NORWEGIAN MINISTRY OF EDUCATION AND RESEARCH

Consultation paper – Research Ethics in Norway

This document is a part of a consultation paper published by the Ministry of Education and Research in July 2015, with proposed amendments to Act No. 56 of 30 June 2006 on ethics and integrity in research (the Research Ethics Act). The paper is published on the Ministry of Education and Research's website (English version of parts of the paper will be published end July: https://www.regjeringen.no/no/dokumenter/horing-om-revisjon-av-forskningsetikkloven/id2427309/).

The English version of the consultation paper consists of the following parts:
Item 1 Introduction
Item 5 Researchers and research institutions' responsibilities as regards research ethics
Item 6 Research institutions' duty to process research ethics cases
Item 9 The definition of Scientific misconduct
Item 14 Proposed Act relating to ethics and integrity in research (Research Ethics Act)

The consultation is open for comments until 31 October 2015.

More information about research in Norway:
- The Ministry of Education and Research: https://www.regjeringen.no/en/topics/research/id1427/
- The Norwegian National Research Ethics Committees: www.etikkom.no/EN
- The Research Council of Norway: www.rcn.no

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1. Introduction

The Ministry of Education and Research hereby submits proposed amendments to Act No. 56 of 30 June 2006 on ethics and integrity in research (the Research Ethics Act).

In 2014, the Ministry commenced a reexamination of the Research Ethics Act to assess the need for a revision of the Act. The Ministry prepared a working paper which was sent to certain research institutions, current and former members of the National Commission for the Investigation of Research Misconduct, the Association of Norwegian Research Institutes (FFA), the trade unions Tekna - The Norwegian Society of Graduate Technical and Scientific Professionals and the Norwegian Association of Researchers - NAR, and certain other stakeholders who have been involved in handling misconduct cases. This working paper provided an initial assessment of the current regulations and practices, and discussed the possible alternatives to the current regulation. The Ministry received informal feedback from several individuals, and from stakeholders in the sector and ethics system. The aim was to obtain input from the parties that are most affected so that issues and options were explored as best as possible.

The Ministry organised a conference Å gjøre det riktige: forskningsinstitusjonenes ansvar for forskningsetikk (Doing the right thing: the research institutions' responsibility for research ethics), on 8 June 2015 together with the Norwegian Academy of Science and Letters and the Norwegian National Research Ethics Committees. The research ethics responsibilities of institutions and researchers were discussed at the conference. A partial draft of this consultation paper served as background information in advance of the conference. Here too the Ministry received considerable feedback.

The consultation paper deals with a number of areas, and mainly proposes the following changes:

- Statutory stipulation of the research ethics responsibility of research institutions (Item 5)
- Changes to the system for processing research ethics cases (Item 6)
- Institutions' reasoned opinions in research ethics cases (Item 7)
- Changes in the Commission's composition and mandate (Item 8)
- A clarification of the Research Ethics Act's definition of scientific misconduct (Item 9)
- Deferred public access during the processing of ethical issues at an institution (Item 10)
- The institutions' prerogative to preserve the anonymity of the reporter (Item 11)

The consultation document will also be published on the Ministry of Education and Research's website (under consultations), and parts of the paper will also be published in English.

Any amendments of the Research Ethics Act will be followed up with amendments of the Regulations on Ethics and Integrity in Research (Research Ethics Regulations).

Work on research ethics has two sides. The first, and most important, is to promote good research ethics. This takes place through the daily practices at research institutions by including and raising awareness about ethics throughout higher education and in all research work. The other side is about preventing and handling misconduct in research.

A system has been established with a variety of resources to support the research institutions' work on both of these aspects of research ethics, in the form of national research ethics committees, regional committees for medical and health research ethics and the National Commission for the Investigation of Research Misconduct (elaboration and referrals follow). Both general and subject-specific national research ethics guidelines have been prepared and are revised regularly, and the committees follow and are engaged in the international work on ethics. Likewise, several research institutions have prepared their own guidelines and other materials (elaboration and referrals follow). The work is also supported by international declarations and conventions, such as the Universal Declaration of Human Rights, the UN precautionary principle for sustainable development, the Declaration of Helsinki on Ethical Principles for Medical Research or the Vancouver Protocol with practical and ethical guidelines and requirements used by most medical journals in publishing scientific papers etc.[1]

On the basis of these guidelines and web resources with associated literature references we briefly address in the introduction some of the key issues in research ethics, and we briefly list the areas on which it is important that all those involved in research focus their attention.[2]

[1] http://www.fn.no/Bibliotek/Avtaler/Menneskerettigheter/FNs-verdenserklaering-om-menneskerettigheter, http://unesdoc.unesco.org/images/0013/001395/139578e.pdf, http://www.wma.net/en/30publications/10policies/b3/, http://www.research.mq.edu.au/documents/policies/Vancouver.pdf

[2] In particular, we have made extensive use of the web pages of the Norwegian National Research Ethics Committees, https://www.etikkom.no/, the web pages of the US Office of Research Integrity, https://ori.hhs.gov/, as well as from ongoing work under the auspices of the OECD Global Science Forum on "Research ethics and new forms of data for social and economic research", http://www.oecd.org/sti/sci-tech/oecdglobalscienceforum.htm, where Hallvard Fossheim, associate professor of philosophy at the University of Bergen, is the participating Norwegian expert.

5. Researchers and research institutions' responsibilities as regards research ethics

5.1. Current law

The current Norwegian research ethics system is structured such that, primarily, the individual *researcher* has an independent responsibility for familiarising himself/herself with, and following, recognised ethical standards. This responsibility is explicitly mentioned in the Act, e.g. in that researchers and their work can and must be investigated if there is suspicion of scientific misconduct. The researcher's responsibility is also particularly emphasised in Item 1 of the preparatory works for the Research Ethics Act, which states that "[t]his bill takes a point of departure in the fact that research takes place under a considerable degree of freedom and trust, and thus also a considerable degree of responsibility for the individual researcher." One can therefore say there is a duty of care for researchers in their planning, implementation and reporting of a research project.

In addition to the researchers' duty of care, *research institutions* are obliged to contribute toward ensuring that all research at their institution takes place in accordance with recognised ethical standards. This duty can also be worded as a responsibility for safeguarding research ethics at their institution. Item 3.4 of the legislative history of the current statute reads: *"Researchers, research institutions and the research community at large are responsible for ensuring that research takes place according to sound scientific practice."* The institutions' responsibility is thus not statutory, but has been used as a point of departure for the current Research Ethics Act. The legislative history also emphasises that research institutions are responsible for review and management. This responsibility is primarily based on customary practice and was developed as part of the institutions' internal control system. This means that the research institutions are responsible for ensuring that their research is ethically prudent and conducted in accordance with recognised ethical standards, in order to promote good research ethics, including guidance and teaching in research ethics, as well as to prevent and process potential breaches of the standards.

5.2. Experience and current practice

5.2.1. Introduction

In the spring of 2014, the Ministry of Education and Research conducted a mapping of the ethics system used by State universities and university colleges, and also met with 15 different institutions. The Ministry has also met with the Association of Norwegian Research Institutes (Forskningsinstituttenes Fellesarena (FFA)) and the health trusts. This mapping showed that many institutions have established both general and specific variants of local research ethics guidelines. Many institutions actively utilise guidelines published by the national research ethics committees NESH, NENT and NEM, and have not established their own guidelines. Certain institutions distinguish themselves with well-established routines and broad focus on sound research ethics. Several institutions refer to guidelines/procedures for establishing and conducting research projects, the obligation to report before starting up a research project, and guidelines for processing individual cases, routines for safe storage of personal data in research projects, procedures for following requirements laid down by the Regional Ethical Committees (REK) and similar. Many institutions also have analysis tools which are used to reveal research misconduct, including programmes to prove plagiarism.

The mapping round also showed significant differences in how the institutions handle issues of research ethics. The responses also show that there is substantial variation between institutions as regards whether they have laid down rules that determine the procedure for

issues of research ethics and how they will handle such issues. A few institutions have established or are in the process of establishing their own ethics committees in line with this.

In order to provide a picture of the current practice, the Ministry will present a few specific examples of how various institutions have organised the responsibility for preventing scientific misconduct, processing research ethics cases and/or have established other tools to safeguard research ethics. The examples have been obtained from the institutions' websites or documents submitted to the Ministry from the institutions themselves. These are primarily examples the Ministry finds to be positive. Many of the institutions that are not mentioned have equivalent guidelines. However, certain institutions have little or no guidance on their websites or public documents concerning research ethics. The Ministry has not studied all institutions, but rather a small selection. A few institutions have set up their own investigation committees. The mandate and guidelines for such committees may vary somewhat in form and scope, but their core area is the same. The Ministry has used the following criteria:

- whether research ethics is embedded in paramount management and strategy documents
- whether the institutions have assigned responsibility for research ethics
- whether the institution refers to recognised Norwegian and international ethical standards, or whether the institution has potentially established its own guidelines concerning research ethics standards
- information on websites and extent of online support and materials
- scope of research ethics in doctoral programmes
- whether the institution has routines for processing issues of research ethics
- whether the institution has established a research ethics committee

5.2.2. The university and university college sector

In the mapping round, the State universities and university colleges were asked whether:

1) the institution has established research ethics guidelines
2) the institution has handled specific cases concerning scientific misconduct or cases concerning serious violations of research ethics guidelines/sound research ethics, and how many such cases have been processed.
3) the institution's research ethics guidelines describe the procedure for administrative cases linked to potential breach of research ethics standards or how such cases would potentially be handled at the institution, and whether external expertise was needed to process the case
4) the institution has routines for notifying the National Commission for the Investigation of Research Misconduct, and whether the Commission has potentially been notified in one or more specific cases
5) the institution has adopted resolutions concerning scientific misconduct, whether these have been appealed, and how the potential appeal was processed

The Ministry has also had access to information that the Norwegian National Research Ethics Committees (FEK) have previously gathered concerning the institutions' teaching in research ethics in the doctoral programmes and any research ethics committees.

The mapping shows that most State universities and university colleges have established their own guidelines for what they consider to be recognised research ethics standards, ethical

and/or research ethics guidelines, and guidelines for processing individual cases. Of the responding institutions, 14 had established research ethics guidelines, six had not established such guidelines, whereas four stated that they had other methods of safeguarding research ethics at their institution. Many institutions responded that they were in the process of preparing ethical guidelines. The answers also showed that there is substantial variation both as regards the attention devoted to research ethics issues, awareness surrounding research ethics standards and applicable research ethics guidelines, as well as how the institutions handle research ethics issues.

As to whether the institutions have routines for processing research ethics cases, 11 responded that their case processing follows from the guidelines, four responded that they do not have guidelines that describe the procedure and also provided no information as to how the institution would potentially handle a misconduct case. Three institutions responded that they have other forms of guidelines that describe the procedure.

As to whether the institutions have processed specific cases concerning scientific misconduct or cases concerning serious breaches of research ethics guidelines/sound research practice, 12 institutions responded that they had processed such cases and 13 responded that they had not. In other words, the mapping shows substantial variation as to whether, and potentially how, the institutions have handled research ethics cases. Generally, the large institutions have handled the most cases and have the most experience.

As to whether the institutions have made resolutions in specific cases, whether they have been appealed, and how the potential appeals were processed, 16 institutions responded that they have not made resolutions in such cases, whereas 3 have processed cases that were not appealed. Several institutions refer to the fact that cases they processed locally, have also been brought before the National Commission for the Investigation of Research Misconduct. The mapping round shows that no institutions have processed appeals of resolutions/opinions concerning scientific misconduct. This is most likely related to the fact that most institutions have presumed that there is no right of appeal for such opinions.

In the following, the Ministry will present a few specific examples of institutions' local guidelines for their procedures, and in a few instances also which body at the institution will handle such cases.

