the individual 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 like 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, the latest in 2008. 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 funding agency or a financier, an organization of re-

searchers 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, discussed in Chapter 3. However, although legislation in these cases has entered an expressed ethical area this does not mean that ethics and the law have merged or that ethics have been “reduced” to legalities.

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.

Laws can be created for different reasons and can have different purposes. For example, moral arguments and convictions can play an important role in the decision but the cited motives can be something else altogether.

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 organization 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 special 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 “Beginning July 1 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 man just as I would in Sweden.

Another difference between morals and the law is that morals have no explicit system of sanctions. A break with 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 institutions, also places specific demands on the process of application for funding. It is important to note the difference between these different 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. For a brief presentation of the various degrees of obligation of different regulatory systems, see Section 1.9.

On January 1, 2004, the Act concerning the Ethical Review of Research Involving Humans went into effect. 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, Parliament, has made a choice regarding what the boards should review. Research that does not use personally sensitive data (2 §) and does not entail physical encroachment, aim to affect subjects physically or psychologically, or entail an obvious risk of harming subjects (3 §) 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 are also not to be revealed in the published work.

Research projects outside the scope described above thus *can* 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 significant 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 that apply to research even though they do not explicitly address research. A researcher must thus be familiar with and follow these laws, such as the Personal Data Act and the Archives Act.

It is normal that a funding institution, 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 surface 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 head of research, i.e. the educational institution or other similar body or individual, ensures that the research meets the requirements and conditions dictated by Swedish law. In addition, it is required that the project leader is familiar with current legislation and has an understanding of ethical problems, and that he or she secures the necessary permissions and approvals before the research work begins. This division of responsibilities means that an approval from an ethics review board does not need to be sent to the Swedish Research Council, which was necessary in the past.

The fact that some projects do not need to be, and should not be, reviewed in concordance with the law can also lead to other problems. Primarily 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 will thus not be able to be published internationally. To sidestep this undesirable consequence the possibility was instituted to, through application, receive a so-called *advisory statement* from an ethics review board. In this case the board does not perform a review based on the law but rather ethically evaluates 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.

In many cases, the rules in the Declaration of Helsinki actually offer a clearer and more categorical formulation than the text of the Act. This applies, for example, to questions about informed consent (Declaration of

Helsinki 22, 24–29, 34 §§) and about the selection of participants or research subjects (5, 17 §§). But there are also ethical problems addressed in codes that the Swedish law does not explicitly talk about. One such issue concerns which commercial ties can be regarded as ethically acceptable for a researcher who wants to conduct a certain project. The Declaration of Helsinki (14, 30 §§) expressly dictates that all significant economic connections are to be accounted for in applications and upon publication.

The Swedish Research Council, through its general conditions for research grants (“*Generella villkor för bidrag till forskning*”) which the project leader and department head (or equivalent) through signature agree to follow, requires that involved researchers have no commercial ties that are in conflict with the research community’s requirements of objectivity, independence and openness. This applies to any ties involving the entire project, not only sub-projects, and for the whole grant period. In accordance with this stance, economic information and a list of other ties are also requested on the form that is submitted to an ethics review board. The Act concerning the Ethical Review of Research Involving Humans says nothing on this subject, however. Certain ties in research can be questioned even if they are not illegal. As long as the researcher’s integrity, the quality of the research and the observation of openness are not neglected, it is important that the researcher cooperate with authorities, commercial organizations and others to make it possible to develop new products and ideas (for further discussion see Chapter 2).

Another aspect the law does not address is how research material is allowed to be used. A common ethical criterion is that material collected for scientific purposes may only be used to this end and cannot be used as instruction material or for commercial purposes. The ethics review form does not contain any questions about the use of material, and the Act also does not mention anything about the archiving of material or how it may be published. Codes, on the other hand, can be very clear on this issue. The ethics review form does, however, request information on both archiving and publication; it must thus be construed that if something is lacking in these areas the project does not meet the criterion of protecting the research subjects’ integrity, which is mentioned in the Act. On the other hand, the Act says nothing about these particular factors being decisive.

It is most likely that well established codes, primarily the Declaration of Helsinki and the previously drafted ethical praxis for review, have formed the foundation for what information should be considered important and should therefore be provided on the review form. (Important ethical and legal questions about the handling of integrity-sensitive material are discussed in Chapter 4.)

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, generalizability, transferability, reproducibility, transparency, etc. can be interpreted and applied in somewhat different ways within various research areas such as history, the social sciences, medicine and the 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 stigmatization of individuals and groups. Unfortunately, there are also examples of cheating in studies on methods for treating breast cancer or associations 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 (I), in which there is no fundamental opposition between the different 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 criticized.

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.

1.9 Various regulatory systems

Laws are made by Sweden's Parliament, and are binding. *Statutes* or *ordinances*, issued by the government, and *authorities' regulations and directives*, issued with support from laws and ordinances, have the same legal character. Authorities can also issue *general counsel* – recommendations for how one can or should act within a certain area or in a certain situation.

Within the EU there are *ordinances*, 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.

Guidelines can be issued by authorities or different non-governmental organizations and assemblies. Though such documents are not binding, their content can be generally accepted.

Declarations, resolutions and *statements* are also generally issued by organizations 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. Other varieties of declarations that sometimes appear are *recommendations, opinions* and *statements*. These are most often not intended to be binding, but Swedish authorities have found it problematic to depart from, for instance, the Council of Europe's recommendations.

Ethics codes often have an even more pronounced voluntary character. They usually take up 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 organization, the environment, etc.

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SO YOU THINK
WE CAN AWARD
YOU A COUPLE OF
MILLION FOR "A PROJECT
SO SECRET IT
CAN'T BE
DESCRIBED"?

ER, COULD
WE HAVE IT
IN CASH?

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

2.1 The purpose of the research

2.1.1 Some types of research

There are different 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 that the researcher seeks new knowledge without a certain application in mind, and this can lead to unexpected and groundbreaking discoveries. *Applied* and *commissioned* research both have a decided aim. The goal of these two types is to be of use to the party who has 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 in medicine can lead to improved clinical diagnostics and treatment, or be applied in practice in the production or improvement of products, in planning, in decision-making, in changes to organizations and communication strategies, etc. Besides providing knowledge about a specific area, all types of research offer 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 an important element of society. The value of new knowledge is stressed in many different contexts. What is it that makes research valuable? Scientific knowledge has a value not only as an instrument, that is 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 motivated in this way. Later, its results might also prove to be good instruments to promote something we consider useful and beneficial to society; but the nature of research prevents us from knowing in advance where its results will lead us. The desire to know and understand is very often sufficient motivation 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 ability to compete industrially, or creating more job opportunities. It also concerns promoting other values that have to do with *critical thinking*, better quality of life and a revitalized public debate.

Meanwhile, history shows that the intended reasons for research sometimes do not coincide with its actual effects. Research that can make it possible to develop new, 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 thus to optimize the possibilities to use the positive effects of research and minimize the negative ones. A lively ethics debate is an important element of these attempts.

The task of colleges and universities not only includes cooperating with the surrounding society and informing about their activities, but now also includes “working for research results obtained at the college to be of beneficial use” (“*verka för att forskningsresultat tillkomna vid högskolan kommer till nytta*”, ch.I, 2 § Sweden’s Higher Education Act, SFS 1992:1434, with amendment regarding beneficial use through Parliamentary resolution, 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 can be more *personal*, such as curiosity or a desire to solve problems, 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 regarding researchers' personal motives.

The motives for research can come to characterize the intellectual environment and focus of the research. In an environment where the importance of commercialization and patents is singly stressed, room 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 everything else risks appearing isolated and elitist. This type of goal conflict often goes hand in hand with certain types of research, such as clinical research.

The risks involved with goal conflicts are reduced when one is in an environment where a debate is kept alive and where an open and generous view of the researchers' motives is maintained. The important thing is *that*, not *why*, someone wants to contribute to research, and that the significance different motives have for a research environment and for the focus of the research is discussed openly within research groups, institutions 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. Additio-

nally, 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 a statistically significant difference. But if you want to answer the question by comparing the children who have received the flu vaccine, for instance, 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 head of research, 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 institution.

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 than on the importance of the research question. Today, a great many studies are conducted that do not allow for conclusions – and “unnecessary” research is conducted in the sense that its questions have already been answered. This has been shown in, for example, systematic reviews by the Swedish Council on Health Technology Assessment (SBU) of different medical fields.

