



Ethics Assessment in Different Countries

Denmark: National level institutions

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Annex 4.c

Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries *Deliverable D1.1*

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1 ABSTRACT

This report gives an overview of ethics assessment procedures, principles and values as well as the organisational structures of four non research ethics committees. The reports shows how all four organisations operate on a non-binding basis, and are either embedded in the Danish ministries, acts as advisory councils or function as temporary issue-based organisations in university settings.

2 EXECUTIVE SUMMARY

Denmark has a variety of different institutions that works with ethical assessment of research, technology and innovation. The objective with this case study is to do an in depth study of the ethical assessors that are found in public institutions other than the Danish Research Ethical Council (REC). In terms of assessment of research and innovation, these institutions potentially make up a ‘middle ground’ in between research ethics proper and technology assessment proper. It is therefore interesting to study these institutions as information regarding their practices will inform further work in SATORI regarding comparison of cross-European practices.

In this study four different ethical assessment institutions have been identified as belonging to this middle-ground. They have been classified depending on different categories of ethical assessment such as bioethics, medical ethics and professional ethics as well as their authority and organisational status. These institutions have different objectives. The Danish Council of Ethics aims to provide advice to the Danish Parliament and to create public debate about developments in biotechnology. The Danish Centre for Bioethics and Risk Assessment aims to assess questions regarding ethics and risk as well as broader societal concerns in connection with biological research. The Council for Animal Ethics follows general developments in animal protection and provides ethical assessments of these developments. The Danish Committees on Scientific Dishonesty aims to assess individual cases of research misconduct on the basis of complaints

Ethical assessment in these institutions follows a range of different principles and values. The Danish Council of Ethics performs analysis on ethical issues related to emerging research and innovation. The Council is guided by respect for the integrity and dignity of the human being and future generations as well as respect for nature and the environment. The Danish Centre for Bioethics and Risk Assessment deals with the ethical and (animal) welfare implications of biotechnical research and innovation, and they stress values such as transparency in decision-making, public acceptability of research and innovation, and responsibility in governance. The Council for Animal Ethics follows developments affecting animal welfare and employ a broad array of ethical research in a problem-oriented approach. The Danish Committees on Scientific Dishonesty promote the values of honesty, transparency and accountability as characteristics of responsible conduct of research.

The procedures and tools for assessment are diverse. The Danish Council of Ethics makes use of interdisciplinary analysis in which ethical evaluation is supported by analytical elements taken from risk assessment, forecasting, technology assessment, legal analysis and policy analysis. The Danish Centre for Bioethics and Risk Assessment bases its ethical assessments on an underlying STS-inspired analysis, making interdisciplinary use of risk assessments, social scientific studies of public opinion, market studies and critical analysis of public decision-making. The Council for Animal Ethics bases its opinions on thorough state-of-the-

art analysis of research and innovation, policy-analysis, and a flexible issue-based framework of ethical analysis. The Danish Committees on Scientific Dishonesty publishes a set of guidelines based on international standards for scientific conduct and investigates allegations of research misconduct.

3 INTRODUCTION

The objective of this case study is to do an in-depth study of the ethical assessors that are found in public institutions other than the Danish Research Ethical Council (REC). In this study four different ethical assessment institutions have been identified as belonging to a group of ethics assessors working at the middle ground in between research ethics and technology assessment.

Please note: This country report was an early pilot study in the SATORI project, and does not conform to the format of country studies in the SATORI D1.1 Annex. It is a very limited study of ethics assessment and guidance in Denmark, since it only studies four Danish public institutions at the national level that engage in ethics assessment or guidance. However, the four institutions are studied in more detail than is done in other country reports.

3.1 BASIC DESCRIPTION OF THE ASSESSOR CATEGORY, INCLUDING SUBTYPES

This in-depth case study of ethical assessment of research and innovation in Denmark describes those assessor types, which are found in public organisations other than research ethical councils (RECs). The focus of the case-study is thus on a ‘middle-type’ of ethical assessment organisations, which play variants of the role of ‘ethical assessor’ that are beyond the scope of research ethics proper without fully falling into other assessment domains such as technology assessment, social impact assessment, or environmental impact assessment. The category of organisations investigated can be defined as ‘national non-REC public ethical assessment of research and innovation’.

This abstractly defined category of ethical assessment organisations can be broken down as follows:

		Organisational status	
		Independent, publically funded	University institute
Sub-field of ethics	Bioethics	2 (1)*	1
	Medical ethics	(1)*	-
	Professional ethics	1	-

* One organisation (the Danish Ethical Council) has a mandate to assess both ethical issues connected to biotechnology-in-society and medical ethics issues in the health sector.