The University of Oslo (UiO) has established guidelines for research ethics and refers both to the university's own responsibility, as well as the individual researchers' responsibility:

> *"The university is responsible for ensuring that its research is conducted in line with the set framework, e.g. in the Universities and University Colleges Act, the Public Administration Act, as well as in terms and conditions from external sources of funding. The heads of institutes and deans must continuously follow up to ensure that the framework is observed. The individual researchers have an independent responsibility for ensuring that their research is conducted in line with good research practice, recognised scientific and ethical principles, and within a fixed framework."*[3]

UiO also has a dedicated action plan for promoting sound research practice and preventing scientific misconduct. The purpose of the action plan is to ensure that all employees follow

[3] http://www.uio.no/forskning/om-forskningen/etikk/

applicable statutes and the general rules for sound research practice in the individual disciplines. UiO also has a dedicated page on research ethics on its website under for employees – research ethics. Here you can find relevant information. UiO has also established a research ethics committee that handles research ethics cases.

The University of Bergen (UiB) has established a Committee for Academic Integrity which has developed its own ethics pages on the website and has editorial responsibility for these pages.[4] The website is intended to instil a high level of ethical awareness in employees and students. It is pointed out that UiB wants its employees and students to take responsibility for communicating a high ethical standard to new colleagues and fellow students, where supervisors, educators and advisors have special responsibility. UiB places partial responsibility for research ethics with its managers.

The University of Stavanger (UiS) may be the institution that goes to the greatest lengths to place the responsibility for research ethics – both with the institution itself through specific people, as well as with the individual researcher. It follows from the institution's *institutional procedures for processing research ethics cases* (excerpt):

> «*The institution's responsibility*
> *The University Board is responsible for ensuring that the university's research activities maintain a high standard of research ethics. The university management is responsible for ensuring that institutional procedures for handling research ethics cases have been prepared and that the organisation has been made satisfactorily aware of national research ethics guidelines.*
> *Deans and heads of institutes/centres have managerial responsibility as regards research ethics and must contribute toward developing a robust research ethics culture in the faculty/centre/institute.*
> *The dean is responsible for ensuring that the faculty trains and keeps its scientific employees up-to-date on research ethics issues. Equivalent responsibility is safeguarded by the research centres' management.*
> *In addition to advisory services, faculties and centres must have a quality assurance system for their research processes which takes into account research ethics considerations. This must include requirements for colleagues and managers to have access to the research processes, and that the units conduct specific assessments of the quality of the research processes, including ethical considerations.*
>
> *The individual researcher's responsibility*
> *Research ethics is primarily the responsibility of the individual researcher. The individual is obliged to conduct his/her research in line with generally recognised ethical principles linked to data acquisition, analyses, conclusions, publication, any harmful consequences, personal data protection and the relationship to the principal, if any. All researchers must give their colleagues access to their research processes as part of the quality assurance of the research effort, and all researchers are obliged to contribute to quality assurance of research processes at their unit. All co-authors of a publication are obliged to ensure that the work has been conducted in a manner that conforms with generally recognised principles of research ethics.*» [5]

[4] http://www.uib.no/ledelsen/73794/etikk-ved-uib and http://www.uib.no/ledelsen/73937/etikk-i-forskning

[5] http://ansatt.uis.no/forskning/forskningsetikk/institusjonelle_prosedyrer_for_behandling_av%20forskningsetiske_saker/article8745-4096.html

It is also pointed out that the individual researcher is obliged to familiarise himself/herself with the Research Ethics Act, research ethics guidelines and information from the Norwegian Social Science Data Services (NSD) concerning the Data Protection Official scheme and processing personal data.

UiS also has a dedicated page on research ethics on its website under research and PhD studies – PhD studies – PhD guide – course of study phase – research ethics.[6] Here you can find links to applicable UiS regulations, research ethics guidelines and the Research Ethics Act.

The UiS procedures for handling nonconformities stipulate that, in research ethics cases of a less severe nature, the colleagues involved must work together to find a solution that is fully acceptable for all parties. If this is not successful, the closest line manager must be included, but in cases of a more severe nature, the line management must be included. It is also pointed out that, in the event of particularly severe nonconformities/breaches of ethical guidelines or in the event of justified and well-founded suspicion of such serious matters, the management must appoint an independent group comprised of members with relevant expertise.[7]

The University of Tromsø – the Arctic University of Norway (UiT) states in its guidelines that researchers are obliged to familiarise themselves with applicable research ethics guidelines. The University writes on its website that *"The University of Tromsø will shall use national and international principles as a basis for ensuring sound research practices. The various research area have their own special ethical challenges and researchers and students are responsible for familiarising themselves with, and following, the standards for sound research practice within their area. The standards can be found in the guidelines for the national research ethics committees.* »[8]

UiT has also established its own research ethics committee.

The University of Agder (UiA) states that the University's contributions to national and international research depend on colleagues having conscious ethical attitudes toward their research activities. UiA has established four core values for the University's research: transparency, trust, responsibility and respect.[9] UiA does not refer either to the researchers' or institution's research ethics responsibilities.

> «*A ruling in Redelighetsutvalget is not an administrative decision that can be appealed to a higher body, but the committee's reasoned opinion may be included if the faculty or anyone else with a legitimate interest wants to bring the case before the National Commission for the Investigation of Research Misconduct. The case can also be submitted to the Commission if special reasons so indicate.* »

UiA has established the following guidelines for processing cases concerning suspicion of scientific misconduct at the University of Agder:

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[6] http://ansatt.uis.no/forskning/forskningsetikk/article7887-3789.html

[7] http://ansatt.uis.no/forskning/forskningsetikk/institusjonelle_prosedyrer_for_behandling_av%20forskningsetiske_saker/article8745-4096.html

[8] http://uit.no/ansatte/organisasjon/artikkel?p_document_id=194802&p_dimension_id=88199&p_menu=48968

[9] http://www.uia.no/forskning/om-forskningen/etikk-og-personvern

- «*All reasoned suspicion of scientific misconduct against an employee at the University of Agder or student at one of the University' doctoral programmes must be reported to the Rector with copies to the Research Director and dean of the relevant faculty. This report must include the name of the researcher(s) under suspicion, and the basis for this suspicion. The basis for the suspicion must be documented to the extent possible. (..)*
- *If the suspicion is clearly unfounded, the case must be rejected from further processing at the University. If the available documentation provides a basis for further investigation, this must be initiated. (..)*
- *When further investigation is initiated, the Research Director must ensure that a sufficient amount of background case information is obtained for the university to have an adequate basis for making its decision. If necessary, the person who reported the suspicion and/or the suspect, must be summoned for new conversations.*
- *(…) If needed, a committee must be appointed consisting of at least 2 people with expertise in the researcher's specific discipline. The committee shall assess whether the case is severe enough to be submitted to the National Commission for the Investigation of Research Misconduct.* » [10]

The University also has routines for notifying the person at which the case is aimed and giving him/her the opportunity to make a statement and for taking minutes from any conversations. It also follows from the guidelines that, when scientific misconduct has been established in connection with scientific dissertations that form the basis for awarding degrees from the University of Agder, the University must consider whether or not to revoke the degree.

The Norwegian University of Science and Technology (NTNU) has ethical guidelines for NTNU employees, a dedicated Research Ethics Committee and an Ethics Portal. [11] Here emerges it in Item 5 that the individual researcher has an independent responsibility for ensuring that his/her research is carried out in line with sound research practice, recognised scientific and ethical principles, and the framework agreed both internally and externally. The NTNU management is responsible for ensuring that the research is conducted pursuant to statutes, regulations and ethical guidelines. The topics addressed in the guidelines are linked to sound research ethics practice, academic community and guidance, publication, professional disagreement, the obligation to report and right to publish, as well as financial diligence for externally funded projects. The ethical guidelines include a number of links, for example to the Norwegian National Research Ethics Committees' guidelines, to NTNU's Research Ethics Committee and to NTNU's reporting procedures. The Ethics Portal is a website for all NTNU employees and has a special focus on research ethics and personal ethics dilemmas. The objective is to stimulate ethical reflection at all levels at NTNU. Several major ethics seminars have been held at NTNU in recent years; both for the Board and for deans, vice-deans and all department heads. This is part of the effort to raise awareness and mature the dialogue surrounding ethical dilemmas in research.[12]

[10] http://old.uia.no/portaler/forskning/etikk_og_personvern/vituredelighet

[11] https://innsida.ntnu.no/wiki?p_auth=BQSlY4mT&p_p_id=36&p_p_lifecycle=1&p_p_state=exclusive&p_p_mode=view&p_p_col_id=column-1&p_p_col_count=1&_36_struts_action=%2Fwiki%2Fget_page_attachment&p_r_p_185834411_nodeId=24647&p_r_p_185834411_title=Etiske+retningslinjer+for+ansatte+ved+NTNU&_36_fileName=Etiske+retningslinjer+2015+04+14.pdf

[12] http://www.ntnu.no/etikkportalen

NTNU has established a Research Ethics Committee with five members, including an external member who is an attorney. The Committee must hear and give an opinion on cases in the event of suspicion of scientific misconduct. The Committee is also tasked with hearing other types of cases that concern research ethics when so requested by the Rector or deans. The Committee has been given its own mandate and regulations, but dedicated routines have also been prepared for case processing in the faculties in the event of suspicion of research misconduct. NTNU aims for suspicions of research misconduct to be handled immediately within the unit in question.

The Norwegian School of Economics (NHH) has established *the Research Ethics Committee at NHH*. The Research Ethics Committee is the NHH group's advisory body for research ethics. The Committee must hear and give its opinion on research ethics cases originating from alleged breaches of scientific integrity and sound scientific practice in the NHH group. The Committee must hear and give its opinion on research ethics cases of a general nature brought before the Committee by the Rector. The Committee can independently initiate cases based on allegations or suspicions. The Committee's opinions must be in writing and must contain a reasoned assessment. The Committee can recommend submission to the National Commission for the Investigation of Research Misconduct, or for the institution itself to make a resolution in the case. NHH's basic principles for processing individual cases linked to scientific misconduct:

> "*a. Allegations of and suspected scientific misconduct shall be dealt with in a fair and proper manner.*
> *b. A person accused of scientific misconduct is innocent until the board has reached a decision that he/she is guilty of scientific misconduct. If there is any doubt in relation to the evidence on which the misconduct allegation is based, the accused shall be given the benefit of the doubt.*
> *c. Cases shall be processed in a manner that ensures reasonable progress and prudence in each individual case. The Committee is subject to the rules and duty of confidentiality laid down in the Public Administration Act. Special consideration shall be given both to the accused and, if relevant, the notifier. The purpose of this is to prevent violations of the right to privacy and reputation of the person concerned.*
> *d. Persons accused of scientific misconduct shall be notified and given access to the grounds for the case. They are also entitled to comment on and refute the allegations that have been made, cf. Sections 16 through 21 of the Public Administration Act.* »

The institutions' relationship with the National Commission for the Investigation of Research Misconduct

In the mapping round, the institutions were also asked whether they have routines for notifying the National Commission for the Investigation of Research Misconduct when they process research ethics cases, and whether the Commission has been notified in one or more specific cases. The vast majority of institutions responded that they do not have routines for notifying the Commission, but several point out that this is considered in each individual case. The regulations for Bergen University College's Research Ethics Committee state that cases processed by the Committee must be reported to the Commission. The University of Bergen has equivalent guidelines for its Committee for Academic Integrity. The University of Oslo responded that it does not have routines for notifying the Commission, and is of the opinion that this is also not required by the current regulations. Deficient reporting to the Commission is the reason why there is no comprehensive, systematic documentation in this field.

The Norwegian Association of Higher Education Institutions (UHR)

The Norwegian Association of Higher Education Institutions (UHR in 2007) has also adopted guidelines for processing issues of research ethics. UHR is a collaborative body for universities, specialised university institutions and accredited university colleges in Norway. UHR has asked its member institutions to adhere to these guidelines, and the individual institutions follow up in different ways. They can thus provide an indication of how cases are processed by individual institutions, and it is assumed that institutions which have not established their own guidelines, will use UHR's guidelines if a case should arise involving a potential breach of recognised ethical standards.[13]

5.2.3. The research institutes

Research institutes are institutions that primarily engage in research. Common forms of organisation include foundations, limited companies (privately or publicly owned), or administrative bodies. The purpose of the research institutes is to contribute research of high quality and relevance for application in commerce, public administration and in society at large. Compared with other countries, Norway has a significant institutional sector.