Funding institutions 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 are 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, 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 can cover injury due to medication regardless of whether it has been determined 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. For the testing of new medicinal substances at universities and colleges, where no pharmaceutical company belonging to the Swedish association for pharmaceutical insurance (*Läkemedelsförsäkringsföreningen*, LFF) participate, the Legal, Financial and Administrative Services Agency (*Kammarkollegiet*) has signed an agreement of association with LFF. These projects are to be reported to a designated contact person at the university or college. For experiments conducted outside the areas of healthcare

¹ *Research subject* refers to a “living person observed for the purposes of research”. Other typical expressions are *subject*, *interview subject*, etc.

there is often no specific insurance that applies, and it is up to the researcher to ensure that the research subjects have sufficient coverage.

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 realizes 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 have blinkers on or be 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 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 defy 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 steer 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 synthesizing a virus that caused a lethal epidemic a long time ago. You realize 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 various 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 benefit ²

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 different ways: some may increase their income, others may get treatment that lengthens their life expectancy, and still others may experience an improved quality of life.

If the aspects of merit and the possibility to compete for resources are included in the concept of benefit, the researcher and the department where the research is conducted can also be said to benefit from the research. 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 new ideas and hypotheses for future research.

Many important discoveries have been unexpected, and have sometimes occurred in the search for something else (e.g., Teflon). They have occurred purely coincidentally (e.g., dark energy) or by mistake (e.g., penicillin).

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.

But it is obviously necessary that the researcher realizes 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.

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 polymerized 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 a commission the researcher has received, in competition with others or not. Finally, funding can also be obtained through grants from a funding institution from 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, that have a specific focus, for instance the Swedish Cancer Society and 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 possibilities 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 financier 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, which your doctoral students are dependent on.

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

Funding institutions, 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 financier 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 commercialization. From society's perspective, it is important that new findings come to 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 financiers 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 financiers, who reimburse the department for the researcher's contribution. Some institutions even have a special organization for commercialization, 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 organization. Research in this context can be of many types: everything from groundbreaking 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 financiers and researchers over the publication and interpretation of results, sometimes leading the researcher to suppress "undesired" 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 certain organization.

What would you do in the following situation?

You are working with technical research on new light, strong materials. You see a possibility to apply for a patent and have started a company along with some entrepreneurs to commercialize the products. However, the commercialization 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 star

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 cru-

cial that a researcher 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 for the surrounding world to be informed if a researcher has a private profit interest in a certain project and for commercial ties, such as details about ownership shares or research grants, to be 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 devaluate. If this should happen, it could cause the researcher to lose credibility for a long time to come. In projects of commercial importance, even the company will 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 recognized within the research community. These principles have also been thoroughly discussed and argued for in theory of science and methodology books.

Different conditions and focuses in a study must be clarified and motivated. 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 characterized by a systematic and critical analysis of carefully collected data. Possible sources of er-

rors should be identified and discussed. The argument 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, this greatly contributes to its quality.

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 that 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 divided, 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 considered at all. 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 generalizability and more or less claimed objectivity of the results can stand 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 socialization of different ethnic groups, etc. Mostly internationally, there are research ethics discussions on so-called participant observation, a method used in the social and behavioural science fields, among others.

2.3.3 Observational studies conducted through participating, observing and recording

For some research questions participant observation, overt or covert, can be used. However, this research method raises a number of ethical problems.

The methods of participating, observing and/or audio- or video-recording can be used in many 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 people’s interaction. In some situations covert participant observation is used, but this type of secret or disguised research is rare and should be the exception rather than the rule.

The ideal situation is always that those who the research applies to should be informed that they are the subject of research, and should also in most cases have given written consent in advance. If the research uses personally sensitive data, or other material that should be ethically reviewed according

to the Personal Data Act (see Chapter 3), approval must be obtained from an ethics review board.

Overt observation studies, in which participants know research is being conducted, are used, for example, to study the work within different organizations 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.

In some contexts, for example during covert observation, the researcher must depart from the requirement to provide information and obtain consent in advance. In this case, these requirements must be met afterwards. If the project falls within the scope of the Act concerning the Ethical Review of Research Involving Humans, the researcher must obtain approval – before the study is conducted – from a regional ethics review board, that he or she can depart from the requirement that information be given and consent be obtained in advance.

Ethical considerations are very important in participant observation. The researcher is responsible for preventing harm and ensuring that the identities of those being observed are not revealed. Although this requirement can seem difficult to meet, it is necessary.

One way to observe people is to video-record them. Research using video can intrude on individuals' private lives and integrity, since it is possible to identify them. Video-recording should thus only be used when it would be impossible to reach the same results using 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 filming be done in a respectful and responsible way. The individual's integrity should be respected. If underage subjects are to be filmed, the same rules apply as in other research on children. This means that if a child is under 15 years of age, both guardians as well as the child must consent to participate. The information about the study should be written so that the child can understand it.

Just as in other research, video-recording should be preceded by detailed information and then consent. This information should describe the aim of the research and stress that participation is voluntary. Those who are asked to participate should also be informed about exactly what the researcher intends to analyse in the video as well as why other forms of recording are not considered appropriate or sufficient.

Also, the information (which should be provided both orally and in writing) given to the informants should contain more detailed information about the following:

- Whether the video will be edited, e.g. to disguise people's faces and/or voices
- Whether copies will be made of the video, and if so how many copies will be made
- Whether the video will also be used for other purposes than the research, e.g. in teaching
- Whether other analyses besides those already accounted for will be performed – in such cases, both the regional ethics review board and the informants must give approval
- Whether the informants will have the possibility to watch the video (this is preferable)
- That any associations between the video and other personal data will be coded
- How and where, and how long, the video will be stored

After an informant has been given detailed information, consent should be obtained according to the procedure above, normally in writing. In some research fields, though not all, it is customary that consent is given in two steps: first, the informant is allowed to express an opinion on and, if applicable, consent to the video-recording. Then, after the informant has had the chance to watch the video, he or she has the opportunity to give consent for the researcher to continue the work of analysing it. Sometimes consent can also be given to show the video to people named in advance, such as researchers, students, patient associations or the like.

The informant should verify that he or she has received information that it is possible to at any time withdraw the consent for the researcher to analyse, use and show the video. In the research protocol as well as the information given to the informant, it should be stated whether or not the video material will be destroyed if the informant withdraws consent. If it is stated that the material will be destroyed in the case of withdrawn consent, this should be done – or the video should be given to the research subject, as long as he or she is the only one in the video. If more people are in the video, the identity of the person not wishing to participate should be edited out if possible.

A video should be stored securely, so that it is inaccessible to unauthorized people and is not destroyed due to carelessness. If the video material is transferred to a computer, the computer should naturally be password-

protected. The researcher must ensure that only those who are authorized have access to the video.

2.3.4 Sources of error and reliability

When a scientific study starts to produce results, you are faced with the difficult 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 overestimating the significance of the results you have arrived at and exaggerating their holding power far beyond the area in which you have found them to apply.

Within most research traditions a careful error analysis, or at least a discussion of possible error sources and other conditions that might affect the soundness of the results, is required. 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 that you 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 vari-

ous ways in the name of science. This was the general aim 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 must not 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 various types, some other issues have now come to the fore. This type of research is based on data and information about people, which are collected and analysed. The research subjects contribute in a different way than those who directly participate in, for instance, clinical trials of new medicines. Those who contribute to a register study do not need to be aware that they are part of the study and thereby an object 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. Study design and the presentation of results are important elements in alleviating unfounded (or well founded) worry over discrimination and stigmatization. The likely value of new knowledge must thus be weighed against the risk that subjects' integrity will be compromised and the need to protect people's 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 brought up new research ethical issues. With questionnaires and interviews, the requirement that the participants' identities are protected is met through the use of code keys and by masking and anonymizing their 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 and nano research have garnered a great deal of interest, as have the commercialization of research and the effects of research on the environment and society from a more global perspective. Besides traditional research ethical 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 fertilized egg's moral status and, for instance, whether methods like nuclear transfer from one cell to another are ethically acceptable. The existence of gaps in knowledge and uncertainty, about what happens when nanoparticles 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 point to the need for method development in this area.

Issues concerning the commercialization 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 globalization 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 financiers. This enables research that might otherwise not have been possible to conduct, but also brings to the fore issues of control, dependency and the supervision of research.