Bioethics takes up considerable space in the field. Different organisations focus on different sub-sets of bioethical assessment issues. These include risks in connection with biotechnological development, broader societal implications of biotechnological development, and animal ethics. Non-ethical participatory assessment of biotechnology has been carried out in the domain of parliamentary technology assessment.

Medical ethics is treated in close connection with issues of biotechnology-in-society. Assessment of technology for use in the health sector is mandated to the domain of medical technology assessment.

Professional ethics has traditionally been divided between a central oversight function, which dealt narrowly with the avoidance of dishonesty and plagiarism in science, and individual universities' initiatives to follow and implement internationally agreed ethical principles for scientific conduct in the broader sense. No common ethical checklist has been applied to applications for national research funding. This trend continues in a recently proposed national code of conduct for research integrity, which also focuses narrowly on honesty, transparency and accountability in science.

3.2 OBJECTIVES

The objective with this case study is to perform an in-depth study of the ethical assessors that are found in public institutions other than the Danish Research Ethical Council (REC), which has been described thoroughly in the EU-REC project. For each relevant institution identified, the case study describes: the aims pursued by the organisation in carrying out ethical assessment; the objects of assessment and the level at which they are assessed; the institutional structures; the ethical values and principles applied in ethical assessments; and the procedures and tools used in assessment.

3.3 METHOD AND SAMPLE CONSIDERED IN THE CASE STUDY

The case study was carried out as a desktop study. The field under investigation is made up of four organisations:

- The Danish Council of Ethics
- Danish Centre for Bioethics and Risk Assessment (CeBRA)
- Council for Animal Ethics
- The Danish Committee on Scientific Dishonesty

As mentioned initially, these organisations make up a middle layer that falls in between the national RECs (coordinated by the Danish National Committee on Biomedical Research Ethics) and organisations representing other established assessment domains such as environmental assessment and technology assessment. In operational terms, this middle layer has been identified by excluding from the analysis the organisation studied in the EU-REC project while including other 'key actors' with regard to 'ethics in science and society' as categorised by the MASIS project's national report on Denmark¹.

¹ Mejlgaard, Niels, Carter Bloch, Tine Ravn and Lise Degn, "Monitoring policy and research activities in Europe (MASIS): National report, Denmark", DG Research 2011.

4 THE ORGANISATIONAL AIMS OF ASSESSMENTS

4.1 THE DANISH COUNCIL OF ETHICS

The Danish Council of Ethics aims to provide advice to the Danish Parliament and to create public debate about developments in biotechnology, which are seen to affect human life, food, nature, and the environment, as well as ethical issues arising in health care, especially with regard to reproductive technology. The council produces independent advice aimed mainly at the Minister of Health while at the same time seeking to stimulate public debate on the matters of the Councils concern. While the Minister of Health has no instructional power towards the Council, the Minister is not obliged by the recommendations given by the Council.²

4.2 THE DANISH CENTRE FOR BIOETHICS AND RISK ASSESSMENT

The Danish Centre for Bioethics and Risk Assessment aims to assess questions regarding ethics and risk as well as broader societal concerns in connection with biological research. Their assessment activities are mainly focused on research carried out at Danish Universities. The purpose of providing these assessments is to ensure that these central institutions follow a common approach to the ethical issues in question. The Danish Centre for Bioethics and Risk Assessment addresses a broad audience of public decision-makers and interest groups involved in the governance of animal welfare, food and agriculture. The advice of the Centre is non-obligatory.³

4.3 THE COUNCIL FOR ANIMAL ETHICS

The Council for Animal Ethics follows general developments in animal protection and provides ethical assessments of these developments. The aim is to contribute to national law-making processes regarding animal husbandry, research involving animals, and animal welfare in general. The Council for Animal Ethics plays a crucial role in the legislative process in that it informs the Minister about the ethical aspects of proposed national or European legislation regarding animal welfare. The opinions of the Council are non-binding, but given their official status, the opinions serve as important points of orientation for parliamentary debates and debates among societal parties in the National Committee on Animal Welfare.⁴

4.4 THE DANISH COMMITTEES ON SCIENTIFIC DISHONESTY

The Danish Committees on Scientific Dishonesty aims to assess individual cases of research misconduct on the basis of complaints in order to ensure the credibility of Danish research and prevent dishonesty. The Danish Committees on Scientific Dishonesty produces decisions concerning allegations of misconduct, the consequences of which must be enacted by the parties involved (researchers, universities, funding agencies, and others). Some decisions concern minor infractions, which can easily be remedied by the researcher(s) involved, while decisions concerning major infractions may lead to disciplinary action by universities or even