Much of the research that takes place at research institutes is commissioned research. This could pose special challenges, e.g. as regards research independence, the researchers' academic freedom and research ethics. This is why awareness surrounding research ethics is important. Bioforsk has addressed potential conflicts of interest in commissioned research in their research ethics guidelines linked to e.g. the principal's management prerogative as regards choice of methods, application of results, publication, potential loyalty conflicts and independence for researchers and institutes.

The Association of Norwegian Research Institutes (FFA) is a professional body for all research institutes that are subject to the Research Council of Norway's institute policy and which are qualified for receiving basic funding from the State, currently 48 institutes. In 2014, FFA established a dedicated research ethics committee for the research institutes. The institutes wanted such a committee to support them both generally and in specific cases relating to research ethics. The institutes also see a need for measures to prevent cases of misconduct, system development in order to discuss and maintain awareness concerning research ethics, reputation-building, etc. The committee will process both misconduct cases and other research ethics cases and issues, and will also have a facilitating, advisory and support role and contribute to establishing a culture for ethics in the sector. The committee is working on a template for research ethics guidelines in the research institutes. This template uses the following definition of research ethics:

> «*The Committee presumes that the term research ethics includes both issues of misconduct and other research ethics issues. The Committee furthermore assumes in its terminology that research ethics is linked to the actual research and not other ethical issues which may arise around this research. The question as to whether an institute, for ethical reasons, should perhaps refrain from research in certain fields, is not a question of research ethics in the Committee's use of the term. An employer may face ethical issues in the same way, but they are not automatically research ethics issues merely because the employee is a researcher.* »

[13] http://www.uhr.no/documents/EtiskeRetnLinjer2_2.pdf

Several institutes have established ethical guidelines. However, it is somewhat unclear whether, and to what extent, these also include – and focus on – research ethics.

Bioforsk has both general ethical guidelines and research ethics guideline.[14] The foreword to the research ethics guidelines states the following:

> «*Following up research ethics is both an individual, collective and institutional responsibility. Bioforsk management will ensure that employees are familiar with the guidelines and their content, and that a research ethics culture is developed on the basis of statutes and recognised research ethics. In day-to-day work, the individual employee must ensure compliance with the guidelines. If one has become aware of, or is of the opinion that certain research activity is not in line with applicable research ethics, the employee is entitled and obliged to report this.* »

SINTEF's ethical guidelines state that ethics are a management responsibility. They have established an Ethics Council and Ethics Representative, which will contribute advice and guidance, and will help ensure transparency surrounding ethical choices. Research ethics is an integrated part of the ethics work.

The Institute for Energy Technology (IFE) established ethical guidelines and basic values for IFE in 2012. Item 4.1 *Research Practice* states that research shall not conceal, distort or falsify anything - be it in planning, conducting or reporting. It also follows from the guidelines that each individual is responsible for exercising appropriate and veracious research practices. The guidelines place the responsibility with the individual researcher. IFE has also established an Ethical Council that will provide guidance and advice to IFE's management and employees in ethical issues.

The Ministry knows that the research institutes have processed multiple research ethics cases, but does not have an overview of how they are processed. Certain institutes have their own committees/councils (SINTEF, IFE) for processing such cases. Bioforsk has established notification procedures.

The FFA board has, following a proposal from its research ethics committee, established procedures for handling individual ethics cases. The committee shall restrict its efforts to advice and support, and the guidelines also state the following:

> «*Individual cases from institutes that are brought before the Research Ethics Committee for the Institute Sector, must be investigated by the institute. Local committees that elucidate individual cases must have relevant professional expertise, be familiar with research ethics issues and have access to legal expertise.*»[15]

5.2.4. Health trusts

Research is one of the four statutory tasks assigned to the health trusts. Each individual health trust is an independent research institution which is responsible for ensuring that its research takes place in accordance with the regulations and ethical guidelines. The health trusts' systems for internal control must also include ethics. Sound ethical research practices are e.g.

[14] http://www.bioforsk.no/ikbViewer/Content/70667/etiske_retn.pdf and http://www.bioforsk.no/ikbViewer/Content/70666/FER_NO.pdf

[15] Minutes from meeting of the Research Ethics Committee for the Institute Sector, Tuesday, 9 September 2014: http://ffa.abelia.no/getfile.php/Dokumenter/Referat%20m%C3%B8te%201-14%20090914.pdf

one of the main goals in the Northern Norway Regional Health Authority's research strategy, and the region is in dialogue with the health trusts concerning institutional responsibility in research.

A number of health trusts have set up routines for handling the responsibilities surrounding research covered by the Health Research Act and other relevant legislation. For example, the routines for health research at the University Hospital of North Norway (UNN) state the following: «*The internal control system is a practical tool for researchers to plan, conduct and complete research projects so that they are in line with sound and ethically prudent medical and health research. The internal control system at UNN and the Faculty of Health Sciences at the Arctic University of Norway (UiT) has routines that aim to ensure that ethical, medical, health, scientific and privacy matters are safeguarded."* Furthermore: "Institutions responsible for research, represented by the University Director/Hospital Director, shall ensure that the research takes into consideration privacy and information security, as well as ethical, medical, health and academic matters." Handling undesirable incidents and deviations is part of the internal audit system for research activities. In matters concerning conflicts of interest, UNN has used the Research Ethics Committee at the University of Tromsø. Suspicions of potential severe breaches of research ethics standards are forwarded to NEM.

Oslo University Hospital Trust and Akershus University Hospital Trust have, in cooperation with the University of Oslo (Faculty of Medicine) established an ombudsman scheme[16] for research, which handles cases linked to misconduct in research.

All research projects that entail research on human subjects, must be presented to the Regional Committees for Medical and Health Research Ethics (REK) for approval, cf. Section 4 of the Research Ethics Act. The specific boundaries for which research projects will be covered by this follows from Section 2 of the Act relating to medical and health research (the Health Research Act). Regulation No. 955 of 1 July 2009 relating to the organisation of health research has been laid down in pursuance of this Act. This includes organisation and advance approval of medical and health research on human subjects, human biological material or health information. The regulations set requirements e.g. related to internal controls by the research institutions. The regulations also set special requirements for collaborative projects (multi-centre studies).

The Health Research Act stipulates that the Norwegian Board of Health Supervision has supervisory responsibility for medical and health research. The Norwegian Board of Health Supervision can intervene if research projects or research biobanks are operated in a manner which may have harmful consequences for research subjects or others, or are otherwise unfortunate or imprudent. It will supervise such research regardless of where it takes place: Health institutions, universities, university colleges and other research institutions. The Norwegian Data Protection Authority has regulatory authority as regards the use of health information in research. The Norwegian Medicines Agency must supervise the clinical testing of medicines.

The Norwegian Board of Health Supervision conducted a risk assessment within health research in 2012. The risk assessment indicated no significant risk of serious harm to physical

[16] http://www.med.uio.no/forskning/om/etikk/forskningsombud/index.html

health among research subjects. Failure in the administration of the entire research process was considered to be the most important risk area, especially within the administration of health information and biological materials. The risk areas have a lot to do with responsibility and compliance with legislation. Management follow-up was pointed out as particularly important in order to reduce the risk level within health research.

Research ethics assessments for health research are not limited to the assessment of and preparations for obtaining advance consent from REK. The institutions are nevertheless responsible for following up progress, both during the planning phase, the implementation phase and in subsequent reporting. The institutions are responsible for safeguarding research ethics, even for research projects for which advance consent is *not* required. Ethical responsibility and assessments are not restricted to the advance consent for the project in the ethics committee system, but must be done continuously in all phases of the project.

The regional health authorities are subject to requirements for their internal control system.

5.2.5. Research in commerce and industry

The Research Ethics Act and the research ethics standards also apply in principle for researchers and thus research that is conducted in commerce and industry. It is primarily in the individual researcher's and the individual enterprise's own interest to include research ethics as part of the quality requirements for their own research. The public interest is primarily evident in two contexts: in connection with publication and public funding. If research conducted in commerce and industry is to be published, then research ethics standards must be used as a basis in quality-assurance. Furthermore, society must set requirements for research ethics in order to award public research funding to an enterprise. This is done e.g. through the general requirements set by the Research Council of Norway for all funding recipients.

An increasing number of research projects are conducted in collaboration between public research institutions and private enterprises. In public/private collaboration projects, the research institutions are required to ensure that the private partner accepts that the institution's research ethics guidelines be used as a basis for the collaboration.

5.3. The Ministry's assessments

5.3.1. The individual researcher's responsibility and duty of care

The current Norwegian research ethics system is structured such that, primarily, the individual researcher has an independent responsibility for familiarising himself/herself with, and following, recognised ethical standards. Such a duty of care entails that everyone involved with the research is obliged to familiarise themselves with applicable research ethics regulations; both statutes, regulations and research ethics guidelines. The duty of care applies to all researchers in Norway and research abroad if this research is conducted by researchers employed by Norwegian employers or if a significant share of the funding comes from Norway. A number of institutions have already specified the duty of care in their internal guidelines.

Several of the research ethics cases that have been processed in recent years have shown that, nevertheless, there is a need to further clarify the researchers' duty of care both for researchers, research institutions and other sources of funding, and society at large. The

Ministry is of the opinion that there is a need to establish by law an obligation for researchers to exercise due care and take reasonable steps to ensure that research in Norway is prudent and takes place in accordance with recognised ethical standards. Such a rule will raise awareness surrounding the risk of misconduct in research, and thereby contribute to preventing misconduct.

Proposed statutory wording of requirements for researchers' duty of care:

Section 3(1):

Researchers shall exercise due care and act in a manner which ensures that all research, including preparations for research, reporting of research and other research-related activities, follow recognised ethical standards.

In certain instances, practices at a research institute may contribute to giving researchers a misleading or incorrect impression of the applicable recognised ethical standards. For example, this could apply to practices that violate recognised norms for quotation and good reference practices when re-using one's own early texts, texts prepared as a group which are reused by one or more group members internally, or in connection with applications for research funding, etc., as well as rules for co-authorship. This could contribute toward a researcher not having sufficient knowledge of research ethics standards.

When the individual institution processes cases concerning potential breach of recognised ethical standards, its assessment as to whether the researcher has exercised the necessary due care will focus on whether the researcher was, or should have been, familiar with the standards that are relevant in the specific case. The researcher is not required to actually know the standards, it is sufficient that he/she should have been familiar with them. A researcher has been academically trained through an extensive education, and will in most instances have received research ethics training as part of their education, even if the quality of this training may vary. Being misled about the recognised ethical standards can thus only be asserted in a limited number of cases. One aspect of the assessment will be whether the researcher has reasonable grounds for not being aware of the standards. The border between the prudent and the negligent must be drawn through practice based on a concrete assessment in each individual case. The duty of care for breaching recognised ethical standards may vary. As regards severe instances of scientific misconduct, forgery, fabrication, and plagiarism, there are very few instances where a researcher could be entirely unaware of the standards. This could be different as regards less severe instances of breaches of recognised ethical standards.

5.3.2. Research institutions' responsibility for research ethics

The need to regulate by law research institutions' responsibility for research ethics

There appears to be broad agreement as to the fact that the individual research institute has responsibility for research ethics. What this responsibility entails, and how it should materialise in practice, however, appears to vary substantially between the different research communities. Most institutions agree that the most important part of this responsibility is to ensure that both public and private research takes place in accordance with recognised ethical standards. Cases in recent years have shown that the extent to which the institutions have established routines and systems that work satisfactorily in order to handle this responsibility, varies. Research has primarily been a self-regulating system, where the research community itself has prepared research ethics guidelines, ensured compliance with the standards, and reprimanded researchers who do not comply with the established standards. This system has

been generally successful, particularly within the largest institutions with extensive research experience. The experiences of other institutions have been more mixed.

Stronger internationalisation and greater global competition mean that individual researchers are under substantial pressure. New control systems make it easier to detect certain types of research misconduct today than it was before. It is claimed that several minor and major deviations from research ethics standards occur in current research and are nor made known. There is no reason to believe that the risk of misconduct in Norwegian research has been reduced. The research institutions' responsibility for research ethics will be more important, particularly in order to establish a good research ethics culture at the institutions.