Human rights are universal. Because research ethics principles are based on and protect these rights, they can be accepted in various cultures. At the same time, they 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 is thereby placed in a cultural and social context. Some values reflect technical and economic development, while others are more slow to change and are based on more basic human needs.

3 ETHICS REVIEW AND OTHER APPROVAL REVIEW

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

3.1 Ethics review and other approval review of research involving humans

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

On January 1, 2004 the above-mentioned law (2003:460), the Act concerning the Ethical Review of Research Involving Humans, went into effect. Some changes were made to the law in 2008; the presentation below refers to the law after these changes. There are also other laws whose content makes them applicable to research, for instance the Personal Data Act (*personuppgiftslagen*, PUL) and the Archives Act.

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

It is the researcher who, together with the head of research³, applies for ethics review, when the research falls within the law's description. With post-graduate projects, it is the supervisor's responsibility to see that they are ethically reviewed. If you are not sure whether an application is necessary, it is possible to contact the applicable regional ethics review board (*regional etikprövningsnämnd*, REPN) with your question. Simply starting or

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

completing a research project that falls within the law's description 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 responsible parties) and the type of application (new project or supplementary application), and a special form is used for application. For concrete information on how to apply and who should apply, as well as forms, etc., see www.epn.se or the CODEX website at www.codex.vr.se.

A research project should 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,
- carries an obvious risk of physical or psychological harm to the research subject, or
- entails studies on biological material that can be traced to specific individuals.

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

- entails the handling of sensitive personal data according to 13 § of the Personal Data Act (SFS 1998:204), including information on race, ethnic origin, political views or religious conviction, or personal data according to 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 is to be ethically reviewed, regardless of how the data has been collected and whether or not the researcher has obtained the participants' consent. (This is stricter than in the first version of the law.)

When an ethics review board evaluates a project, it has a number of aspects to note and take a stand on. 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. People's welfare should be placed before the needs of society and science, and the value of the knowledge the research will contribute must be considered to outweigh 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 design.

For the board to be able to approve certain types of research, *informed consent* must have been obtained from the participants (research subjects, etc.). The law also briefly describes what should constitute this consent and from

whom and how it can be obtained. For example, in research on children or the psychologically disabled it can be necessary to obtain consent from a guardian or custodian.

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 physical or psychological 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.

The further standards for consent in the Declaration of Helsinki, however, can entail that informed consent has to be obtained anyway, so that a research project can actually be carried out (see, e.g., Chapter 9).

Research projects that fall outside the scope of the Act concerning the Ethical Review of Research Involving Humans can naturally 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 institutions, 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 2007:1069 with instructions for regional ethics review boards, 2–3 §§). This allows the board to state that they see no ethical obstacles to conducting the project. This corresponds to an approval based on review according to the law. An advisory statement can also contain advisement 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, and their offices are in Göteborg, Linköping, Lund, Stockholm, Umeå and Uppsala. There is also a central ethics review board (CEPN), in Stockholm. The boards, that is each REPN and the CEPN, are individual authorities and are independent of each other. Applications and decisions are public, and can be acquired from the board in question.

A head of research who has received a rejection from an REPN can appeal this decision and have the project reviewed by the CEPN; there is an extra

fee for this. A regional board also has the possibility to turn a case over to the central board, if its members are not in agreement for some reason.

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 an ordinary judge, and has ten members with scientific competence, of whom one serves as scientific secretary and five represent the general public.

The central ethics review board is also headed by a chairperson who is or has been an ordinary judge. It has six members, of whom four have scientific competence and two represent common interests. Here, too, one of the scientific members serves as scientific secretary. A number of legal counsel also work at the Stockholm office of the central ethics review board.

In addition to the task of addressing decision appeals and cases handed over from regional boards, the central board also monitors the observance of the Act concerning the Ethical Review of Research Involving Humans and the provisions issued with support of the law.

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 required that approval be obtained from the Swedish Medical Products Agency (see 13–14 §§ of the Medical Products Act, 1992:859). This also applies to trials on 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 are to be conducted (rules and general recommendations regarding clinical trials for human use, LVFS 2003:6, with changes made in LVFS 2006:1). Application to the Medical Products Agency should be made by the sponsor, that is the individual, company, institution or organization responsible for starting, organizing and/or funding the clinical trial. More information on regulations and the steps of the application process can be found at 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 provided to the general public via the website www.clinicaltrialsregister.eu. On this website, things like ethics committee decisions regarding clinical trials on children will be publicly accessible.

To conduct a research project involving the irradiation of research subjects with ionizing 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 ionizing radiation, SSMFS 2008:35). For multicentre studies, an application must be sent to all local radiation protection committees within the study's scope.

According to 10 § of the Personal Data Ordinance (1998:1191), the automated processing of personal data on constitutional genetic predisposition that has resulted from genetic testing must be reported to the Data Inspection Board at least three weeks before the processing is to be performed. This applies whether or not the data are deemed sensitive and whether or not the treatment will be performed with consent. It is a punishable offense not to report this.

3.2 Research on animals and animal ethics

3.2.1 The use of laboratory animals

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 man, and partly for the sake of animals themselves.⁴

⁴ 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 estimates that half a million laboratory animals were used in Sweden in 2008. Sweden's definition is considerably broader, however, including all animals used for scientific purposes. Based on the Swedish definition, the Board of Agriculture estimates that 6.8 million laboratory animals were used in Sweden in 2008, of which 5.8 million were fish collected to evaluate the fish population in Swedish waters; half a million were used in studies of behaviour, living conditions or livestock management systems or were euthanized for the use of their tissues or organs or to serve in the development of patents, etc.; and half a million were actually subjected to invasive procedures, at minimum a needle-prick (the Swedish Board of Agriculture, *Användningen av försöksdjur i Sverige under 2008*, report dnr 31-502/09, table 1).

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, not to mention their being used in treatment, before they have been tested on animals or through another appropriate method to arrive at dependable research results.

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 people's health and the environment.

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

An EU directive on the welfare of laboratory animals and the ethics review of research on animals was recently passed (2010/63EU),⁵ with the purpose of harmonizing existing laboratory animal welfare contributions 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; however, a country is allowed to have stricter rules if they were already in place before the directive went into effect. In the Swedish case, another change is that research on squid must now be ethically reviewed. All countries have two years to incorporate the directive into their respective legislation, which means that certain adjustments will likely be made in the Swedish Animal Welfare Act. Information on this process can be found on the Board of Agriculture's website at www.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

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

concerning views on mankind, that is humans' essence, function and task, and not least their position in relation to other living beings. In addition, ethical notions regarding animal experiments are influenced by our common 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. This is clearly demonstrated in the so-called paradox of animal experimentation, which summarizes the dilemma that animal experimentation entails: *we use (non-human) 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 motivate the suffering we cause)*. (See also Rodman.) This paradox is not new; it has existed as long as animal experiments have been conducted, at least since the ancient world. Man has always stood in relation to all other animals, but different notions of how people should relate to animals have been dominant at different times and have reflected the norms and values of those times and cultures. It cannot be assumed that a unified view would exist on how this human-animal relationship should look within one and the same era and culture.

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

3.2.3 The ethics committees on animal experiments: their organization and task

Experiments using animals can only be conducted at a facility approved by the Swedish Board of Agriculture and 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 established 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. All documents are available to the public, and are kept by the respective committee. Alt-

though it is highly unusual, a decision can be appealed to an administrative court. A total of approximately 1,700 applications are reviewed yearly.

The responsibility for the ethics committees on animal experiments and the review function, which since 1979 had rested with the Central Laboratory Animals Board (CFN), was moved to the Board of Agriculture in 2007 (after the review function had been performed by the Animal Welfare Authority during the period 2004-2007).

There are seven ethics committees on animal experiments in Sweden in six university towns (Stockholm has two committees). Each committee has fourteen members.

Some facts

The chairperson and vice chairperson of the ethics committees on animal experiments are members of the legal profession, and of the twelve other members half are scientists or staff who work with laboratory animals and half are laymen, of whom at least one represents an animal welfare organization. It is a 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 importance of the experiment against the suffering inflicted on the animals and determine whether the importance is sufficient to justify the animals' expected suffering. This is a difficult 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 on how the animal can be affected.

Central questions that must be answered by the applicant for the committee to be able to make an adequate judgement 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 all applications.

A researcher who wishes to make a sound decision in the question of whether or not an animal experiment is motivated must, just like the ethics

committees on animal experiments, consider the purpose of the research by *weighing the expected importance 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 research itself. He or she must think about whether, for example, it applies to a great number of people – each suffering relatively little – or if it is a matter of only a small number of people who each have a great deal of suffering or a handicap that affects their everyday lives.