² Danish Council of Ethics, “The History and spheres of work of the Council”. <http://www.etiskraad.dk/Om-Raadet/Historie.aspx>

³ Center for bioetik og risikovurdering/Center for Bioetisk og Risikovurdering (CeBRA). <http://bioethics.ku.dk/>

⁴ Miljø- og Fødevareministeriet ‘Dyreetisk Råd’. <http://fvm.dk/ministeriet/raad-og-udvalg/dyr/det-dyreetiske-raad/>

legal proceedings by damaged parties or the state. The decisions in themselves, however, are typically anonymised and have no direct legal consequences.⁵

5 OBJECTS AND LEVELS OF ASSESSMENT

5.1 THE DANISH COUNCIL OF ETHICS

The Danish Council of Ethics follows general developments in biotechnology and may choose to address these on its own initiative. The Council may also take up or be asked to take up issues of immediate concern in the health sector.

5.2 THE DANISH CENTRE FOR BIOETHICS AND RISK ASSESSMENT

The Danish Centre for Bioethics and Risk Assessment addresses issues of general concern, which are directly relevant to individual research projects undertaken by the four research institutions supported by the C⁶entre. These four centres include: Earth Science at Aarhus University, National Food Institute at Denmark's Technical University, Faculty of Science at Copenhagen University and Central Copenhagen University.⁷

5.3 THE COUNCIL FOR ANIMAL ETHICS

The Council for Animal Ethics takes up issues of general relevance to animal husbandry, research involving animals, and animal welfare in general.⁸

5.4 THE DANISH COMMITTEES ON SCIENTIFIC DISHONESTY

The Danish Committees on Scientific Dishonesty assess individual cases of alleged misconduct in research.⁹

6 INSTITUTIONAL STRUCTURES

6.1 THE DANISH COUNCIL OF ETHICS

The Danish Council of Ethics was established by law in 1988 as an independent body under the Ministry of the Interior and Health (later renamed as the Ministry of Health and Prevention). The Council of Ethics as a whole is appointed by the Ministry. The Council refers to a standing parliamentary Committee, the members of which are elected annually by proportional representation to reflect the make-up of Parliament. Members of the Council itself are appointed partly by Parliament and partly by other ministries. Members appointed by Parliament outweigh those appointed by the ministries 9 to 8, while the Minister of Health

⁵ Ministry of Higher Education and Science, "The Danish Committees on Scientific Dishonesty". <http://ufm.dk/en/research-and-innovation/councils-and-commissions/the-danish-committees-on-scientific-dishonesty>

⁶ Danish Council of Ethics, "The History and spheres of work of the Council". <http://www.etiskraad.dk/Om-Raadet/Historie.aspx>

⁷ Center for bioetik og risikovurdering/Center for Bioetisk og Risikovurdering (CeBRA). <http://bioethics.ku.dk/>

⁸ Miljø- og Fødevareministeriet 'Dyreetisk Råd'. <http://fvm.dk/ministeriet/raad-og-udvalg/dyr/det-dyreetiske-raad/>

⁹ Ministry of Higher Education and Science, "The Danish Committees on Scientific Dishonesty". <http://ufm.dk/en/research-and-innovation/councils-and-commissions/the-danish-committees-on-scientific-dishonesty>

appoints the chairperson among the designated members. The Council is obliged to work collaboratively with other relevant bodies such as the Central Research Ethical Committee, the Council for Animal Ethics, and others. The work of the Council is supported by a secretariat employed by the Ministry on the recommendation of the chairperson of the Council.¹⁰

6.2 THE DANISH CENTRE FOR BIOETHICS AND RISK ASSESSMENT

The Danish Centre for Bioethics and Risk Assessment was established in 2000 as a coordinating link between Danish institutes active in the field of gene technology. The Centre had a temporary status and 2000-2009 it was funded from various sources of project financing. In the period from 2009-12, four university institutes acted as co-owners of the Centre by supplying it with basic funding. Since 2013 however, the Centre is fully embedded in Copenhagen University's Institute of Food and Resource Economics.¹¹

6.3 THE COUNCIL FOR ANIMAL ETHICS

The Council for Animal Ethics is an official advisory body established in 1992 under the Danish Veterinary and Food Administration, which is in turn an administrative body under the Ministry of Food, Agriculture and Fisheries. In matters concerning animal welfare and ethics in connection with research, the Council has historically co-authored opinions with the Danish Council of Ethics. The Council for Animal Ethics is a sister organisation to two other councils concerning animal welfare under the Ministry, namely the Animal Welfare Council and the Council concerning the Keeping of certain Animals (e.g. exotic animals). Among other duties, the three councils feed advice and opinions into a National Committee under the Ministry, where agricultural associations, research institutes, animal welfare organisations, and other relevant ministries gather to consider legislation drafts from the European Commission as well as draft recommendations from the Council of Europe.¹²