The mapping shows that certain research institutions have taken their responsibility seriously and have established good systems for developing sound research ethics practices at the institution. Many institutions have sound routines for handling their research ethics obligations, including assigning responsibility for compliance with research ethics at the institution, establishing routines for training researchers in research ethics and handling issues of research ethics, e.g. linked to scientific misconduct. Other institutions have no, few or at best deficient, routines or practices for handling issues of research ethics, and appear not to be equally aware of their ethical responsibility. A substantial majority of the institutions have no information about research ethics either on the institutions' websites or in the form of ethical guidelines or other materials that have been available to the Ministry during preparation of this consultation paper. Many research institutions have deficient regulations and routines, which may result in unfortunate or poor handling of research ethics issues.

Today, there are significant variations in how the institutions handle research ethics issues, and we have identified a lack of routines, follow-up and compliance with recognised ethical standards. The Ministry is of the opinion that the current system is insufficient, and there is therefore a need for considering establishing by law the principle of research institutions' responsibility for research ethics.

Establishing the responsibility by law will strengthen research ethics work by clarifying the institutions' responsibility, and will contribute to raising the status and quality of research ethics work. More detailed clarification is also important in order to achieve more uniform practice at the institutions.

The institutions' responsibility is in addition to the research ethics responsibility of the individual researcher. Both the individual researcher and the institution may be held accountable for breaches of research ethics standards. The institution's obligation will not exempt the individual researcher or vice versa. This will ensure greater compliance with recognised ethical standards.

Which research institutions should be subject to the requirement
In this context, the term "research institutions" is limited to public institutions where research is one of their primary objectives, and to private institutions where research is their main purpose (research institutes, etc.). Other institutions that conduct research sporadically or to a limited extent, or private enterprises' research departments, should also observe recognised research ethics standards. However, it would not be right to require that they use specific routines and similar. In certain contexts, institutions will also be required to follow research ethics standards, for example if they receive research funding from the Research Council of Norway (directly or as members of a consortium). We presume that research ethics will also

be a topic e.g. in connection with considering publication of research from private enterprise. The specific content of the requirements in the draft Section 3 must be adapted to the type of institution.

One argument against establishing this by law could be that there are limited policy instruments available for ensuring follow-up. Most universities, university colleges and health trusts *are owned* by the State, and the ministries, as owners, have the power to issue instructions to the institutions. As regards private universities and university colleges that receive State funding, the Ministry can issue guidelines through terms and conditions for the funding. As regards *research institutes* that receive basic State grants, the Research Council has the opportunity to withhold funding. Here the Ministry proposes a self-declaration scheme for research institutes that receive basic grants. Vis-à-vis *private research players,* this policy instrument will be linked to receiving public funds. The Research Council currently has general terms and conditions associated with research ethics for awarding research funding.

In this context, the term "candidates" in the training requirement has the same definition as in the Universities and University Colleges Act, which means that the term includes both students and PhD candidates, cf. Item 6.4 of Odelsting Proposition No. 71 (2008-2009) *Om lov om endringer i lov 1. april 2005 nr. 15 om universiteter og* høyskoler (Concerning the Act relating to amendments to Act No. 15 of 1 April 2005 relating to universities and university colleges).

Proposed statutory requirements for researchers and research institutions:

Section 3(2):

A research institution must ensure that research conducted at the institution takes place in accordance with recognised ethical standards. The institution is responsible for

- *a) necessary training of candidates and employees in recognised ethical standards*
- *b) ensuring that everyone who conducts or participates in the research are familiar with recognised ethical standards*
- *c) having routines in place for processing cases involving potential breaches of recognised ethical standards*
- *d) considering whether, as part of the processing of cases pursuant to litra c, there is a need for requesting an opinion from a committee pursuant to Section 6(1)*
- *e) having routines in place for reporting to the National Commission for the Investigation of Research Misconduct about research ethics cases at the institution.*

Further details about the specific requirements in the proposal

The first subsection obligates the institutions to establish systems or plans which ensure, insofar as possible, that research conducted at the institution takes place in accordance with recognised ethical standards. For universities and university colleges, this will be a continuation and expansion of the their obligation pursuant to Section 1-5 of the Universities and University Colleges Act to ensure that e.g. research is conducted in concurrence with recognised scientific and ethical principles. Establishing these requirements by law will primarily help the generally diligent and honest researcher obtain the necessary training and support from his/her institution and advisors. It may be difficult for an institution to fully protect itself against the small minority of researchers who intentionally violate the standards.

These responsibilities are specified in litras a through e. Litra a) obligates the institutions to provide training in research ethics. This training applies to both candidates and employees. The requirement for *necessary* training entails that this must be considered specifically based on e.g. the type of institution and field of research. There will, for example, be a need for more extensive training for those who conduct health research. The researchers must receive adequate training so that they can fulfil their requirements pursuant to the first subsection of this Section. The connection between first and second subsections is meant to create a reinforcing effect; researchers can set requirements for training at their institution, and the institution can require that researchers participate in training.

Litra b) is aimed at everyone at the institution, as well as external partners in research projects. One group at the institutions is particularly important; the advisors. Knowledge about ethics, awareness about and good attitudes toward ethics must be developed and further developed continuously. It is important that the institutions have venues for discussing general and specific issues, venues where new and experienced people can address issues that may arise – is a form of prevention and ensuring sound research ethics.

Litra c) entails that the institutions must establish routines that ensure processing of cases involving potential breaches of recognised ethical standards. Anyone can address cases involving potential breaches of recognised ethical standards. Experience has shown that some inquiries are unfounded, or are primarily inter-personal conflicts, or may involve an academic disagreement. The institution must assess whether or not the inquiry provides a basis for more detailed investigation by a research ethics committee, or whether the inquiry is obviously unfounded. Here the institutions must establish routines for who will undertake this assessment.

Literas d) and e) are addressed under Item 6.

6. Research institutions' duty to process research ethics cases

6.1. Current law

6.1.1. The term "research ethics cases"

The Ministry will henceforth use the term "research ethics cases" about *all* types of cases where there is a question of insufficient compliance with recognised ethical standards. Cases of scientific misconduct (misconduct cases) are the most serious incidents of violations of recognised ethical standards, and must not be confused with research ethics cases in general. Research institutions must process all types of research ethics cases; both serious and less serious.

6.1.2. Processing at the research institutions

Institutions' responsibility to process research ethics cases

Responsibility for ensuring that research is conducted in an ethically acceptable manner is incumbent on the research institutions and individual researcher, and the ethics system is based on research institutions themselves taking the necessary steps to deal with cases where there is suspicion of violations of recognised ethical standards. Section 11.2.4 of the preparatory works to the Research Ethics Act shows that the definition of scientific misconduct *falsification, fabrication, plagiarism and other serious breaches of good scientific practice that have been committed wilfully or through gross negligence when planning, carrying out or reporting of research* in no way exempts institutions from the responsibility to prevent and deal with matters that fall outside the definition of scientific misconduct. Responsibility for prevention and processing applies to both serious and less serious research ethics cases. Universities and State university colleges are required to have established procedures for handling research ethics issues, and procedures for processing research ethics cases. The proceedings will basically follow ordinary case-processing rules at the institutions. It is up to the individual research institution to determine how and at which body. In many cases, the institution will establish a special committee (permanent or ad hoc) to handle and process (investigate) individual cases where violations of ethical standards are alleged. In some cases the institutions may also collaborate on establishing such committees. The Research Ethics Act applies to all sectors that perform research. Research stations delineated in Item 4.3.2 also have a responsibility to ensure proper handling of such cases. As the mapping phase, see Item 5.2, showed, there is variation in how institutions deal with research ethics cases.

Rules of procedure

For public institutions, the administrative proceedings provisions of the Public Administration Act apply. The impartiality rules and principles that a decision must not be taken without giving appellants and defendants the opportunity to comment on the case (the principle of hearing both sides of a case) and rules on the right of access are particularly important. Furthermore, there are rules on rights as a party to a case, that the decision shall be taken "without undue delay", the right under certain conditions to make oral statements, the right to be represented by a lawyer and duty of secrecy about "personal affairs." In addition, the Freedom of Information Act and Archives Act/Archives Regulation also apply. Committees will generally be regarded as part of the institution, and the responsibility rests on the institution. The Public Administration Act, Freedom of Information Act and the Archives Act/Archives Regulation shall apply throughout the proceedings of research ethics cases, and in the follow-up after the committee's report is issued.

For research institutions outside the public sector, there are general expectations for sound and fair proceedings in general, and general administrative law principles will be of great help.

Sanctions
The Research Ethics Act does not regulate the issue of sanctions or other reactions on the basis of violation of recognised ethical standards. It must be said to be both a right and an obligation for a research institution to assess whether labour law sanctions or other sanctions or reactions are appropriate. These may include the withdrawal of awarded doctoral degrees, withdrawal of publications, mandatory ethics courses.

Appeals procedure
Institutions subject to the Public Administration Act have the right to appeal decisions. Following a statement from the Ministry, opinions on scientific misconduct are not to be regarded as an individual decision, and thus carry no right to appeal. While an institution may choose to make their own arrangements for appeals, the Ministry is not aware of any cases where this has been done. If institutions impose sanctions on the basis of a misconduct case, this will usually be an individual decision that can be appealed pursuant to the Public Administration Act.

For cases concerning compulsory termination of doctoral studies due to scientific misconduct, the Ministry or a special appeals body, is the appeals body, cf. Section 4-13 of the Universities and University Colleges Act. Under Chapter 4.8 of the preparatory works to the Act (*Prop.59 L (2013-2014) Amendments to the Universities and University Colleges Act*) concerning compulsory termination of doctoral studies, the Ministry has the authority to consider and decide appeals of the proceedings. In cases where an appeal is lodged against the content of the opinion, i.e. the assessment of whether scientific misconduct is present, the Ministry will appoint an ad hoc committee with the necessary professional expertise. The Ministry will then decide the appeal on the basis of the expert opinion, including whether there are grounds to impose sanctions (terminate doctoral studies). This appeals procedure was established to comply with the right to appeal Commission opinions pursuant to the Research Ethics Act. If the right to appeal opinions of the National Commission for the Investigation of Research Misconduct is removed, the right to appeal the review of scientific misconduct pursuant to the Universities and University Colleges Act will also lapse.

6.1.3. Processing by the National Commission for the Investigation of Research Misconduct

The National Commission for the Investigation of Research Misconduct currently has two main tasks: It has a guiding role vis-à-vis institutions and it can process individual cases where there are questions of whether scientific misconduct has occurred. The Commission shall be a national resource on which institutions can draw in dealing with research ethics cases, first and foremost through guidance, including as regards requirements for legal safeguards. The Commission's guidance function is not enshrined in the Research Ethics Act, but follows from the duty to provide guidance under the provisions of the Public Administration Act, see Section 11.

The issues dealt with by the Commission
The Commission's duties in individual cases arise from Section 5 of the Research Ethics Act and Section 6 of the Research Ethics Regulations. The Commission shall assess and hear specific cases where there is suspicion of serious instances of scientific misconduct, and issue

an opinion as to whether research in Norway has been scientifically dishonest. In individual cases, the Commission can issue a statement on system failure in the institution, but the Commission cannot solely scrutinise an institution's policies/system handling of research ethics cases or research ethics issues in general. It is the Commission itself which assesses whether an enquiry provides grounds for further examination or is manifestly groundless. If the Commission is to be able to hear a case, it must involve allegations of scientific misconduct in scientific work. There are no time restrictions on the issues the Commission can handle. The Commission may also handle cases where a researcher's name has been wrongfully associated with an allegation of dishonest research. In such cases, the Commission can hear the case in order to help exonerate the researcher and restore his or her reputation. The Commission can reject cases at its own discretion, including cases that are not considered serious.