The application is submitted on a special form and according to the instructions provided by the Board of Agriculture (D174), www.jordbruksverket.se. Before a committee can make a decision on the application, the research department's responsible administrator must approve the experiment in its entirety and guarantee that the necessary resources will be available.

Then, the committees' task is to make their legally binding decision on the application and 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 laymen's task is to confirm the societal importance of the animal experimentation and 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. The committee has the right to reject an application if it is incomplete, but in practice this occurs very seldom. Instead, the committee can request supplementary information on those parts it deems insufficiently described or discussed. Many applications are therefore supplemented before being addressed by a committee. When necessary, a committee can also summon the applicant to a meeting to clarify something, or call on an expert for an opinion. The committee can rule 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 unity among the committees, a three-part categorization has been established. Based on this, the applicant him or herself judges whether the experiment in its entirety entails mild, moderate or severe suffering

for the animal – this is the experiment’s so-called classification of severity. Here, both researcher and committee can refer to the list of experiments according to degree of difficulty 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 various reasons for this. Reasons can include the researcher not wanting to cause animals to suffer, or that it is relatively costly to house animals. A third reason, which is being discussed more lately, 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 agreement. This implies partly that animal experiments and clinical trials may need to be better coordinated, and partly that animal experiments do not always provide meaningful information for the treatment of humans (Perel et al. 2007). An example of the latter instance is studies aimed at developing methods for treating rheumatoid arthritis by studying patients’ tissue samples (Klareskog L, Rönnelid J 2008). Here we can see two of the motives 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 to, among other things, better evaluate and calculate side effects of cancer treatment. Cells can also be cultivated, for instance to test the effect of certain chemicals on reproduction or to use cell models to test for adverse side effects of medication on the liver.

In Sweden there is governmental support for research grants for alternative methods to animal experimentation, according to the principle of the three Rs (i.e. methods that refine, reduce and/or replace animal experiments), which can be applied for through the Swedish Research Council. It is also possible to apply for research grants from the Swedish Fund for Research Without Animal Experiments, at www.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 organization 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 Ethically evaluating 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 acceptable. Every experiment, however, must be preceded by an ethical evaluation. The following concepts, given in italics, can help in highlighting important questions to ask in this evaluation of what is ethically acceptable.

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*. It is common that intrinsic value is 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. It can be of varying degrees depending on the user or beholder.

It is not unusual for an individual to be regarded 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 (Brambell, R, 1965).

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 ques-

tion. 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 (Cavalieri, P, Singer, P, 1994). 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 value* and integrity – and therefore rate a high level of protection. It is unrealistic to believe that we can arrive at one single all-inclusive reason why humans hold this exceptional position. Perhaps the philosophers are right when they say it is impossible to motivate it in any other way than to say that someone born by a person thereby has the right to a certain moral protection that is not afforded other living beings (Egonsson, D. 1999). 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 questions we choose to conduct research on, 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?

More than 33 million 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 man, is the only animal 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? Think from both a researcher's and a layman's evaluation perspective.

3.3 Genetically modified organisms

Work 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, falls under a detailed system of rules. 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 authorities, www.gmo.nu.

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 unauthorized 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 possible 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 as a whole will be conducted in another country, even if researchers from Sweden participate and Swedish funders contribute money. Ethical standards that are self-evident in Sweden can 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 or cheaper to conduct studies, or involve less extensive application procedures. If these advantages come at the cost of the integrity of the research, in many cases it involves a violation 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 are to inform funding institutions 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 institutions and journals.

Here, the Swedish legal requirement of ethics review is less comprehensive. However, as mentioned earlier, in Sweden it is possible 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 when 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 do to so. In cases in which a regional ethics review board has refused to issue a statement, this has had serious consequences on the researchers’ possibilities to obtain further funding and to be published. It is desirable that a legal obligation be established for the ethics review boards to issue statements to those who request them – or at least that this become common practice.

There are issues concerning the withdrawal of consent that are problematic for research ethics. In biobank research, the research subject has the possibility to withdraw 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 rules on the 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.

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HOW MANY
INDIVIDUALS ARE YOUR
STATISTICS BASED ON?

SORRY, I CAN'T
DISCLOSE HER
NAME!

4 HANDLING OF RESEARCH MATERIAL

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", published on the Swedish Research Council's website in 2007.

4.1 Background and problems

The fundamental openness in all public organizations 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, with the latest update in 2008.

However, the Declaration of Helsinki is not legally binding. This was reiterated by the Swedish Court of Appeal in western Sweden in a case a number of years ago that received a great deal of attention, and the European Court of Justice recently (2010) upheld the ruling of the Swedish court.. The issue was a request that a researcher in Göteborg make public the research material from a controversial study on children with neuropsychiatric disabilities.

Thus, 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 come up 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 can be revealed in studies).

In these cases, the requirement for public access, openness and transparency sometimes comes into conflict with the requirement to protect research subjects' and informants' personal integrity. 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 general discussions on ethical issues in the handling of integrity-sensitive material. Awareness of both the rules and problems needs to increase within the research community.

4.2 Interest considerations and various types of research

In research one must, in a reasonable way, compare the importance of many types of interests – all of which are legitimate but 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 life protected, and patients' interest in information they have given their doctor remaining only between them.

Funding institutions for basic research, like the Swedish Research Council, have an interest in openness and transparency. The Swedish Research Council does not support secret research. Other funding institutions can, from a societal perspective, have an interest 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. Integrity protection in connection with research must be provided in forms that are in agreement with the provisions of the Archives Act.

How this weighing of interests is done depends on aspects including what 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 Law on Patient Data and the Archives Act apply. It is therefore important to keep different 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 collected material 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 the various authorities, primarily the Swedish National Archives.

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 addressed in a paragraph in the Official Secrets Act.

Standards for *professional secrecy* apply to some professions through law as well as ethical rules. All who work within healthcare, dental healthcare and social service, for instance, must observe professional secrecy. This means that they are not allowed to discuss patients' and clients' health or personal situation with unauthorized individuals, or in any other way communicate this information. Similar standards for professional secrecy also apply to, for example, psychologists and clergy.

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

Confidentiality entails protection from unauthorized individuals gaining access to the information, but the research group can use code keys to associate information or samples with specific individuals – which is usually necessary in longitudinal studies, for instance, or in order to be able to scrutinize the research. The question of who is and is not authorized, however, is not something for the researcher to ultimately determine. 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 be 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 studied subjects.

4.4 What can researchers promise?

There are some things researchers are not allowed to promise and yet do 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 are to be publicly accessible and that information can fall under the category of secrecy only if it is covered by a specific paragraph in the Public Access to Information and Secrecy Act. The protection this provides is limited in time. The law contains a chapter that addresses secrecy for the protection of the individual in research (Ch. 24). But in addition, the law contains many other provisions that the researcher may have to address, for instance regarding secrecy for the protection of the individual within healthcare in Chapter 25 of the law.

Most of the regulations on secrecy include a damage prerequisite that determines the extent of the secrecy. When it is requested that information covered by such a secrecy regulation be made available, the authority where it is being stored (e.g. a university or a county council) is required to evaluate whether this can be done. In some cases the secrecy is absolute; that is, the information covered by the regulation is to be kept secret without damage review if someone requests access to it. The decision in an individual case can be complicated by the fact that the law also provides exceptions to the secrecy requirement as well as secrecy-breaking regulations.

Those who are interested can read more about issues of official secrets in a handbook published by Uppsala University (in Swedish), *“Hantering av allmänna handlingar vid universitetet”* (3rd edition, 2009), which can be downloaded from the university’s website (<http://regler.uu.se>; select *Universitetsövergripande maldokument/Kommunikation/Arkiv och registratur*).

4.4.2 Professional secrecy?

Professional secrecy is related to secrecy. Secrecy includes professional secrecy, since information being deemed secret also entails a requirement of professional secrecy about it. However, the opposite is not true.

If professional secrecy applies within a certain project, this does not necessarily mean that what is said during this project is automatically deemed to be secret or that it falls under the Official Secrets Act. Furthermore it can happen that a researcher, through his or her work on a project, becomes aware of something that legally must be reported (e.g. child abuse or paedophilia). In such cases, the obligation to report outweighs the secrecy requirement; professional secrecy thus does not take precedence over Swedish law.