6.4 THE DANISH COMMITTEES ON SCIENTIFIC DISHONESTY

The Danish Committees on Scientific Dishonesty were established in 2002 as part of a larger re-structuring of the ministerial area of research, innovation and higher education. There are three Committees each covering one of the major research areas (Health and Medical Sciences; Natural, Technological and Production Sciences; and Cultural and Social Sciences). Each Committee has six members and a common chairperson, all of which are appointed by the Minister. The Chairperson is a high court judge, and the Committee members are recognized scientists recommended by the Research Council. The Committees on Scientific Dishonesty are part of an institutional landscape made up among others of the Danish Research Councils, which serve to promote excellence and competitiveness in science, and the Danish National Committee on Biomedical Research Ethics and the Regional Health Research Committees (i.e., RECs).¹³

¹⁰ Danish Council of Ethics, "The History and spheres of work of the Council". <http://www.etiskraad.dk/Om-Raadet/Historie.aspx>

¹¹ Center for bioetik og risikovurdering/Center for Bioetisk og Risikovurdering (CeBRA). <http://bioethics.ku.dk/>

¹² Miljø- og Fødevareministeriet 'Dyreetisk Råd'. <http://fvm.dk/ministeriet/raad-og-udvalg/dyr/det-dyreetiske-raad/>

¹³ Ministry of Higher Education and Science, "The Danish Committees on Scientific Dishonesty". <http://ufm.dk/en/research-and-innovation/councils-and-commissions/the-danish-committees-on-scientific-dishonesty>

7 ETHICAL VALUES, PRINCIPLES AND ISSUES

7.1 THE DANISH COUNCIL OF ETHICS

The Danish Council of Ethics was set up to deal with ethical issues arising from research and development in health and biotechnology. Historically, the issues that made it clear that an Ethical Council was needed were those of genetic engineering, assisted reproduction and foetal examination. The Council is guided by respect for the integrity and dignity of the human being and future generations, as well as respect for nature and the environment. The law establishing the Council explains that “respect for the integrity and dignity of the human being also encompasses the early phases of human life, including fertilized human eggs and embryos. Respect for nature and the environment is based on the presumption that nature and the environment having a value in their own right”. Issues concerning animal welfare fall outside the mandate of the Council.¹⁴

7.2 THE DANISH CENTRE FOR BIOETHICS AND RISK ASSESSMENT

The Danish Centre for Bioethics and Risk Assessment deals with ethical and (animal) welfare implications of biotechnical research and innovation. The Centre’s website does not contain an official statement of values and principles, but the concrete assessment projects undertaken stress values such as transparency in decision-making, public acceptability of research and innovation, and responsibility in governance.¹⁵

7.3 THE COUNCIL FOR ANIMAL ETHICS

The Council for Animal Ethics follows developments affecting animal welfare. The council works from the understanding that humans have obligations towards animals, and that animals have rights, and they work with the key concept of animal welfare. According to a note published in 2015¹⁶, in using animals, humans have the following base obligations: making sure that the use of animals is for an acceptable purpose, making sure the animals have a good life, and showing respect for the integrity of the animals. Furthermore, the council specifies animal welfare as both the possibility for animals to live their life according to their natural and social instincts and to be kept under circumstances that minimise the occurrence of disease, injury and (accidental) death. The latter of these conditions may not be used as an excuse for not fulfilling the first.¹⁷

7.4 THE DANISH COMMITTEES ON SCIENTIFIC DISHONESTY

The Danish Committees on Scientific Dishonesty promote the values of honesty, transparency and accountability as characteristics of responsible conduct of research.¹⁸ According to the

¹⁴ Danish Council of Ethics, “The History and spheres of work of the Council”. <http://www.etiskraad.dk/Om-Raadet/Historie.aspx>

¹⁵ Center for bioetik of risikovurdering/Center for Bioetisk og Risikovurdering (CeBRA). <http://bioethics.ku.dk/>

¹⁶ The Council for Animal Ethics, “Note on Animal Ethics, Animal Welfare and the work of the Council for Animal Ethics”, 2015.

<http://www.foedevarestyrelsen.dk/SiteCollectionDocuments/Det%20Dyreetiske%20Raad/Dyreetik,%20dyrevelf%C3%A6rd%20og%20arbejdet%20i%20Det%20Dyreetiske%20R%C3%A5d.pdf>

¹⁷ Ibid.