Both research institutions and individuals may request the Commission to take up a case. It is pointed out in the preparatory works that institutions can request the Commission to take over a case, and it is particularly in cases where the research community/institution should not or cannot hear cases due to impartiality, lack of resources or the like, that the Commission should hear cases as a body of first instance. The Commission can also take over a case at its own initiative, even if it has already been handled at the institution. The criteria that the Commission uses in its assessment must be within the limits set by the Research Ethics Act and the Public Administration Act. The Commission must meet Public Administration Act requirements for proper procedure, including exercising prudent judgment. The Commission's discretionary powers include e.g. emphasising the severity of a potential misconduct case, and the results of the investigation undertaken by the local institution. Allegations of deficiencies in the proceedings, for example in the form of disqualification, during an institution's handling of an allegation of scientific misconduct may be relevant factors when the Commission considers whether to hear the case.

The Commission has no obligation to assess administrative procedure at the institution even if there are allegations of procedural errors at the institution. This is because there is no right of appeal to the Commission for decisions made by the institutions. Institutions do not currently have a legal obligation to submit serious cases to the Commission. However, in the preparatory works the Ministry requires the institution to inform the Commission of the case should it choose to handle it itself. Furthermore, in a letter dated 6 August 2009 from the Ministry, all State universities and university colleges were requested to inform the Commission about serious matters handled at the institutions.

The cases that have been handled by the Commission
The Commission hears between seven and ten cases a year, most of which have been dismissed or transferred to local processing. There is thus little practice. Altogether, the Commission has only substantively heard three cases in eight years (up to and including 2014). The cases heard have been deemed particularly difficult or fundamentally important.

The first was a case about research at the University of Bergen on the spread of salmon viruses. The case concerned allegations of scientific misconduct related to an article in the journal *Archives of Virology*, authored by three researchers at the University of Bergen. The Commission investigated allegations of misconduct related to three factors: 1) improper presentation of the research material, 2) improper and skewed use of other scientific publications and research results, and 3) presentation of categorical conclusions without sufficient grounds. The Commission unanimously found that there were no serious violations

of sound scientific practice. The Commission therefore concluded that the authors had not acted dishonestly. The opinion was announced on 6 April 2011.

The other was a case from BI Norwegian Business School, where the issue was whether there was plagiarism in a doctoral thesis written at business school and approved following its presentation in 2004. A unanimous Commission concluded that there was plagiarism in the thesis, and that the objective criteria had been met. The majority were of the opinion that the procedures employed by the defendant in the thesis were grossly negligent and that scientific misconduct was thus present. The minority believed that there was no basis for calling the conduct grossly negligent. The Commission unanimously agreed that on several points there were grounds for criticising the handling of the thesis at BI, in part because the school used an improper standard for determining what must be called plagiarism. The opinion was announced on 19 March 2012. The case was appealed to the Ministry, which appointed an external ad hoc appeals committee to hear the appeal, hereinafter referred to the Appeals Committee. The Appeals Committee joined the Commission's minority and concluded that the researcher could be blamed for his acts, but not to the degree required by the legal norm, and that the researcher had therefore not been scientifically dishonest. The reason was that a lower due diligence requirement was in place at the time in question, and the researcher had cited sources in accordance with normal practice at BI, and that the researcher was mistaken about research ethics standards. The opinion of the Appeals Committee was announced on 28 January 2013.

The third was a case from the Institute for Energy Technology (IFE), where the issue was whether three researchers at the Institute for Energy Technology (IFE) had been scientifically dishonest in their work on four project reports, one journal article and an erratum to this. The pieces were written in the period 2008 to 2010. The Commission concluded that there had been serious breaches of sound scientific practice in three of the six contested documents. This concerns three project reports, where extensive plagiarism was present. The Commission concluded that the defendant authors had not acted wilfully or with gross negligence and that they thus have not acted dishonestly in the sense of the Research Ethics Act. However, the Commission criticised IFE for serious system failure, particularly for mistaken understanding of norms for good reference practice, misapplication of norms for co-authorship, improper internal investigation procedure and undocumented, varying reporting practices. The opinion was announced on 19 October 2012.

The requirement for a clear preponderance of evidence
Section 10(4), second sentence, of the Research Ethics Regulations states that a clear preponderance of evidence is required to assume that the defendant has acted dishonestly. The requirement for a clear preponderance of evidence applies to facts related to both the objective and subjective conditions in Ethics Act's misconduct term.

Appeals of Commission decisions
Under Section 5 of the Research Ethics Act, the Commission's opinions can be appealed in the same manner as individual decisions under the Public Administration Act. The Ministry is the appeals body for procedural appeals, while appeals against the content of opinions must be heard by a specially appointed committee (ad hoc committee). An ad hoc committee with the necessary professional, research ethics and legal expertise shall be appointed for each appeal.

In the 2006 consultation paper for the Research Ethics Act, the Ministry proposed that the right to appeal should be restricted to case procedure and the question of impartiality. The

Ministry's proposal was based on the assumption that the committee did not made individual decisions, that the matter in most cases would have been thoroughly discussed/dealt with internally in the institution/organisation in question before it was heard by the committee, and that committee's opinion was to be sent to the employer. On the basis of the consultation responses, the bill was amended.

While anyone can report a case for possible violation of research ethics standards, it is a requirement under the Public Administration Act to have a legal interest in the appeal (a certain proximity to the case) in order to lodge an appeal.

The Ministry has heard an appeal on a written opinion on points of fact from the Commission. This is referred to above. Furthermore, the Ministry has heard 10 cases concerning appeals of proceedings in the Commission. These are cases which the Ministry itself handles. None of the cases were successful. The cases largely involved an interpretation of the extent to which the Commission may choose to dismiss matters from investigation, and the requirements for proper procedure before dismissal decisions are made.

Sanctions
Chapter 7.2.3 of the preparatory works for the Research Ethics Act states that any sanctions against a researcher that the Commission finds has acted dishonestly, are to be enforced by the employer or a potential funding source. The Commission has no ability to sanction the individual researcher or research institution. In cases where the Commission issues an opinion, the opinion shall also be forwarded to the institution where the person in question is employed.

6.2. The Ministry's assessments

6.2.1. Research institutions' duty to process research ethics cases

Research institutions currently have a duty to process individual cases where there are questions about whether the research at the institution is not in conformity with recognised ethical standards. Reference was made above to the fact that some institutions have procedures for dealing with such cases. The examples show that some institutions have well-established procedures, while others do not. Institutions seem to establish procedures when they face a specific case. The review of practice shows that research ethics cases can be treated differently depending on where the case occurs.

The institutions must establish guidelines for dealing with research ethics cases, and there is a proposal to include this as a requirement in the proposed Section 3 (see Item 5.3.). The assessment of whether research work has taken place in accordance with recognised ethical standards should be done by an autonomous committee comprised of members who possess professional, legal and ethical expertise. Handling such cases can be difficult. This is especially true when there are allegations of scientific misconduct, and with the distinction between serious violations committed intentionally or through gross negligence and, e.g., individual mistakes. In preparing guidelines and procedures, other, more experienced, institutions might be able to assist. The Ministry proposes that the Commission should have one external member in part to ensure that the Commission is independent of the institution.

However, in the Ministry's opinion, the research institutions will, and must, on the whole have sufficient expertise in the content of the research ethics standards to deal with such matters themselves. These are skills that must be present in the institution to conduct the necessary

preventive work, including training, see also the discussion of institutional responsibility in Item 5.3.2. Many institutions will still benefit from collaboration with more experienced institutions with respect to drawing up procedures and the like, and possibly also for dealing with particularly difficult cases.

The national research ethics committees NESH, NENT and NEM are an important resource for institutions in their efforts to clarify what recognised ethical standards are and how they are to be understood. Through their previous experience, and through the preparation of research ethics guidelines, the committees have amassed considerable knowledge in understanding and using key research ethics standards, defining the role of advisors, etc. The Commission has experience and can guide the handling of research ethics cases. For resource-related reasons, the committees and Commission cannot serve all research-performing institutions and individual researchers, and must primarily help the institutions take on these responsibilities themselves, in addition to dealing with cases of a more fundamental nature.

To ensure that the institutions deal with reports of possible breaches of recognised ethical standards, the Ministry proposes to legislate the principle of the institutions' responsibility to deal with such violations, including assessing whether a case brought before the institution provides grounds for further investigation or is manifestly groundless. The purpose of the enactment is not to micromanage proceedings, but to lay down some general guidelines for procedure. The institutions also have a responsibility here to seek to resolve individual cases at the lowest possible level and as early as possible. However, this must be done without it being seen as an attempt to "sweep the problems under the carpet".

Research that does not take place according to recognised ethical standards, weakens the credibility of research and science as a basis for education, dissemination and innovation. Such violations may therefore undermine society's motivation to prioritise funding for research. The Ministry therefore believes that it is important that the institutions focus their attention not only on the most severe cases but on *all* research that does not take place according to recognised ethical standards. Research institutions must handle the most serious cases of research that has not taken place according to recognised ethical standards along the less serious cases.

The most serious cases of violations of ethical standards are characterised as scientific misconduct, i.e. falsification, fabrication, plagiarism and other serious breaches of good scientific practice (see more about this definition in Item 9). Examples of other serious breaches of sound scientific practice (besides falsification, fabrication and plagiarism) are:

- Withholding, deception about, or selective/hidden discarding of unwanted results.
- Unilateral or distorted interpretation of own results and conclusions.
- Misleading use of statistical methods.
- Misleading or concealment of information about one's own scientific efforts and/or scientific results and the contributions of each person. Wrongfully stating the writer's role etc.
- Withholding significant methodology details
- Incorrect information about academic qualifications in applications, etc.
- Destruction of research material to prevent investigations of misconduct in research
- Withholding significant criticism. In such cases, a researcher should contact relevant organisations to subject the problems to a broad investigation

Examples of other, less serious cases may include:

- Reporting research results or methodology in a misleading manner
- Publishing results multiple times ostensibly as new and novel results (so-called self-plagiarism)
- Recording and storing results and research materials in an inadequate manner

The lists of which cases are serious and less serious are not exhaustive.

Proposed statutory requirements for researchers and research institutions:

Section 6. Committees that can issue an opinion in research ethics cases

Research institutions must have an autonomous committee that can issue an opinion in cases concerning possible violations of recognised ethical standards. The committee shall have the necessary expertise in law, research and research ethics and have at least one member who is not employed by the institution.

The Ministry creates the National Commission for the Investigation of Research Misconduct, an autonomous commission, and appoints the members of the Commission. The Commission shall have the necessary expertise in law, research and research ethics, and the chair must have a Candidate of Law degree or Master of Laws degree. The Commission shall guide research institutions in research ethics.

Further details about the specific requirements in the proposal

The proposed Section 6(1) places a duty on each institution to have a committee that processes those research ethics cases the institution considers necessary, cf. Section 3 (d). Several institutions have already established such committees. Each institution is not necessarily required to have its own committee; institutions can work together on this. The committee should primarily be used to handle the more serious cases. It will be up to the institutions to decide whether it is appropriate for the same committee to handle other research ethics cases and whether it should have a role in prevention work, including the guidance of researchers, advisors and students or as an advisory body. The important thing is that each institution has clear guidelines as to who does what and the relationship between various functions and bodies.

The proposed Section 6(2) is a continuation of Section 5(1) of the Research Ethics Act concerning the Commission. The contents of the second subsection will depend on whether the right to appeal opinions about violations of recognised research ethics standards is handed from the institution to the Commission, see the discussion in Item 6.2.2.

6.2.2. Questions about the right to appeal opinions in research ethics cases

As discussed in Items 6.1.2 and 6.1.3 the current system has unequal means of redress depending on whether research ethics cases are handled by the Commission or at the research institution. Because opinions in research ethics cases are not individual decisions, a formal right of appeal of such opinions from research institutions has therefore not been established. Commission opinions are appealable to the Ministry, which serves as the appeals body for appeals concerning the proceedings of the Commission, while appeals concerning the contents of the opinion are heard by a specially appointed committee.

The Ministry believes it is unfortunate to have a system where there are different rights according to which body handles similar cases. The Ministry therefore proposes the

introduction of an equal right of appeal for such cases, regardless of who has handled it in the first instance. The Ministry has considered two alternative solutions, both of which call for the research institution itself to handle *all* research ethics cases at the individual institution, and that the Commission shall not hear cases as a first instance. The Commission's opinions will be final in both options. The reason for this is that the Commission is the body that has acquired the most expertise and experience with respect to handling cases of scientific misconduct. An appointed ad hoc committee would therefore probably not have equivalent expertise.