4.4.3 Anonymity?

In some cases, the anonymizing of information is a condition set by an ethics review board for its approval of a study. This can be done, for ex-

ample, by cutting away personal information on completed questionnaires or samples, making it impossible to associate a certain answer or sample with a specific individual. In some types of studies the individual person's identity is not relevant, for instance studies on variations in positions on a certain issue in a specific group over time. In such situations, researchers can naturally promise anonymity.

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

4.4.4 Confidentiality?

The Declaration of Helsinki also stresses the importance of confidentiality and of the researcher taking measures to protect research subjects' integrity and right to the protection of their private life. This is stated in Article 23 in the latest version of the Declaration from 2008, 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 minimize 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. It could be a case of, for example, 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 can 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 collected material can be 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 requires it), 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 research subjects the measures taken to prevent, or reduce, the risk that sensitive personal information will be spread. 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 naturally a risk that some people 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 under the condition that they assume or take over the professional secrecy promised by the previous researchers.

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

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 long period of time. But it is neither ethical nor legally acceptable for an individual researcher or research group to deviate from the rules due 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 acceptable? 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 personal property. This can possibly be the case if the research is privately funded and conducted by individuals not associated with normal research environments.

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 organization 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 organization and fall under the Official Secrets and Archives Acts.

The material from a completed research project should therefore be stored and archived, and if it is integrity-sensitive there are special requirements on 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, research results must be able to be verified,⁶ 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 can also be of great value in itself, for example if it documents the conditions in society today which future generations may have an interest in.

Whether, when and how an organization can sort material is addressed in the Archives Act. If material is considered valuable, for instance for the way our current society will be regarded in the future, it should be saved. The National Archives should be consulted as to how to proceed. Certain material that is over ten years old can be transferred to the National Archives after an agreement has been reached in the matter.

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

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.

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5 RESEARCH COLLABORATION

5.1 Introduction

Research is an activity that involves the accumulation of significant amounts of knowledge, and its results can be of lasting value for many people. That means that research can be very rewarding for the 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 fundamentally collaborative endeavours, with a large number of interested parties.

In fields of research where large-scale projects need to be undertaken, perhaps involving heavy investments in instrumentation, large computer programs, massive 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, possibly including hundreds of researchers scattered across the globe. Such collaborative projects do not come about by themselves.

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

5.2 Relations with fellow researchers

Perhaps the most common reason for establishing scientific collaboration is to broaden the capabilities available 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, 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 in 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. The division of labour should be a realistic one. It is important to establish a time plan for the various parts of the project, even if it has to be updated as the work progresses. 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 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 crystallizes out, with some researchers not contributing in accordance with 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 different roles which various participants assume in a collaborative research project are not always what everyone would wish. 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 different participants’ contributions. 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 postgraduates 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 PhD 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 or the like. 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 different 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 realize 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 organizations. Sweden is often represented on the governing bodies of such organizations 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 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 organizations concerned.

5.4 Commercial aspects

A growing proportion of Swedish research is paid for by external funding organizations, 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 foots part of the bill for such research projects. According to the Swedish Research Council's current (2010) rules, a researcher may not allow another funding body to defer publication for more than two months, if it is not a case of a patent application (in which case publication can be deferred for up to four months). Many public funding bodies have similar rules.

The largest international database for the registration of clinical trials is the US-based ClinicalTrials.gov, developed by the National Institutes of Health (NIH) in collaboration with the Food and Drug Administration (FDA) in response to a law established in 1997. There are rules dictating the conditions under which ongoing studies are to be reported to and registered in the database, among other reasons 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 organizations when, as often happens, they involve PhD 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 PhD 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 is taking care of publication, and publishes the studies with the results most favourable from its point of view 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 are to be assigned (either wholly or partially) instead to the university where the work has been 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: in 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) has to 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 agencies will seek to clarify the real management structure of projects and the capabilities of those actively involved in them. It makes for greater 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, and clearly that applies especially to large-scale projects. Such projects, moreover, have resources which they can devote to this purpose. Resources also need to be set aside for documentation.

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

What would you do in the following situation?

Your research group has become part of a major international consortium that is to build a large instrument at a synchrotron light source. You take on the task of developing the sensitive detector system, a project that involves you yourself as research group leader, two postdoctoral fellows, a research engineer and two PhD students.

Two years into the project, the most important partner in the consortium pulls out. The group concerned now has new leaders, with different priorities. An American group is prepared to take its place, but they also want to provide the detectors, to a different design which, it turns out, outperforms your own. The other members of the consortium seem inclined to accept the American offer, leaving the work which you, and especially your PhD students, have put into the project out on a limb. What is more, there is a risk of you ending up with no funding for your group.

If, on the other hand, you can persuade the research council to increase its grant to the project as a whole, you could use it as an argument for keeping your group involved. You would be able to “buy your way back” into the project.

Do you try to secure a larger grant, despite the fact that, scientifically, the project would benefit from the American detectors?

5.6 Questions of responsibility in multinational research projects

5.6.1 Starting points

Questions 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 the research and professional ethical literature, but they have been addressed in connection with investigations of research misconduct. Who bears the responsibility for inconsistencies or for intentional or unintentional mistakes?

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 distribution 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 financiers like 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).

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 these actors, others include financiers, participants and collaborators in the research project:

- 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 coordinate 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”, of which the coordinating research director is usually Chairperson.

A reasonable starting point is that each research director on his or her respective level is responsible for ensuring that the control mechanisms at this level are 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 comprehensive 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 morally and legally) and responsibility for different issues.

What would you do in the following situation?

A large multinational research project, partly financed with funds from the medical technology industry, is testing a technology this industry is marketing and is criticized 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 financier.

You suspect that someone has made a mistake, possibly unintentionally but perhaps to benefit certain interested parties. Should you report this? To whom? The project employs a great 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, many researchers' careers can be damaged. But if you do not report it, you could be contributing to the research being misleading and the medical technological device being used incorrectly and causing harm, or even risking people's lives.

5.6.2 Conditions of responsibility

What conditions must be met when it comes to responsibility? This question can have both a descriptive and a normative sense. In the first case, it refers to the conditions that apply in different contexts, while in the second it refers to the conditions that should apply – perhaps with reference to the guidelines according to which one is conducting the research.

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 of responsibility is that the person who is held

accountable must be able to influence or prevent things he or she is responsible for. 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 complemented with other conditions. In some cases, it is not sufficient that a person held accountable for something that has happened has influenced or neglected to influence it. It is also required that he or she realized the consequences of his or her actions. Knowledge and intent clauses can thus sometimes be needed as a complement to the causal conditions.

Normative clauses on carelessness can 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 take action to prevent it, though he neither realized he was doing this nor intended to do it. But he should have realized it. In this case, a carelessness clause can be cited.

It can be a good idea to carefully clarify the responsibility of people farther down in the hierarchy as well. This can 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; to say this is not to suggest that it is necessary to reduce the management capacity of international and national research directors.

What would you do in the following situation?

An investigation reveals that a researcher has broken international rules and thereby proven herself unsuitable to continue as research director and supervisor. However, the vice-chancellor at the university where the researcher works chooses to ignore this and lets her continue in these positions. A number of colleagues who question this are 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?

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 can 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 laws apply and how they 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.

Article 2 (f) of the EU Directive states that “The investigator is responsible for the conduct of a clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the leader responsible for the team and may be called the principal investigator.” In this definition, “investigator” can reasonably be interpreted as referring to the locally responsible investigator.

A sponsor, according to 2 (e) of the Directive, is the party who is responsible for initiating, managing and/or financing a clinical trial. The sponsor can be an individual, a company, an organization or an institution. Article 9 of the Directive states the sponsor's responsibilities. The sponsor is not allowed to begin a clinical trial until the ethics review board has issued a favourable opinion. It is also the sponsor (not a coordinator at any of the levels discussed earlier) who is to submit the application for approval to the proper authority in the country where he or she intends to conduct the trials. Article 10 discusses the conditions under which amendments can be made to the trial protocol, and who the sponsor should notify of this.

An important paragraph in the Act concerning the Ethical Review of Research Involving Humans is 11 §, which states 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.

Chapter 3, 1 § of the Swedish Medical Products Agency's regulations and general advice on clinical trials of drugs for human use (LVFS 2003:6) states, among other things, that in multicentre trials the contact that is necessary between the Medical Products Agency, the sponsor and the responsible investigators at the participating trial sites can be handled by an investigator assigned with coordinating the work at the various sites, i.e. the coordinating investigator. It also notes that the same competence standards apply to coordinating investigators as those for responsible investigators, even if the coordinating investigator does not bear personal responsibility for a trial site.