¹⁸ Ministry of Higher Education and Science, “The Danish Committees on Scientific Dishonesty”.

<http://ufm.dk/en/research-and-innovation/councils-and-commissions/the-danish-committees-on-scientific-dishonesty>

latest code of conduct by the Committees' (2014)¹⁹, they seek to ensure the trustworthiness of Danish research with a focus on avoiding breaches in six specific problem areas, namely: Research planning and conduct, Authorship, Data management, Collaborative research, Data management, Publication and communication and Conflicts of Interest.

8 PROCEDURES AND TOOLS

8.1 THE DANISH COUNCIL OF ETHICS

The Danish Council of Ethics monitors developments and submit statements regarding the issues within its mandate. The Council makes use of interdisciplinary analysis in which ethical evaluation is supported by analytical elements taken from risk assessment, forecasting, technology assessment, legal analysis and policy analysis.²⁰

8.2 THE DANISH CENTRE FOR BIOETHICS AND RISK ASSESSMENT

The Danish Centre for Bioethics and Risk Assessment bases its ethical assessments on interdisciplinary research, risk assessments, social scientific studies of public opinion, market studies and critical analysis of public decision-making.²¹

8.3 THE COUNCIL FOR ANIMAL ETHICS

The Council for Animal Ethics bases its opinions on thorough state-of-the-art analysis of research and innovation, policy-analysis, and a flexible issue-based framework of ethical analysis.²²

8.4 THE DANISH COMMITTEES ON SCIENTIFIC DISHONESTY

The Danish Committees on Scientific Dishonesty publishes a set of guidelines based on international standards for scientific conduct and investigates allegations of research misconduct. The Committees may also address general questions regarding misconduct if these are of a broader societal relevance.

In their latest report on a Danish code of conduct, the following international standards serve as a basis:²³

- The Singapore Statement on Research Integrity (2010)
- The Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations (2013)
- The European Code of Conduct for Research Integrity (2011)

¹⁹ Ministry of Higher Education and Science, "Danish Code of Conduct for Research Integrity".

<http://ufm.dk/en/publications/2014/files-2014-1/the-danish-code-of-conduct-for-research-integrity.pdf>

²⁰ Danish Council of Ethics, "The History and spheres of work of the Council". <http://www.etiskraad.dk/Om-Raadet/Historie.aspx>

²¹ Center for bioetik af risikovurdering/Center for Bioetisk og Risikovurdering (CeBRA). <http://bioethics.ku.dk/>

²² The Council for Animal Ethics, "Note on Animal Ethics, Animal Welfare and the work of the Council for Animal Ethics", 2015.

<http://www.foedevarestyrelsen.dk/SiteCollectionDocuments/Det%20Dyreetiske%20Raad/Dyreetik,%20dyrevelf%C3%A6rd%20og%20arbejdet%20i%20Det%20Dyreetiske%20R%C3%A5d.pdf>

²³ Ministry of Higher Education and Science, "Danish Code of Conduct for Research Integrity". <http://ufm.dk/en/publications/2014/files-2014-1/the-danish-code-of-conduct-for-research-integrity.pdf>

These guidelines are meant to serve as internal guidelines for the proper conduct of researchers, partly by implementation in planning, and partly as a teaching tool for young researchers. The guidelines do not aim to cover all aspects of the research process, leaving much up to individual researchers and research institutions with regard to the responsible design and conduct of research.

Investigations of misconduct must narrowly concern “scientific dishonesty”. Scientific quality or research directions are outside the scope of the work of the Committees. Investigations involve consulting the parties involved with the accused being allowed to respond in writing to the allegations made against him/her. This process is generally reiterated once after which a decision is made by the Committee with involvement of special committees or external experts as appropriate. There is, however, great freedom on the part of the Committee chairman to adjust the process as needed.

9 CONCLUSIONS

The Danish ethics assessment organisations, under investigation perform ethics assessment in different areas and with different aims. Two of the organisations are directly embedded in Danish Ministries (Committees on Scientific Dishonesty, and the Council for Animal Ethics), while the Danish Council of Ethics, accepts assignments from parliament, but is an independent council in an advisory role. The Danish Centre for Bioethics and Risk Assessment finally, was an initiative by several university centres and as such differs from the others in this respect. The organisations also perform their ethics assessments in differing ways. The Danish Council of Ethics, The Council for Animal Ethics and the Danish Committees for Scientific Dishonesty all have their members appointed for them, and the number and constitution of their councils or committees is determined by law. They also all have their main areas of concern and guiding principles written down; either as codes of conduct, or as ‘notes’ or mentioned in their constitutional text. Common for all the organisations is that their advice, opinions and evaluations are not binding.