Alternative 1
The first option is no right of appeal against opinions about scientific misconduct.

Research institutions handle research ethics cases and issue opinions which are final and cannot be appealed. The Commission will continue to hear individual cases by reopening a case in cases where, e.g., the case has not been adequately handled in the institution, the law has been misinterpreted, or in areas where there may be a need to change practice. The Commission's role will then be streamlined as purely a final instance. If the Commission issues an opinion in a case, it will be final. The right to appeal to the Ministry will be removed.

In this option, the Commission's main task will be to advise and guide the research institutions in their efforts to establish good routines for dealing with research ethics cases, legal interpretation and the like and also to be able to advise on specific issues.

Alternative 2
The second option is the establishment of a right to appeal all opinions about research that has not taken place in accordance with recognised ethical standards, from the research institutions to the Commission. The right of appeal will be similar to the right of appeal under Chapter IV of the Public Administration Act. Under this option the Commission will become a purely appellate body. Its role as an appeals body will also restrict the Commission's guidance role in specific cases.

Assessment
Both options provide equal treatment of the right to appeal an opinion. Either a right of appeal is introduced only for opinions from institutions or no right of appeal will be granted.

The advantage of introducing a right of appeal is that the researcher will always have the right to have the case heard twice (by two instances). Through the appeals process the appeals body could ensure that the case is processed in accordance with ordinary administrative law principles (rule of law principle). The right of appeal will help to ensure that the process surrounding the handling of research ethics cases is in accordance with applicable law, thus ensuring that cases are properly handled.

A right of appeal will contribute to more transparency and better processes at the institution. Institutions may have an interest in avoiding public awareness about research misconduct, and so have a vested interest in hushing up and embellishing the case. We see in some cases that there are close ties between the person reviewing the case and the person being reviewed, and often also the person who has raised the issue of possible violations of ethical standards.

Practice at both research institutions and the Commission has shown that a majority of reports of misconduct arise in connection with and/or are caused by personal conflicts. Such cases can often be difficult to handle locally. Even though an institution has orderly procedures and safeguards impartiality rules, having an appeals process will be viewed as reassuring. The downside is that the right of appeal can be used by all parties to delay a case.

A right to appeal opinions from institutions will entail a substantial reorganisation of the current system. The system will be far more extensive, and the time it takes to process cases will be considerably longer and could be lengthy. Practice shows that local proceedings can quickly take a few weeks to several months. The practices of the Commission have shown that the Commission uses an average of six months to handle the most serious cases. This depends on the complexity of the case and whether there is a need for external experts. Decisions on possible sanctions might have to be put on hold as long as the question of whether a violation of research ethics standards has occurred has not been finalised. It is difficult to impose a procedural deadline on an appeals committee, as this will vary with the complexity of the cases and, inter alia, access to members. A full appeals procedure will also pose challenges when it comes to finding members for the appeals committee and, if necessary, new scientific experts.

New legislation that clarifies the responsibilities of the institutions will help to raise the quality of the institutions' work, likely reducing the need for a right of appeal. The Public Administration Act's general rules on impartiality, contradiction, etc. apply to all commissions and committees that deal with research ethics cases. The current system has not revealed any significant procedural violations at research institutions, although in some cases there have been reasons to criticise certain circumstances.

The Ministry proposes that in a model without a right of appeal, the Commission should have the power to take over research ethics cases. This will help ensure that serious and fundamental cases are reheard. One example is the BI case (see discussion under Item 6.1.3 where BI's Research Ethics Committee used incorrect premises in its proceedings. In this case the Commission elected to take over the case. The Ministry believes this case shows how the Commission takes over important and fundamental cases where the proceedings at the research institutions are inadequate. To ensure that the Commission will have a real opportunity to review cases, the Ministry proposes requiring research institutions to report (commenced and completed) research ethics cases to the Commission. The Commission must ensure effective methods for exchanging information between themselves and institutions on matters that have been dealt with, and how the institutions have followed up the case with any sanctions. This will be important information for the Commission in its efforts to guide the institutions and any further action. The Commission currently has a role as an advisor to institutions in their handling of research ethics cases. This role will have to be greatly reduced if the Commission is to serve as the appeals body. It will not be able to provide guidance in individual cases, as it may lead to disqualification in one of the appeals.

Continuation of the current arrangement without a right of appeal means that cases where a body of research work is to be assessed by research ethics guidelines are handled in essentially the same manner as assessments of the professional qualifications of such research workers with respect to new positions/promotion: by peers in an instance.

It will be possible to bring a case concerning possible breaches of research ethics guidelines before the Parliamentary Ombudsman and the ordinary courts. This will help safeguard legal protection considerations regardless of the right of appeal.

A right of appeal will also have economic consequences and significant resources will be needed to handle cases. The Commission will have a completely different role than today, and the Commission's members will probably have a significantly higher workload. There may be a need for buy-outs at a certain percentage of employment. This may have implications for recruitment to such posts. The research institutions will be assigned new duties relating to case preparation and evaluation of appeals before submission to the appeals body.

A third option could be that the right to appeal will be granted in cases where a research institution issues an opinion confirming the existence of scientific misconduct in a particular case. This will give the researcher against whom such a serious opinion is levelled an opportunity to have the case reheard. Such a solution will be interpreted by many as offering the researcher better protection, in that the most serious cases can be reheard, and accommodate the concern that there might be institutions that have less expertise in handling such cases in an appropriate manner.

The Ministry has weighed the disadvantages and benefits and believes that researchers' legal protections are adequately safeguarded by (i) stipulating requirements for research institutions' handling of research ethics cases, by (ii) granting the Commission the power to test cases, by (iii) providing a right to appeal any sanctions, and by (iv) providing that cases can be brought before the Parliamentary Ombudsman or ordinary courts. In the Ministry's opinion, the most important element is the researcher's power to appeal against sanctions imposed by research institutions.

In the Ministry's opinion, Alternative 1, the preservation and continuation of the current system, will be the best solution for handling research ethics cases. The change will mean that the current right of appeal to the Ministry will lapse, the Commission will be given greater responsibility to guide the institutions and the institutions will have a responsibility to report research ethics cases to the Commission.

Proposed statutory stipulation of committees that handle research ethics cases:

Section 6. Committees that can issue an opinion in research ethics cases

Research institutions must have an autonomous committee that can issue an opinion in cases concerning possible violations of recognised ethical standards. The committee shall have the necessary expertise in law, research and research ethics and have at least one member who is not employed by the institution.

The Ministry creates the National Commission for the Investigation of Research Misconduct, an autonomous commission, and appoints the members of the Commission. The Commission shall have the necessary expertise in law, research and research ethics, and the chair must have a Candidate of Law degree or Master of Laws degree. The Commission shall guide research institutions in research ethics issues.

Alternative formulation for the first and second subsections (with right of appeal from institution to Commission):

Section 6. Committees that can issue an opinion in research ethics cases

Research institutions must have an autonomous committee that can issue an opinion in cases concerning possible violations of recognised ethical standards. The committee shall have the necessary expertise in law, research and research ethics and have at least one member who is not employed by the institution. The National Commission for the Investigation of Research Misconduct is the appeals body for the committees' opinions.

The Ministry creates the National Commission for the Investigation of Research Misconduct, an autonomous commission, and appoints the members of the Commission. The Commission shall have the necessary expertise in law, research and research ethics, and the chair must have a Candidate of Law degree or Master of Laws degree.

6.2.3. The National Commission for the Investigation of Research Misconduct's role in the handling of research ethics cases

The Commission's role in the handling of research ethics cases will be largely governed by whether or not a right of appeal is established from research institutions to the Commission. Common to both options in Item 6.3.2 is the maintenance of the Commission, although the Commission's role will be different. The Ministry believes that the Commission has, and should continue to have, an important role in the Norwegian research ethics system. This is particularly necessary because the research institutions compete against each other, both for projects and students/staff.

The Commission has only investigated a handful of cases, which suggests that the Commission has interpreted its mandate narrowly. Section 5 of the Research Ethics Act is a dynamic provision whose content is dependent on national and international practice. In the Ministry's opinion, the Commission should investigate more cases of misconduct in order to create more practice in a new area. There is still considerable doubt about the interpretation of the Research Ethics Act's definition of scientific misconduct seven years after the Commission was established. This uncertainty could have been remedied if the Commission had dealt with more cases of misconduct, thereby clarifying legal limits through practice.

The Ministry proposes that the research institutions be required to inform the Commission about research ethics cases. Such communication shall include information about allegations, the proceedings and any sanctions.

9. Definition of scientific misconduct

9.1. Current law

The Research Ethics Act defines scientific misconduct as "*falsification, fabrication, plagiarisation and other severe breaches of sound scientific practice that are committed intentionally or with gross negligence in planning, implementation or reporting of research"*. This definition entails that a researcher will have exhibited scientific misconduct if he/she acts in violation of sound scientific practice in research work (objective criteria), and the researcher can also be blamed for the action by either having acted intentionally or with gross negligence (subjective criteria). The assessment must thus be made on both objective and subjective criteria. It follows from the definition that all parts of the chain of actions in a research project can be included in the assessment as to whether scientific misconduct has occurred. The researcher is thus personally responsible for ensuring that research takes place in an ethical manner both during planning, implementation and reporting of results. Scientific misconduct does not cover academic disagreement. In this context, the term "misconduct" is used with a more narrow definition than in everyday parlance.

The definition of scientific misconduct was established by law in 2007. The background was that it form the basis for the Commission's work, and provide the Commission with a framework for its tasks. During the drafting of the Research Ethics Act, the Ministry considered both a broad and narrow definition of scientific misconduct, and chose a narrow definition that would only cover the most severe instances of misconduct. The definition would also clarify for the researchers which standard should be used as a basis for the Commission's work. As described in Item 5, research institutions must process all cases involving breaches of sound scientific practice, including the less severe cases. The definition was not meant to exempt research institutions from their responsibility to prevent and process cases that fall outside the definition, but which nevertheless can be classified as breaches of sound scientific practice (see Chapter 11.2.4 of the preparatory works).

The definition of scientific misconduct does not cover the validity or veracity of scientific theories, nor does it cover the research quality of a scientific product.

<u>Falsification, fabrication, plagiarism and other serious breaches</u>

The objective criteria in the definition of scientific misconduct are "*falsification, fabrication, plagiarism and other serious breaches"* of sound scientific practice. The conditions refer to the type of action, and are intended to be legal standards that can be developed further through the research community, and which require practice in order to obtain more precise definitions. The purpose of establishing by law "*falsification, fabrication, plagiarism and other serious breaches"* as the definition of scientific misconduct, was to provide a statutory basis for the most severe breaches of scientific practice. The Ministry was of the opinion that this could give researchers more predictability as regards the definition of scientific misconduct. The condition "*other serious breaches"*, delimits against less severe instances of breaches of sound scientific practice. The background for the delimitation was e.g. a desire for the National Commission for the Investigation of Research Misconduct to only process the most severe instances of scientific misconduct. National and international research ethics principles, including the Declaration of Helsinki, the Vancouver Protocol, and national research ethics guidelines from NENT and NESH, provide guidance in the interpretation of the Research Ethics Act. The misconduct standard is determined by the research ethics standards, as they are expressed at any given time in research ethics guidelines and through international standards.

Intentional or grossly negligent action

The Act's subjective conditions for scientific misconduct are the culpability requirements "*intentionally or with gross negligence"*. Subjective criteria require a certain discretionary assessment in order to consider whether the terms have been met, and a concrete comprehensive assessment must be undertaken in each individual case. In the preparatory works, the Ministry presumed that:

> *"In order for the requirement of intentional action to be met, it must be proven that the researcher has intended to act in a manner that falls under the definition of misconduct. The action must have been committed knowingly."*

The Ministry has seen that the preparatory works have been interpreted as expressing that the intent requirement is only fulfilled when it has been proven that the researcher has intended to act in a manner that falls under the definition of misconduct, and that the action must ha been committed knowingly. When the Act requires intent, it is of no consequence which of the forms of intent have been displayed. The intent requirement thus includes all forms of intent, both direct intent (where the person in question has acted with wilful intent to achieve the consequence), oblique intent (where the person in question has held the consequence as assured or predominantly likely, i.e. at least 51 per cent likely), and conditional intent (where the person in question is of the opinion that the likelihood of the consequence occurring is less than 51 per cent, but has decided to carry out the action even if the consequence should occur).[17] This entails that responsibility can be assigned if the action was committed with intent, even if the *consequence* of the action was not intended. In other words, *deliberate intent* is not required in order to satisfy the intent requirement. This is also substantiated by the fact that the minimum culpability requirement in the Act is gross negligence.