Further, it states that it behoves the responsible investigator to ensure that there is access to suitable and competent personnel, that the necessary resources are available, and that those working on the project receive relevant information about the trials. The evaluation of whether these standards have been met is the responsibility of the ethics committee.

In the same document, in Chapter 3, 9 §, it is established that the sponsor is responsible for seeing to it that those working with the trials in the sponsor's organization have sufficient competence to perform the tasks assigned them, as well as for ensuring that there are written instructions for conducting the work and that these are followed. The sponsor is also responsible for ensuring that continuous quality control (monitoring) and quality assurance (auditing) are performed on the methods used and the data collected.

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. The same applies in cases of conflict of interest.

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 organizing 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 possibility 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 the discussions during such meetings.

The same applies to the all-important publishing phase. There are a number of international guidelines to follow here, for example the so-called Uniform Requirements which are discussed in other parts of this book (see Chapters 6 and 9). The coordinating research director has to see to it 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, this delegation must be clear and everyone affected by it needs to understand what they are responsible for. However, such a delegation does not free the coordinating research director from ultimate responsibility. He or she is to 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 logs 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 on national and international levels are responsible for presenting the possible 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?

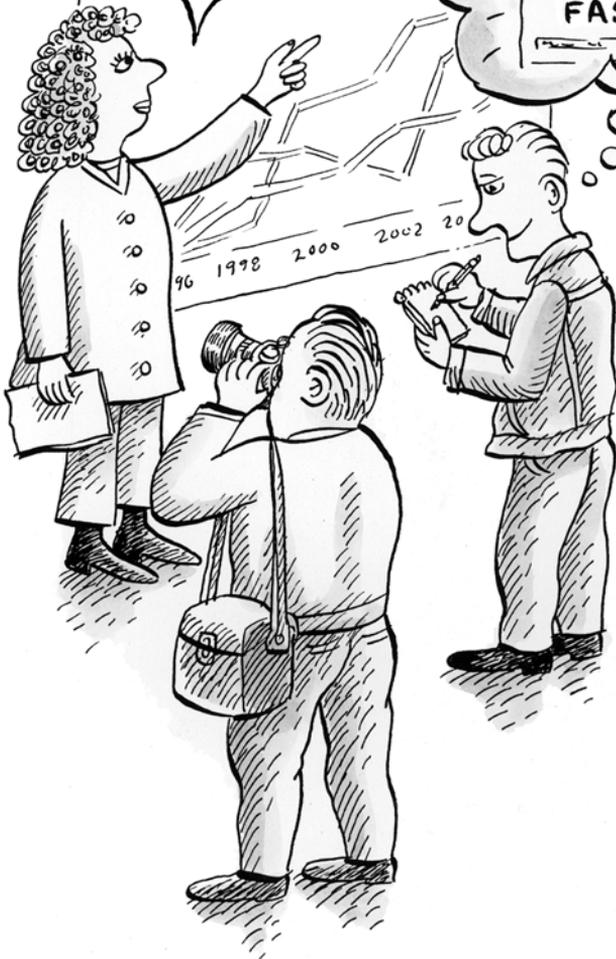
What do you do, if you have the possibility to influence the case? How do you motivate your decision? Is there common practice or some rule you believe you can cite?

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...THE RESULTS
SUGGEST A
SLIGHT RISE IN ROAD
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TO WILDLIFE...

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**KILLER
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SPREADING
FAST**



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, say, only to publish them if a particular outcome is obtained.

Research results are normally reported in writing, either in book form or as articles in scholarly journals. In many fields of research, for example in medicine and the natural sciences, it is now common in Sweden and other countries 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 PhD student alone.

In the humanities and social sciences, the monograph – a single, coherent text, written by the PhD 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.

Publication serves several purposes. Only if the results are made public does the research conducted contribute effectively to the transmission 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 scrutinize and discuss the results achieved. The report which the researcher presents consequently has to meet a number of quality standards.

In addition, publication serves as an announcement of what the investigator (or group) 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 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. According to the Swedish Research Council, currently (2010) a researcher may not allow a body providing co-funding to delay publication for more than two months, unless a patent application is planned, in which case a time limit of four months applies.

6.2 Disclosure of financial and scientific dependence

When publishing one's results, it is important to 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 organization 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 scrutinize 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 missing data must be reported and the statistical analysis clearly explained. Empirical studies must also be presented in such a way that their reproducibility can be tested; and 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. An account of the assumptions underlying the conclusions drawn, the limitations of those conclusions and the area in which they apply, for example, and a discussion of possible objections are crucial quality factors in the publication of research.

6.4 The “third task” and the media

According to Chapter 1, 2 § of Sweden’s Higher Education Act, one of the main tasks of the country’s universities is to inform the general public about research. This usually is called the “third task” and is often achieved through the media.

It is important in this context for researchers to understand that the media are concerned with discovering and transmitting 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 clear tendency to stress the dramatic are part of the basic strategy in most media.

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

The public’s trust in research is the foundation for public funds being used to support research. Therefore, researchers should make it a point to inform the general public about new research results much more than they do today, but also address and discuss current scientific issues brought up in the news and public 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 is to decide 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 were the first time this had happened? Does it depend on what type of issue he talked about?

6.5 Open access and publication on the Internet

A form of publishing that is becoming increasingly common is publication on the Internet – electronic publishing – which can take two different forms. One is original publication in online journals that correspond to traditional ones except for the fact that they do not issue a printed version (these can have a fee or allow so-called open access, i.e. free access and use). The other is supplementary publication, in which a manuscript published in the traditional way is also made available on the Internet through parallel publication.

The parallel publication can either have the same format as the original or be an “author’s version” (the way the text looked before it was formatted by the publisher). Today, universities often also require that a doctoral students’ thesis summary be published on the Internet.

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 signers of this declaration mean to encourage researchers to publish their results on the Internet and allow free access to them, to develop methods for ensuring the quality of online publication, and to work towards open publication being counted as a merit in the evaluation and hiring of researchers.

Additionally, the Swedish Research Council has declared that researchers granted funding from the authority are to publish their scientifically reviewed texts in journals and from conferences in a way that is accessible to everyone. As scientific authors are not normally paid for their articles, they lose no income by allowing the free distribution and use of what they have written.

Open access to scientific publications has a number of advantages. For the researcher, it is an excellent way to quickly present results and make his or

her texts easily accessible. It makes publications available to researchers at departments that cannot afford to subscribe to expensive journals, as well as to students and teachers who can freely use them for educational purposes. The more readers a text has, the greater the chance is that it will be of benefit. The OECD has strongly stressed that scientific work supported by public funds should also be accessible to everyone.

However, it is important that researchers – at least for now – check a journal's or publisher's terms before parallel publication. Which version, if any, can I publish without violating the copyright and do I need the publisher's permission? There is also reason to consider whether it is a good idea to publish author's versions. If the journal has edited the text or made substantial changes to the proof (i.e., the publisher's version), there can be two different versions of the text. This can cause confusion and may lead to the lower quality version being cited.

Finally, there is a problem of the costs of electronic publishing – albeit significantly lower than those involved with publishing in paper format – often falling on the author(s) via fees. Doesn't this shut out certain people or groups with limited economic resources?

For now, the Swedish Research Council's rules concerning open access only apply to scientifically reviewed texts in journals and conference reports, and not monographs or book chapters. This applies to the Council's publications from the beginning of 2010 and onwards. A researcher can also present his or her research on a personal website, as an e-book or through RSS channels, on blogs or wikis, etc; however, the customary requirements of collegial review should always be applied.

The technological development has also brought with it the beginnings of a thorough change in the area of scientific publication. To follow this development, see for example <http://openaccess.kb.se/>, a blog that provides information on the ongoing development and discussion.

6.6 Publication as a measure of worth

Since the number of published works play a decisive role when the merits of researchers are compared, for example when he or she is applying for a position, there is a temptation to break research results down into “least publishable units”, so as to be able to present a larger number of titles. 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 which 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 can be mistakenly listed separately, 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 review 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. A publication with no citations has no value whatsoever in the bibliometric model.

In sum, 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. Probably it is 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, even when the results are published outside traditional academic circles. If authors foresee a risk of too much being read into the results in the media, they have a responsibility to try to preclude that risk, especially if it might cause harm to third parties.

In general, a good scientific presentation will include an active discussion of the results by the author. That 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 of 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*, 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 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 different authors' contributions are also not taken into account. 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 opportunity to be 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 possibility to approve 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 naturally 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 jeopardized 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. The author in question had in other words 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 was he in a position to influence the drafting of the articles or to choose not to be listed as co-author if he had felt unable to accept the contents. And obviously he could not have approved the final versions of the texts.

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 have been 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. In our opinion, 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 what is more is 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?

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7 OTHER ROLES OF THE RESEARCHER

Demands for quality and integrity are also relevant to discuss in connection with tasks associated with the researcher role. Here we will discuss the roles of supervisor, teacher, advisor and committee member.

7.1 The supervisor and postgraduate supervision

7.1.1 The tasks of the supervisor

There are many ways to be 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 students and guide the research which they are undertaking.

One important task is to work with the supervisee to define a suitable thesis project and to draw up an individual plan of study consistent with the general plans laid down by the faculty and the department. The extent to which postgraduates are able to choose and shape their research topics can vary, however. In some research areas 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 possibility to influence this. It is therefore important for the supervisor to discuss with the supervisee, before a topic is chosen, the basic requirements of the intended project. Where more than one supervisor is appointed, the different supervisors' functions and relationships to the postgraduate should be clearly defined from the outset.

The supervisor serves as 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 which the student produces and who comments on results, as well as on questions of interpretation and method. The supervisor thus acts as both adviser and critic. The role of constructive critic is very important, but difficult. Criticism on a scientific point should not be withheld out of a misguided concern not to hurt the supervisee's feelings; the consequences for the postgraduate at a later stage could be devastating.

Although supervisor and PhD 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 that is basic to the interaction between the two always takes precedence. The supervisor has a responsibility to ensure that no circumstances arise that could jeopardize 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 supervisor and supervisee, different arguments and approaches are tested and views and ideas exchanged. Sometimes it is also important in such contexts to consider how justice can best be done to the two parties' contributions as the work continues and the results are published. In the thesis the PhD student should clarify any contributions by others, including his or her supervisor.

But it is also important that, if the supervisor uses or develops on ideas from the student, this is done in consultation with the student and no attempt is made to conceal their origins. Ideas which the supervisor suggests to the supervisee 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 jeopardizing the student's work.

7.1.3 The thesis and its presentation

The ultimate goal of the PhD student's research is to produce and present a scholarly dissertation. The supervisor decides, in consultation with the student and the examiner appointed for the discipline concerned, when the work can be considered complete and its public defence arranged. A host of different factors will be taken into account 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 wishes, for example to see a postgraduate gain his or her PhD as soon as possible, can also figure in. 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 postgraduate

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 these standards. The supervisor should discuss the relevant documents with the supervisee 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 PhD 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, 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 under the applicable rules.

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 (*Yrkesetiska 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 exists or there is cause to suspect that it might. This is often referred to as conflict of interest due to delicacy. If you are uncertain whether a conflict exists, you should disclose this to the party requesting your participation. In order to avoid problems as much as possible, different organizations have established rules concerning conflict of interest, for example the Swedish Research Council (2006).

It is also important to base assessments of this nature on a 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 in which one's ethics can be tested is in the assessment of someone else's work, for example when a researcher reads a draft of an article or a manuscript submitted to a journal 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 avoid various conflicts 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 could be reduced if it were 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 or referees. 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 work, 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 first must 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.

What would you do in the following situation?

You are refereeing an article and discover that the authors have made a great deal of a discovery 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, e.g. 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. There needs to be 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.

As a member of a board or committee outside the research community, it is important to realize 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 exaggeration or concealment.

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THE ONLY DIFFERENCE
BETWEEN YOUR TEXT
AND SHAKESPEARE'S
"HAMLET" IS THE TITEL.
HOW DO YOU EXPLAIN
THAT?

I THOUGHT
"DIE HARD"
SOUNDED
BETTER!

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 planning of various kinds (e.g. in health care, social work, road safety or education), and so on. 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 hard 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 US 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 the iceberg. In a study from 2007, for example, 18% of participating American 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% 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 financier (de Vries et al. 2006, Normal Misbehavior...). 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...).

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 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

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 defined in two ways in this context: in a narrower sense, presupposing an intention to deceive the reader, or as something that can be found to have occurred without any need to speculate on whether the author had such an intention to deceive.

The definition of research misconduct used by the Swedish Research Council's expert group for the investigation of suspected misconduct was formulated by Associate Professor 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 like continued carelessness, for example when a researcher would have been immediately able to realize that the results were distorted or when his or her own contribution is described incorrectly.

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 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 actually 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) plagiarizing 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 naturally 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 others' results, ideas and methods. The researcher bases his or her work on the 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. For more on this, see 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 made known. It is important to have one's contribution acknowledged, not only for a researcher personally but also for the research community and so that the academic merit system will continue 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 other authors' material must make the reader aware that the idea or formulation is not his or her own. Avoiding plagiarism is normally very simple. Generally stated, someone using someone else's data, methods, ideas or formulations should credit the author and usually also supply 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 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 others' ideas, hypotheses, distinctions, concepts, etc., to avoid accusations of plagiarism it usually suffices to state whom the material has been borrowed from, 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. Additionally, it is common practice within a number of subject areas to use standardized 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 use others' results and ideas in various ways. Publication means that a text is now available to the general public and can thus be legitimately used by others. However, a researcher can also have access to material before its publication, for instance through lectures, presentations, congresses and other meetings, or in conversations with other researchers. Researchers, before using someone else's material they have had access to in such a way, should think about the situation in which they were given access to it.

As a guideline, one can say that lectures given at larger conferences or by established researchers can be regarded as published, and their content can be used in accordance with the rules presented above. However, one should be more careful with presentations or lectures from small conferences, seminars and the like, as well as lectures given by doctoral students. Doctoral students are often talking about their own projects, which have not been completed, and normally participate in conferences to get feedback to improve their ongoing work. It is not a given that a lecture in this context 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 can be used, naturally citing their 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-plagia-

rism. 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 agreement. 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 phrasing agreement can virtually 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 independent 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. It must be considered whether it would have even been available to the accused researcher, as well as 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 take into account 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 PhD 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 PhD 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 gotten their positions by successfully “working the system” (de Vries et al. 2006, *Scientists' perceptions...*, p. 55).

What can or should be done to counteract and prevent research misconduct? The discussion above suggests a number of possible changes. But right now there is a need to address research misconduct within the merit and career systems in place today. Most crucial is to work to create a good research environment, characterized 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.

A university's vice-chancellor has a special responsibility to ensure that the ethical awareness among researchers there is kept at a high level. According to Chapter 1, 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 learning 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

organization'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 to create and maintain good research ethics. For doctoral students, the supervisor's contributions can be supplemented with classes in research ethics as well as 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' composition 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 plagiarize 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 getting on, how their texts look while under production, etc. offers fewer opportunities for misconduct than one where everyone works in isolation without an exchange of ideas or texts. Thus, active work with seminars at a department can be a way to strengthen research ethics. If I know my colleagues want to know something about my research, material, texts – i.e., how the work on my research project is going – this in itself will be an inhibiting factor if I am 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 can also be a case of students, postgraduate students or researchers simply happening to read an article or presentation and recognizing 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 can discover research misconduct in similar ways include reviewers at journals and experts working with position applications.

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 be 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 responsible parties.

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 an especially serious offence. There are measures that employers can take: a change in the offender's job description, transfer or even termination. Sanctions could also include barring the offender from the use of laboratories for a time, freezing funding, removal from positions of trust, etc. In the collegial environment in which research takes place, such measures often have a very major impact, a point that should be taken into account when sanctions are determined. Sanctions must naturally be proportionate to the nature of the misconduct concerned. Repeated or more comprehensive research misconduct is more serious than a single case concerning only one detail. In this context it can be interesting to note the rules and procedures followed by the US National Science Foundation (www.nsf.gov/oig/resmisreg.pdf).

Research misconduct should not occur. As part of this mission, the Swedish Research Council wishes to stimulate departments, colleges and universities to develop into the good environments described above. The Council is an authority that, after quality review, issues funding for research, and funding may be terminated when misconduct has been established by the Central Ethical Review Board (CEPN). When someone who has previously been found to have deviated from good scientific practice applies to the Council for new funding, this may be considered.