As regards gross negligence, the Ministry writes as follows on page 54 of the preparatory works:

> *"As regards gross negligence, it has been presumed in case law that there must be a 'qualified censurable act that gives rise to strong reproach for lack of due care'. In these instances, the researcher must thus have given rise to strong reproach for the matter that speaks in favour of misconduct."*

It is also pointed out that an action can be said to fall under the definition of misconduct when the Commission can substantiate that the action has taken place with intent or as a result of gross negligence. There are thus strict requirements for culpability in order for the Commission to presume that there has been misconduct.

9.2. Experience and current practice

The definition of scientific misconduct

The Research Ethics Act's definition of scientific misconduct has mainly raised two issues. Firstly, there is uncertainty as to the content of the terms "falsification, fabrication, plagiarism and other serious breaches" (the objective terms) and where the legal lines will be drawn. This is most likely because the terms are not defined in more detail in the Research Ethics Act, the Research Ethics Regulation, the preparatory works or in the guidelines for the Commission's work, and that the lines have also not been drawn through practice. Secondly, the relationship

[17] The intent requirements are in agreement with the term in Odelsting Proposition No. 90 (2003–2004) Concerning the General Civil Penal Code, p. 115 Item 10.4.

between the objective conditions and "intentional or grossly negligent action" (the subjective culpability requirement) has been challenging to interpret both for the Commission and research institutions.

The definition of scientific misconduct is primarily used by the Commission in its work on misconduct cases, but the research institutions have eventually also started using this definition. Many institutions also use the definition indirectly without referring to the Research Ethics Act.[18]

The term plagiarism

The plagiarism condition has been particularly problematic to apply in practice, and the application of the term has mainly encountered two challenges. Firstly, in a few instances, people have interpreted the term plagiarism to have a subjective element; and secondly, plagiarism in a research ethics context has been conflated with intellectual property rules according to the Copyright Act. The greatest challenge linked to the term plagiarism has been the research institutions' use of the term. The Ministry will now reference a few specific instances:

- The Commission's opinion in a case concerning plagiarism in a doctoral thesis, 19 March 2012. The case was first heard by the Research Ethics Committee at BI. The Commission refers to BI's processing of the case and writes in its opinion on pages 4-5 that: *"It was pointed out that, in order to prove plagiarism, the author must have 'stolen' content from other authors' 'research work' and published it as his/her own. Reiterating 'pure generalities or matters that are commonly known cannot be called plagiarism.*"[19] Here the plagiarism term is interpreted in the context of intellectual property, and not according to research ethics standards. This shows that BI conflated plagiarism in the context of both intellectual property and research ethics.

- One example where the term plagiarism is conflated with intellectual property rules is a case from the University of Oslo from 2011, where an associate professor used excerpts from a master student's exam paper in his/her own scientific article. The University appointed an expert committee to hear the case, and one of the two experts stated that there were multiple examples of transcription and direct excerpts in the text, but that they could not, however, inherently call this transgression plagiarism because it was not taken from a published text. Neither in a research ethics nor an intellectual property context is it crucial that the original text has been published in order for the imitated text to be called plagiarism. However, the Copyright Act contains rules that distinguish between using intellectual property that has and has not been published.

- Another example which shows that the relationship between plagiarism in a research ethics context and in copyright can be difficult to interpret, can be found at Bioforsk, which defines plagiarism as *"presenting an idea, a research programme, a*

[18] Examples include: http://www.bioforsk.no/ikbViewer/Content/70666/FER_NO.pdf, https://www.uio.no/for-ansatte/arbeidsstotte/fa/etikk/forskningsetisk-utvalg/Universitetsstyret210607%20Forskningsetiskeretningslinjerendelig.pdf, http://www.uib.no/ledelsen/74662/vitenskapelige-redelighetsnormer-og-god-vitenskapelig-praksis

[19] https://www.etikkom.no/globalassets/documents/granskingsrapporter/granskingsutvalgets-uttalelse---sak-om-plagiering-i-doktoravhandling-2012.pdf

manuscript, an article or other text/part of text as one's own, i.e. without citation (for example references) to the copyright-holder".[20] (our emphasis)

Different definitions and application of the term plagiarism has created uncertainty as to the content of the term. The Commission has used an objective assessment of the term plagiarism. The Commission has done this by comparing the original text to the new text. There is little practice from instances where a research ethics committee has concluded that a researcher has acted with intent. The Commission has so far not arrived at this conclusion, but in certain cases, researchers have admitted misconduct themselves.

The subjective side of the term plagiarism:
The culpability requirement "gross negligence" has been applied in practice by both the Commission and the research institutions, compared with cases concerning cheating from the university and university college sector, and what otherwise follows from the negligence requirement. This means that there is a lower threshold for a student to be deemed as having acted with gross negligence than for a researcher.

Interpretation of the culpability requirement has been challenging in practice, particularly based on statements in the preparatory works and in the regulation/guidelines for the Commission's work. The Appeals Committee[21] e.g. stated that:

> "*In the assessment of the Appeals Committee, the Ministry's opinion [in the preparatory works] entails somewhat strong guidance on, and delineation of, the scope of culpability under gross negligence in the Research Ethics Act, compared to what would otherwise follow from a traditional legal understanding of this form of culpability"* and further that *"On this basis, the Appeals Committee agrees that the culpability requirement gross negligence entails an high threshold for what can be defined as gross negligence. In the assessment of the Appeals Committee, the opinion in the preparatory works entails that caution must be exercised when proving misconduct in instances where it is considered to be likely that the researcher has not intended to deliberately mislead or misrepresent.*"[22]

Plagiarism in research work has been claimed in a majority of the misconduct cases that have been processed. However, the Commission has less experience with claims of falsification and fabrication. The Commission has not processed cases involving "other severe breaches" of sound scientific practice.

9.3. The Ministry's assessments

9.3.1. Concerning the need for defining scientific misconduct

There has been disagreement as to whether or not the Research Ethics Act should provide a definition of scientific misconduct, and if so, how this definition should be worded. The Ministry has received feedback associated with the definition of scientific misconduct, including criticism of the Act containing a definition, and the actual content of the definition.

[20] http://www.bioforsk.no/ikbViewer/Content/70666/FER_NO.pdf
[21] the Appeals Committee is a special committee appointed pursuant to Section 5(5) of the Research Ethics Act, for an appeal of the Commission's opinion concerning scientific misconduct in a doctoral thesis defended at BI Norwegian Business School. The BI case and the Appeals Committee are described in detail under Item 7.2.2.
[22] https://www.etikkom.no/globalassets/documents/granskingsrapporter/vedtak-klageutvalget_webutgave.pdf

It has been claimed that the definition contributes toward codifying the area of research ethics, and that such codification is a problem because the internal research ethics standards of science are integrated elements in the research and is best clarified and improved in the research communities themselves, and that standards should therefore not be legal standards.

One alternative to codifying the definition of scientific misconduct in the Research Ethics Act, is to instead *refer* to recognised ethical standards. With this approach, the research community's own understanding of scientific misconduct and other breaches of recognised ethical standards will be the sole basis for a misconduct assessment. The challenge with such a wording in the Act, is that it is less appropriate for giving advice as to what the standard of misconduct actually entails. The research ethics guidelines contain no general definition of what is needed for an action to be defined as severe as scientifically dishonest. Use and interpretation of guidelines can also be demanding, e.g. because they are read or interpreted in the same way as the texts of laws. The consequence could be that a researcher is branded as having committed scientific misconduct due to breaches of research ethics guidelines that he/she did not understand.

It has also been claimed that the consequences of codification have led to lengthy processing of research ethics cases with substantial involvement of attorneys. The Ministry believes the fact that research ethics cases are drawn out in time and become more costly for both parties, is an unfortunate development. Nevertheless, it is important that the parties have the opportunity to receive assistance and guidance from attorneys and other representatives at all stages of the case processing. Even if the development appears to be heading toward increased use of external assistance, the Ministry does not view this as entirely negative. Such assistance can help ensure due process. A party's right to be assisted by a representative or interest organisation also follows from the provisions in Section 12 of the Public Administration Act.

One important consideration is the rule of law principle, which means that the standards at the centre of misconduct cases must be based on formal laws. On this basis, the Ministry proposes to uphold a definition of scientific misconduct in the Research Ethics Act.

Who will use the definition?
The Ministry proposes in Item 6 that research institutions must process all research ethics cases, not only the most serious cases. There is thus a question as to whether it is still necessary to have a definition of scientific misconduct in order to maintain a distinction between the severe and less severe research ethics cases.

The Ministry is of the opinion that it is necessary to uphold the definition in order to differentiate the severe cases involving breaches of recognised research ethics standards and the less severe breaches. The term scientific misconduct is used in Norway today. It is also used internationally, and will be used in the future. It is therefore important to have a shared definition, which is used by everyone who is assessing research ethics cases, both at the institutions and in the National Commission for the Investigation of Research Misconduct.

This will ensure a uniform standard, with the goal of preventing researchers at different research institutions being judged differently. The definition has already been used in several of the misconduct cases that have been handled locally at the institutions, which indicates that the term "scientific misconduct" is already incorporated in the sector.

9.3.2. The content of the definition of scientific misconduct

The Ministry has considered whether the current definition of scientific misconduct should be changed, and has also considered alternative wordings.

If the Act's objective conditions are not specified to the same extent as in the current text of the statute, they will, in the opinion of the Ministry, be less suitable to provide guidance for researchers in their work. Removing the conditions "falsification, fabrication, plagiarism and other severe breaches", could thus create greater uncertainty as to the actual content of the misconduct standard. By stipulating the most severe instances of scientific misconduct in the Act, the statute will appear to be more precise, and it will be easier for researchers to predict what behaviour is subject to the definition. The likelihood of a researcher risking a misconduct verdict without having understood the content or significance of the research ethics standards, will thus be reduced. The definition should also, to the maximum extent possible, reflect an international definition.

The definition of scientific misconduct is limited to the most severe instances of breaches of research ethics standards, and the Research Ethics Act distinguishes between severe instances of scientific misconduct and less severe instances. If the conditions "falsification, fabrication, plagiarism and other severe breaches" are removed, the definition will cover more instances than those that fall under the current definition, and will thereby also catch less severe breaches of recognised ethical standards.

The Ministry proposes retaining the current definition, and is of the opinion that further clarifying the act in the preparatory works will be most appropriate in order to prepare conditions. The background for this is primarily the consideration for predictability for the researchers, i.e. the researchers' opportunity to understand what the Act entails, and that the Act's definition of research ethics should be as precise and concrete as possible.

The Ministry is of the opinion that the definition of scientific misconduct should not be expanded, but should only cover the most severe instances of misconduct. This is also the best solution in concurrence with the international definition. Being found guilty of misconduct can have serious consequences for the individual researcher, and there should therefore be a clear distinction between the severe instances of scientific misconduct, and the less severe that border on negligence and pure oversights. Even those with good intentions can make mistakes, without this necessarily leading to a misconduct verdict. This particularly applies if the negligence does not appear to be a pattern, but more like individual mistakes. Misconduct must therefore be distinguished from errors in research. Researchers who discover or are made aware of errors, should be given an opportunity to admit the error, correct it and make sure to minimise the consequences. However, it must be pointed out that research institutions must still fully examine all suspected misconduct in research, not only the most severe cases.

<u>Fabrication, falsification, plagiarism and other severe breaches of sound scientific practice</u>

The Ministry presumes that "falsification, fabrication, plagiarism" are objective criteria.