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 questions of misconduct

It is obligatory to investigate suspected research misconduct in research conducted at universities and colleges, according to the Higher Education Ordinance (SFS 1993:100), although there is no equivalent requirement for research conducted outside academia. The Ordinance does not, however, regulate how investigations should be conducted; this is up to each respective learning institution.

It is common practice that suspicions of research misconduct are reported to the organization – the department, university, etc. – where the suspected researcher works. For instance, if someone discovers that one of his or her colleagues has committed plagiarism this person is to report this to the department head or the dean of the university, who in turn should submit it 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, determines the sanctions that will 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 external help with an investigation and evaluation of misconduct. Since 1 January 2010, the CEPN has had an expert group on research misconduct which can serve as assistance in these matters. The group is completely independent, with no ties to universities, research institutions or the like in order to ensure 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 an expert group handle the investigation. However, the individual may not make this request to the CEPN him or herself; it can only be done by a university or university college. The expert group thus looks into whether or not research misconduct

has been committed. The CEPN does not suggest consequences, however; this is the responsibility of the vice-chancellor or organization head.

When misconduct has been established in connection with the writing of a journal article, good practice dictates that this should be brought to the attention of the journal's editor. The journal should then publicly announce the situation and, in a commonly visible place, issue their regrets and an apology for the publication. The article should 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 one should conduct international collaboration projects. This guide stresses the importance of those involved, through a formal document drawn up before the research begins, establish what rules and procedures will be followed in the case of accusations of fraud or if fraud is actually found. Specific individuals should be assigned the responsibility of actualizing these formalized rules in practice. The OECD guide provides a template for this document. In the case of accusations of misconduct, investigations should be conducted fairly and confidentially, and with integrity.

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9 KEY DOCUMENTS RESEARCHERS SHOULD BE FAMILIAR WITH

9.1 Introduction

There are numerous laws, directives, guidelines and codes of research and professional ethics which researchers need to be familiar with and observe in their work if they are to be able to undertake it in an ethically acceptable, not to mention legal, manner. Which of these documents are relevant naturally varies, depending on the nature of the research concerned. Here, we present a selection of especially important documents.

There are many different kinds of ethical and legal guidelines, and they are obligatory to varying degrees (this is discussed more thoroughly in Chapter 1). In this chapter, we present some of these guidelines. Their status in practice is often unclear, however, and many times a more detailed analysis is needed to determine just how obligatory they are.

9.2 The CODEX website

In collaboration with the Centre for Research Ethics and Bioethics at Uppsala University, the Swedish Research Council maintains a website on which the great majority of documents that may be relevant to the researcher can be found. The site includes all Swedish legislation with a bearing on research: the *Act concerning the Ethical Review of Research Involving Humans*, the *Archives Act*, the *Official Secrets Act*, the *Personal Data Act*, the *Health and Medical Services Act*, the *Animal Welfare Act*, etc.

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 texts dealing with specific issues, 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 ethical issues.

Below we comment briefly on some of the documents of key significance for research in Sweden. The full texts (in some cases in Swedish only) can be found on or through the CODEX site, along with many other relevant and useful texts dealing with closely related issues. The documents are presented here in descending order from those that are the most binding to the more voluntary ones.

9.3 The Act concerning the Ethical Review of Research Involving Humans

Since 1 January 2004, ethical scrutiny of research has been regulated in Sweden by the Act concerning the Ethical Review of Research Involving Humans.

Under this Act, all research on humans which concerns sensitive data, statutory offences and information on judgements in criminal cases, involves physical encroachment on research subjects, the measurement of physical or psychological influence, as well as research that carries an obvious risk of harming subjects physically or psychologically, must be assessed by an ethics review board. Finally, studies on biological material that can be traced back to living or deceased individuals must be ethically reviewed. The Act applies to all research of these kinds, regardless of institutional setting or how it is funded.

The board's review involves an examination of the project description to establish whether it involves any infringement of human rights or 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.

In addition to statutory review of projects, regional ethics boards are also able to carry out advisory ethics reviews, which are required, for example, to obtain financial support or to be able to publish results in certain international journals. Reviews by the regional boards are subject to a fee and should be undertaken within 60 days from receipt of application.

The text of the Act, information about the review process, the regional review boards and the Central Ethical Review Board (which among other things considers appeals from decisions of the regional boards), an application form and other information about ethical scrutiny are available at the website www.epn.se. This material is also available on the CODEX site. The

Swedish Research Council has also drawn up the supplementary *Guidelines for the ethical evaluation of medical research on humans* (www.vr.se).

9.4 Other legislation

In Sweden, universities and other educational establishments that conduct research are public authorities. That means that data collected as part of a research project fall under the legislation that applies to such bodies. Under certain circumstances, therefore, a researcher's data and other material are regarded as constituting "official documents", i.e. documents that have been received or prepared by a public authority. Such material is thus also subject to statutory provisions concerning documentation, confidentiality, disposal and archiving. Relevant texts in this context are the *Freedom of the Press Act*, the *Archives Ordinance*, the *Archives Act* and the *Official Secrets Act*.

Research may involve personal data. Sometimes personal data registers may be established, or information obtained from them. In addition to the Official Secrets Act, the *Personal Data Act* is the main piece of legislation in this area. Other relevant enactments are the *Health and Medical Services Act*, the *Genetic Integrity Act* and the *Law on Patient Data*. The *Biobanks in Medical Care Act* addresses research on biological samples.

The *Animal Welfare Act* and *Animal Welfare Ordinance* apply to research on animals. The Swedish Board of Agriculture also provides supplementary guidelines and general advice.

9.5 Good Clinical Practice (GCP)

For clinical trials of drugs, the relevant document is a guideline on *Good Clinical Practice* (GCP). This document 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 regarding clinical trials for human use. 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 in using GCP (www.efgcp.eu). These documents are intended to harmonize 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.

9.6 The Declaration of Helsinki

The Declaration of Helsinki on biomedical research carries great weight in that it has the backing of the World Medical Association, and has enjoyed widespread acceptance ever since its first version in 1964. It is regarded in the West as binding, even though the FDA, the US Food and Drug Administration, currently requires instead that applicants for their funding follow Good Clinical Practice (GCP).

The Declaration is mentioned in the travail préparatoire of both the Act concerning the Ethical Review of Research Involving Humans and the Biobanks in Medical Care Act, and the above-mentioned guidelines from Swedish Medical Products Agency state that it should be followed in clinical trials. A requirement often laid down in connection with research funding and publication, for example in international journals, is that a medical research project has been assessed against the criteria set out in the Declaration. Recurring updates have been made to the Declaration through reformulations and additions. The current version was adopted in 2008.

The Declaration provides a number of principles regarding, for instance, standards of competence for researchers and a need to weigh the value (benefit) of a research project against the risks it carries while ensuring that the patient's welfare always comes first. It also expresses requirements concerning informed consent: what the information should convey, how consent should be given, who can give it and to whom it should be given. The Declaration of Helsinki also addresses a number of rules concerning when medical research is combined with patient care.

9.7 The Council of Europe's Convention for the Protection of Human Rights and Dignity

The Council of Europe is an organization that works to uphold human rights in its 47 member countries.⁷ 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: Convention on Human Rights and Biomedicine comprises 38 articles, several of which directly or indirectly relate to biomedical research. It deals in particular with the protection of individuals

⁷ The Council of Europe is easily confused with the European Council. The latter consists of the 27 EU countries' heads of state and government, a non-voting Commission President and the Council's own President.

undergoing research and with the conduct of research on persons without the capacity to give consent. One article deals with research on embryos in vitro.

This document, together with the EU Directive on Good Clinical Practice, has directly prompted the new Swedish Ethical Review Act. 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.

9.8 The CIOMS guidelines for research

The Council for International Organizations of Medical Sciences (CIOMS) has, in collaboration with the World Health Organization (WHO), published *International 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.

9.9 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*), since 2010 the Council has included open-access publishing in its publication requirements.

Two international documents are of particular relevance in this context: on the one hand, the *Editorial Policy Statements* of the Council of Science Editors (CSE), on 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 emphasized 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 jour-

nals today also refer to the ethical guidelines provided 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 financers 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 site'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*. 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 universities' and university colleges' handling of questions of research misconduct in its *Riktlinjer för hantering vid universitet och högskolor av frågor om vetenskaplig ohederlighet*.

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

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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. One such interest is our quest for knowledge. 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 researcher's, study participants' and other researchers' interests, 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 intention is to establish 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.



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