Fabrication means e.g. inventing data, descriptions, information, results, etc. There could, for example, be instances where the researcher gives the impression that the experiment has been conducted without this being the case. Fabrication can also be using data and observations

that are not in line with the method description in the research report, or when fabricated results are presented in a research report.

Falsification means e.g. manipulating research materials, equipment, methods, processes, and changing or omitting data, descriptions, information and results without a professional basis. Falsification can, for example, be changing or adapting observations and data, thus changing the result. Excluding results or facts that are significant for the conclusions, may also be falsification. The same applies to selective use of data or methods to better fit the end-result to the theory or hypothesis.

Plagiarism in a research ethics context means using others' texts, figures, tables, results, ideas, methods, processes and similar without indicating this and without listing the source. The most common definition of plagiarism is publishing others' work/texts as one's own, and thereby mislead the reader as to who wrote the text. In a research ethics context, it has been common to refer to Item 28 of the NESH Guidelines, which defines plagiarism as follows:

> "*Plagiarism is, in a research ethics context, stealing content from other authors' and researchers' work and publishing it as one's own. Researchers who use others' ideas or quote from publications or research materials, must list their sources. The most severe form of plagiarism is pure copying. However, plagiarism can also come in other, more refined forms, and can apply for limited results, ideas, hypotheses, terms, theories, interpretations, design, etc. Referring to another work at an early point in one's own text, and then making extensive use of it without further references, is also plagiarism.*"

There has also been some uncertainty surrounding interpretation of this definition. In certain instances, it appears as if these guidelines have been read as one would read the text of a law, and the individual elements are presented as legal terms and conditions. It has been claimed that it is only plagiarism in terms of research ethics if text is copied from "other authors' and researchers' work", and that NESH thus delineates against self-plagiarism and text from public documents. This uncertainty appears to have resulted in incorrect application of the term plagiarism in certain research ethics contexts. In the context of Section 5 of the Research Ethics Act, the term plagiarism is intended to be an objective description of an action, which must then be supplemented with subjective conditions (intent or gross negligence). The objection against an objective plagiarism standard is that, in common parlance, plagiarism may give negative connotations and may thus be socially unacceptable. Not all forms of plagiarism are equally severe, and it may thus appear as unnecessarily stigmatising to be branded a "plagiarist". However, the research ethics plagiarism standard must be viewed in light of the objective behind the rules concerning plagiarism in a research ethics context, which is that researchers must not mislead their readers as to who is behind the research results. This is based on a number of important principles. Firstly, research work must be verifiable. Source references allow a reader to easily find original sources and thereby quality-assure the research work. Secondly, a researcher must not be able to take credit for the work of others and thereby appear to be better or more experienced than he or she actually is. This implies that researchers must also reference sources that are not protected by copyright law, for example public documents and works for which protection has lapsed. It is thus not decisive that the text being used is protected by copyright.

The plagiarism term is used both in research ethics and in copyright law. The core of the content is the same, but it is used somewhat differently in the two different areas. In copyright

law, the term plagiarism is not used in the statute, but is used in legal literature and case law, and then primarily for illegal imitation of the work of others. Works that are not protected by copyright, fall outside such a definition. For example, public documents are not subject to legal protection pursuant to the Copyright Act, cf. Section 9.

In a research ethics context, the term plagiarism will therefore be interpreted more broadly than what follows from ordinary copyright rules. In a research ethics context, the term plagiarism may, in certain instances, also include duplicate publication (in a few instances salamification), paraphrasing and rewriting, plagiarism of ideas, and plagiarism of public documents and facts.

Duplicate publication (self-plagiarism) is when someone publishes the same or very similar results multiple times without stating this fact. In such instances, the researcher will give the reader the impression that the research work has an erroneous novelty value, and reproduction of previously published texts will thus, in most situations, constitute a breach of the originality norm. *Salamification* is an informal designation which means that a researcher splits his/her research results into smaller parts in order to publish as little as possible of the research at once in order to produce more publications from the same research effort and thus be credited for more than one publication (and thereby more honour and potentially more publication points, cf. the publication indicator in the financing system for universities and university colleges). Salamification does not inherently entail plagiarism, but in certain instances it may entail a breach of the novelty norm. This entails that, in some cases, a researcher will have to reference his/her own previous publications. *Plagiarism of ideas* is publishing the ideas of others as one's own. Ideas in research often occur in collaboration or by compiling different research results. It can be difficult to indicate an exact time of when an idea occurs and who is the original inventor of the idea. This will have to be assessed specifically in each individual case.

However, the plagiarism assessment will depend on a discretionary assessment, which will include which parts of the work have been plagiarised, the scope of the plagiarism, etc. Here, the Ministry wants to point out that the definition of scientific misconduct is delineated against less severe breaches. This implies that lesser and immaterial occurrences of plagiarism will not constitute scientific misconduct, but may be a breach of research ethics standards.

In this context, *other severe breaches of sound scientific practice* means severe breaches of research ethics guidelines for impartiality, confidentiality, access to research materials and access to verification. On pages 53 and 54 of the preparatory works, the Ministry lists a few examples of severe breaches of sound scientific practice. A question has been raised as to whether or not intent is required in order for these instances to be counted as scientific misconduct. The Ministry sees that the word "deliberate" in the preparatory works can hardly be interpreted vis-à-vis the Act's culpability requirement, which is intentional or gross negligence. Gross negligence will also be adequate in order to have exhibited scientific misconduct in the mentioned examples.

<u>Intentional or grossly negligent action</u>
The Ministry proposes that the intent requirement should still include all forms of intent. It is primarily the culpability requirement gross negligence, as it is explained in the preparatory works for the Research Ethics Act, which, through practice, has been given content which entails that the threshold for establishing scientific misconduct has been set too high compared with what the Ministry believes it should be. The Ministry therefore proposes

lowering the threshold, and has in this context considered whether to uphold gross negligence as a form of culpability, or whether the culpability requirement should rather be ordinary negligence. Determining that a researcher has exhibited misconduct will be highly dramatic for the person/persons this affects. It may be destructive for his/her research career and may lead to his/her termination from their position. On this basis, the Ministry proposes retaining gross negligence as the lower culpability requirement.

Another consideration is equal treatment of students and researchers who cheat in their own fields. Pursuant to Section 4-7(1)(b) of the Universities and University Colleges Act concerning the annulment of exams or tests, it follows that the board itself or the institution's appeal board, cf. Section 5-1, can annul exams, tests or approval of courses if the candidate intentionally or with gross negligence has cheated in connection with sitting for, or prior to final examination results of, the exam or test in question, or during implementation of the course in question. The Ministry sees it as reasonable to harmonise the regulations that apply to researchers and to students.

Ministry uses the Supreme Court of Norway's understanding of gross negligence in Rt. 1989 p. 1318, which states that, in order for an action to be characterised as grossly negligent, it must represent a marked deviation from ordinary prudent conduct. It must concern conduct which is highly blameworthy, in which the person is thus considerably more blameworthy than in a case of simple negligence. The gross negligence requirement thus does not include a prudence principle, as the current preparatory works have been purported to express. Neither is it decisive for the assessment of negligence that the researcher has an element of dishonest or unfair behaviour which is suitable for achieving an unjust advantage.

Cumulative errors may satisfy the gross negligence requirement. This entails that, in instances where simple negligence is established repeatedly, this may culminate in gross negligence.

In certain instances, a researcher will have committed multiple minor errors that, individually, are so insignificant that they do not inherently entail a breach of recognised ethical standards. If the sum of these errors can be characterised as extensive, the overall research effort may be a breach of recognised ethical standards. The same applies in instances where the same researcher repeatedly commits less severe breaches of research ethics standards. In such instances, the researcher's conduct may entail a breach of the prudence requirement.

14. **Proposed Act relating to ethics and integrity in research (Research Ethics Act)**

Section 1. Purpose of the Act

This Act seeks to ensure that research carried out by public and private institutions is conducted in accordance with recognised ethical standards

Section 2. Scope

The Act applies to researchers and research in Norway and research abroad conducted by researchers employed by Norwegian employers or with funding that substantially comes from Norway. The King may issue regulations on the application of the Act on Svalbard.

Section 3. Requirements for researchers and research institutions

Researchers shall exercise due care and act in a manner which ensures that all research, including preparations for research, reporting of research and other research-related activities, follow recognised ethical standards.

A research institution must ensure that research conducted at the institution takes place in accordance with recognised ethical standards. The institution is responsible for

a) necessary training of candidates and employees in recognised ethical standards
b) ensuring that everyone who conducts or participates in the research are familiar with recognised ethical standards
c) having routines in place for processing cases involving potential breaches of recognised ethical standards
d) considering whether, as part of the processing of cases pursuant to litra c, there is a need for requesting an opinion from a committee pursuant to Section 6(1)
e) having routines in place for reporting to the National Commission for the Investigation of Research Misconduct about research ethics cases at the institution.

Section 4. National research ethics committees

The Ministry will appoint national, autonomous research ethics committees which cover all disciplines, determine each committee's area of responsibility and appoint the committee's members. Each committee shall have expertise in relevant research disciplines, ethics and law and shall have at least one lay member.

These committees shall serve as advisory bodies on research ethics.

Section 5. Regional committees for medical and health research ethics

The Ministry will appoint regional, autonomous research ethics committees in medical and health research ethics, determine the committees' fields of responsibility and appoint committee members. Members shall be appointed on the basis of proposals from relevant bodies. Each committee shall have expertise in relevant research disciplines, ethics and law and shall have at least one lay member.

The committees' responsibilities follow from the Health Research Act.

The National Committee for Medical and Health Research Ethics is the appeals body for the committees' decisions.

Section 6. Committees that can issue an opinion in research ethics cases

Research institutions must have an autonomous committee that can issue an opinion in cases concerning possible violations of recognised ethical standards. The committee shall

have the necessary expertise in law, research and research ethics and have at least one member who is not employed by the institution.

The Ministry creates the National Commission for the Investigation of Research Misconduct, an autonomous Commission, and appoints the members of the Commission. The Commission shall have the necessary expertise in law, research ethics and ethics, and the chair must have a Candidate of Law degree or Master of Laws degree. The Commission shall guide research institutions in research ethics issues.

Pursuant to the first and second subsections, the Commission will issue a written opinion on whether or not research is conducted in accordance with recognised ethical standards. The opinion shall take a position on

a) whether falsification, fabrication, plagiarism or other serious breaches of good scientific practice is present and how serious any violations are
b) whether the persons acted with intent or gross negligence
c) whether there is system failure at the institution
d) whether the scientific work should be corrected or withdrawn

Scientific misconduct is defined as falsification, fabrication, plagiarism and other serious breaches of sound scientific practice that have been committed wilfully or through gross negligence when planning, carrying out or reporting on research.

> **Alternative formulation** for the first and second subsections (with right of appeal from institution to the National Commission for the Investigation of Research Misconduct):
>
> *Section 6. Committees that can issue an opinion in research ethics cases*
>
> Research institutions must have an autonomous committee that can issue an opinion in cases concerning possible violations of recognised ethical standards. The committee shall have the necessary expertise in law, research and research ethics and have at least one member who is not employed by the institution. The National Commission for the Investigation of Research Misconduct is the appeals body for the committees' opinions.
>
> The Ministry creates the National Commission for the Investigation of Research Misconduct, an autonomous commission, and appoints the members of the Commission. The Commission shall have the necessary expertise in law, research ethics and ethics, and the chair must have a Candidate of Law degree or Master of Laws degree.

Section 7. Right to report violations of recognised ethical standards

Anyone may report in writing about possible violations of recognised ethical standards to research institutions and the National Commission for the Investigation of Research Misconduct.

Whoever reports a case, can remain anonymous. Should the person who reports a case state their identity, the body that receives the report, can decide that the person shall nonetheless be anonymised.

Section 8. Deferred public access

Research institutions, committees and commissions may decide in individual cases that the documents shall only be subject to the rules of the Freedom of Information Act when the final opinion in a case is issued.

Section 9. Regulations

The Ministry may lay down supplementary regulations regarding the appointment and administrative procedures of committees and commissions pursuant to this Act.

Section 10. Entry into force

This Act shall enter into force from the date decided by the King.